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ATSDR: PROBLEMS IN THE PAST, POTENTIAL FOR THE FUTURE?

HEARING

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

MARCH 12, 2009

Serial No. 111–10

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CONTENTS

March 12, 2009

	Page
Witness List	2
Hearing Charter	3

Opening Statements

Prepared statement by Representative Bart Gordon, Chair, Committee on Science and Technology, U.S. House of Representatives	30
Statement by Representative Brad Miller, Chair, Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives	5
Written Statement	6
Statement by Representative Paul C. Broun, Ranking Minority Member, Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives	28
Written Statement	29

Panel I:

Mr. Salvador Mier, Local Resident, Midlothian, Texas; Former Director of Prevention, Centers for Disease Control	
Oral Statement	31
Written Statement	33
Biography	166
Dr. Randall R. Parrish, Head, Natural Environmental Research Council (NERC) Isotope Geosciences Laboratory, British Geological Survey	
Oral Statement	166
Written Statement	168
Biography	232
Mr. Jeffrey C. Camplin, President, Camplin Environmental Services, Inc.	
Oral Statement	233
Written Statement	235
Biography	240
Dr. Ronald Hoffman, Albert A. and Vera G. List Professor of Medicine, Mount Sinai School of Medicine; Director, Myeloproliferative Disorders Program, Tisch Cancer Institute, Mount Sinai Medical Center	
Oral Statement	240
Written Statement	243
Biography	247
Discussion	
Explanations of ATSDR's Deficiencies	248
Peer Review	248
More Explanation of Deficiencies	249
Potential Fixes	249
Geographic Prevalence of Deficiencies	251
Public Awareness	252
Asbestos	253
Local Health Protection	254
Vieques, Puerto Rico	254
Colonie, New York	256
Animals as Sentinels of Human Health	259

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00007 Fmt 5904 Sfmt 5904 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

Page

Panel II:

Dr. Ronnie D. Wilson, Associate Professor, Central Michigan University; Former Ombudsman, Agency for Toxic Substances and Disease Registry
Oral Statement 260
Written Statement 262
Biography 263

Dr. David Ozonoff, Professor of Environmental Health, Boston University School of Public Health
Oral Statement 264
Written Statement 266
Biography 268

Dr. Henry S. Cole, President, Henry S. Cole & Associates, Inc., Upper Marlboro, Maryland
Oral Statement 269
Written Statement 271
Biography 301

Discussion
More Animals as Sentinels of Human Health 302
Peer Review 302
Information Access 303
Difficulty With Epidemiology 303
Potential Fixes 304

Panel III:

Dr. Howard Frumkin, Director, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry (NCEH/ATSDR)
Oral Statement 307
Written Statement 309
Biography 317

Discussion
More on Animals as Sentinels of Human Health 318
More on Peer Review 319
Hindrances to ATSDR's Performance 320
More on Potential Fixes 321
More on Vieques, Puerto Rico 322
Changes in Response to Criticism 323
Closing 324

Appendix 1: Answers to Post-Hearing Questions

Mr. Salvador Mier, Local Resident, Midlothian, Texas; Former Director of Prevention, Centers for Disease Control 326

Dr. Randall R. Parrish, Head, Natural Environmental Research Council (NERC) Isotope Geosciences Laboratory, British Geological Survey 334

Mr. Jeffrey C. Camplin, President, Camplin Environmental Services, Inc. 338

Dr. Ronnie D. Wilson, Associate Professor, Central Michigan University; Former Ombudsman, Agency for Toxic Substances and Disease Registry 342

Dr. Henry S. Cole, President, Henry S. Cole & Associates, Inc., Upper Marlboro, Maryland 347

Dr. Howard Frumkin, Director, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) 351

ATSDR: PROBLEMS IN THE PAST, POTENTIAL FOR THE FUTURE?

THURSDAY, MARCH 12, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:05 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Brad Miller [Chair of the Subcommittee] presiding.

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Subcommittee on Investigations and Oversight

Hearing on

ATSDR: Problems in the Past, Potential for the Future?

Thursday, March 12, 2009
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Witness List

PANEL I

Mr. Salvador Mier
Local Resident, Midlothian, Texas, and Former Director of Prevention, Center for Disease Control

Professor Randall Parrish
Head, Natural Environmental Research Council (NERC) Isotope Geosciences Laboratory, British Geological Survey

Mr. Jeffery Camplin
President, Camplin Environmental Services, Inc., Rosemont, IL

Dr. Ronald Hoffman
Professor, Tisch Cancer Institute, Department of Medicine
Mount Sinai School of Medicine

PANEL II

Mr. Ronnie Wilson, *Former Ombudsman, Agency for Toxic Substances and Disease Registry*

Dr. David Ozonoff, *Professor of Environmental Health, Boston University School of Public Health*

Dr. Henry S. Cole, *President, Henry S. Cole & Associates, Inc., Upper Marlboro, MD*

PANEL III

Dr. Howard Frumkin, *Director, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry*

HEARING CHARTER

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

ATSDR: Problems in the Past, Potential for the Future?

THURSDAY, MARCH 12, 2009
10:00 A.M.–12:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

Purpose

Chairman Brad Miller of the Investigations and Oversight Subcommittee of the House Committee on Science and Technology will convene a hearing at 10:00 a.m. on Thursday, March 12, 2009, to examine the Agency for Toxic Substances and Disease Registry's (ATSDR). Last year, the Subcommittee held a hearing and issued a staff report on how the Agency came to issue a scientifically flawed formaldehyde health consultation for the Federal Emergency Management Agency (FEMA). The flawed report and ATSDR's botched response resulted in tens of thousands of survivors of Hurricanes Katrina and Rita remaining in travel trailers laden with high levels of formaldehyde for more than one year longer than necessary.

This hearing will consist of three panels and eight witnesses, including Dr. Howard Frumkin, Director of ATSDR. It will examine ongoing problems at ATSDR, specific cases where local community members, scientists and physicians are critical of the Agency's scientific methods, conclusions and lack of follow-up actions. The hearing will also hear from individuals who have either worked for or with the Agency in the past, including the former ATSDR ombudsman, who will provide their insight into the cause of systematic problems at the Nation's public health agency and potential remedies.

The hearing will explore why ATSDR has refused to change portions of a health report, described by the EPA as "questionable" and "misleading," regarding asbestos contamination on a beach on Lake Michigan in Chicago. There will be testimony from a well-respected medical expert on a rare type of cancer who says the Agency has refused to acknowledge a link between a cancer cluster in Pennsylvania and environmental contamination despite persuasive evidence.

In addition, a British scientist will describe the flawed methods ATSDR used to investigate depleted uranium exposures among residents in Colonie, New York and how he and colleagues succeeded in discovering depleted uranium exposures among 20 percent of the resident population they tested there. A local resident from Midlothian, Texas, known as the cement capital of the world, will explain how and why he and the local community have lost faith in ATSDR's ability to independently and scientifically investigate the health problems that the town's population, particularly its children and animals, have been suffering from that they believe have been caused by the one billion pounds of toxic emissions the town's industries have unleashed into the environment since 1990.

Witnesses:

Panel I

- **Mr. Jeffrey Camplin,** President, Camplin Environmental Services, Inc.
- **Dr. Ronald Hoffman,** Professor, Tisch Cancer Institute, Department of Medicine, Mount Sinai School of Medicine, New York
- **Dr. Randall Parrish,** Head, NERC Isotope Geosciences Laboratory, British Geological Survey
- **Mr. Salvador Mier,** Local Resident, Midlothian, Texas, and Former Director of Prevention, Center for Disease Control

Panel II

- **Dr. Henry S. Cole,** President, Henry S. Cole & Associates, Inc.
- **Dr. David Ozonoff,** Chair Emeritus, Department of Environmental Health, Boston University School of Public Health
- **Dr. Ronnie Wilson,** Former Ombudsman, Agency for Toxic Substances and Disease Registry

Panel III

- **Dr. Howard Frumkin,** Director, National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry

Chair MILLER. This hearing will now come to order.

Good morning and welcome to today's hearing. The title is ATSDR: Problems in the Past, Potential for the Future? The stated mission of the Agency for Toxic Substances and Disease Registry, ATSDR, is to serve the public by using the best science, taking responsive public health actions and providing trusted health information to prevent harmful exposures and disease-related exposures to toxic substances.

The relatively obscure Federal Government agency first came to this subcommittee's attention a year or so ago as a result of ATSDR's health assessment for formaldehyde exposure by Katrina and Rita victims living in FEMA trailers. Government at all levels failed the victims of Katrina and Rita in many ways, but ATSDR's failure was perhaps the most unforgivable. ATSDR's health assessment certainly failed any test of scientific rigor but ATSDR's failure was worse than just jackleg science. ATSDR's failure was a failure not just of the head but of the heart.

FEMA requested the health assessment to use in litigation and requested that the assessment assume an exposure of less than two weeks, knowing that Katrina and Rita victims had already been exposed to formaldehyde fumes for more than a year, and that there was no end in sight to their exposure. Stunningly, ATSDR obliged. Their report gave FEMA just what FEMA asked for. Let me repeat that to let it sink in. FEMA came to ATSDR and said we have been sued, we need a health assessment for exposure to formaldehyde fumes. The folks that have been exposed to those fumes have been exposed for more than a year already and God only knows how long they will be exposed into the future but we want you to assume they were exposed for less than two weeks, and ATSDR said no problem, okay, we can do that. Now, obviously I have had to shorten that story a little bit, but the facts that I have left out are not exculpatory. They are more damning still.

It gets worse from there. FEMA touted the assessment to assure families living in the FEMA trailers that the formaldehyde fumes were nothing to worry about. Dr. Howard Frumkin, who is here today and will be a witness today, was then and is still the director of ATSDR. Dr. Frumkin held a dozen senior staff meetings on the formaldehyde issue over a 6-month period after ATSDR issued the report in February 2007. Only after unflattering scrutiny by Congressional committees including this subcommittee did ATSDR correct the health assessment.

Since then, this subcommittee has heard from many sources of other examples of jackleg science by ATSDR and a keenness to please industries and government agencies that prefer to minimize public health consequences of environmental exposures. Our sources have included outside scientists, residents of communities exposed to various chemicals, and ATSDR's own scientists. Now, one ATSDR staff scientist told our subcommittee staff, ''It seems like the goal is to disprove the communities' concerns rather than actually trying to prove exposures.''

Today we will hear about a small number of the cases that have been called to our attention and about problems at ATSDR that date from the Agency's creation.

And then there is the question of what to do about ATSDR. When federal agencies fail in their mission, the problem is usually a lack of resources. There is no reason to believe that more funding or more staff for ATSDR would result in anything other than a greater volume of jackleg assessments saying not to worry.

We hope that the Obama Administration will take a hard look at ATSDR and we may want to consider legislative fixes. First, there is a possibility of peer review, outside, independent peer review. The statute now neither requires nor forbids ATSDR from getting an independent peer review, and in fact, ATSDR very rarely, if ever, gets a peer review. Most scientists see peer review as helpful, as constructive criticism. ATSDR on the other hand apparently sees opinions of outside scientists as unwelcome, meddling, and as a result, according to the scientists we have talked to, the research design and methodology is often flawed and the research is frequently not sound, accurate or complete. Congress may well want to consider requiring peer review, at least in some circumstances, by legislation. It is hard to know, however, how Congress can require ATSDR's leadership to have the guts to resist political pressure and insist of scientific integrity.

The American people deserve better and so do the many scientists at ATSDR who have dedicated their lives to protecting the public health and devoutly wish that ATSDR faithfully and effectively perform the Agency's stated mission.

[The prepared statement of Chair Miller follows:]

PREPARED STATEMENT OF CHAIR BRAD MILLER

The stated mission of the Agency for Toxic Substances and Disease Registry ("ATSDR") "is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related exposures to toxic substances."

The relatively obscure Federal Government agency first came to this subcommittee's attention a year and a half or so ago as a result of ATSDR's health assessment for formaldehyde exposure by Katrina and Rita victims living in FEMA trailers. Government at all levels failed the victims of Katrina and Rita in many ways, but ATSDR's failure was perhaps the most unforgivable. ATSDR's health assessment certainly failed any test of scientific rigor, but ATSDR's failure was worse than just jackleg science. ATSDR's failure was a failure not just of the head but of the heart.

FEMA requested the health assessment to use in litigation, and requested that the assessment assume an exposure of less than two weeks, knowing that Katrina and Rita victims had already been exposed to formaldehyde fumes for more than a year and that there was no end in sight to their exposure. Stunningly, ATSDR's report gave FEMA just what FEMA asked for.

FEMA touted the assessment to assure families living in the FEMA trailers that the formaldehyde fumes were nothing to worry about. Dr. Howard Frumkin, then and still the Director of ATSDR, will testify today. Dr. Frumkin held a dozen senior staff meetings on the formaldehyde issue over a six-month period after ATSDR issued the flawed report in February 2007. Only after unflattering scrutiny congressional committees did ATSDR correct the health assessment.

Since then, this subcommittee has heard from many sources of other examples of jackleg science by ATSDR and a keenness to please industries and government agencies that prefer to minimize public health consequences of environmental exposures. Our sources have included outside scientists, residents of communities exposed to various chemicals, and ATSDR's own scientists. One ATSDR staff scientist told our subcommittee staff "It seems like the goal is to disprove the communities' concerns rather than actually trying to prove exposures."

Today we will hear about a small number of the cases that have been called to our attention, and about problems at ATSDR that date from the Agency's creation.

Then there is the question what to do about ATSDR. When federal agencies fail in their mission, the problem is usually a lack of necessary resources. There is no

reason to believe that more funding or more staff would result in anything other than a greater volume of jackleg assessments saying "not to worry."

We hope the new Obama Administration will take a hard look at ATSDR. We may also consider legislative fixes. ATSDR was exempted from forced peer review for its "health assessments," but the statute never forbid scientific review and the vast majority of ATSDR's health reports do not go through independent review today. Most scientists see peer review as helpful, constructive criticism. ATSDR, on the other hand, apparently sees the opinions of outside scientists as unwelcome meddling. As a result, ATSDR's research design and methodology is often flawed, according to other scientists, and ATSDR's research is frequently not sound, accurate or complete. Perhaps Congress could require peer review by legislation. But it is hard to know how Congress can require ATSDR's leadership to have the guts to resist political pressure and insist on scientific integrity.

The American people deserve better, and so do the many scientists at ATSDR who have dedicated their lives to protecting the public's health, and devoutly wish that ATSDR faithfully and effectively perform the Agency's stated mission.

Chair MILLER. I will recognize Mr. Broun in a second, but first we will include the staff report that this subcommittee staff has prepared and will be included along with my statement in the record.

[The information follows:]

The Agency for Toxic Substances and Disease Registry (ATSDR): Problems in the Past, Potential for the Future?

REPORT BY THE MAJORITY STAFF OF THE
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES
TO SUBCOMMITTEE CHAIRMAN BRAD MILLER

MARCH 10, 2009

Introduction

Last April the Subcommittee on Investigations and Oversight held a hearing on the Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency of the Centers for Disease Control and Prevention (CDC). The hearing looked at how the Agency produced a scientifically flawed and misleading health consultation on the health hazards of potential formaldehyde exposures by survivors of Hurricanes Katrina and Rita living in travel trailers provided by the Federal Emergency Management Agency (FEMA).[1] Last September the Subcommittee issued a detailed staff report on our investigation which found that: "The leadership of ATSDR obfuscated their role in reviewing and approving the February 2007 health consultation and attempted to abdicate their own responsibility for the Agency's fundamental failure to protect the public's health. Most disturbingly, as the Agency's troubled response to the formaldehyde fiasco unraveled, the leadership of ATSDR attempted to shift blame for the inappropriate handling of the incident to others, primarily [whistleblower Dr. Chris] De Rosa and his staff."[2] Unfortunately, the poor scientific integrity of ATSDR's formaldehyde health consultation and the weak leadership at the Agency that permitted the production of this misleading report which went uncor-

[1] "Toxic Trailers: Have the Centers for Disease Control Failed to Protect Public Health?," Hearing before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives, April 1, 2008, available here: *http://science.house.gov/publications/hearings_markups_details.aspx?NewsID=2133*

[2] "Toxic Trailers—Toxic Lethargy: How the Centers for Disease Control and Prevention Has Failed to Protect the Public Health," Majority Staff Report, Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives, September 2008, available here: *http://democrats.science.house.gov/Media/File/Commdocs/ATSDR_Staff_Report_9.22.08.pdf*

rected for so long—keeping the public in harm's way for a year longer than necessary—was not an isolated incident.

The Agency's mission "is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related to toxic substances."[3] On paper, according to ATSDR, the Agency is deeply involved with the local communities it is intended to help protect, it makes independent, objective health decisions based on the best science available, it conducts exposure investigations to assess health impacts of environmental toxins and it provides and explains the results of their evaluations, medical consultations and investigations to local communities and tribes.[4] In reality, across the Nation local community groups believe that ATSDR has failed to protect them from toxic exposures and independent scientists are often aghast at the lack of scientific rigor in its health consultations and assessments. The studies lack the ability to properly attribute illness to toxic exposures and the methodologies used by the Agency to identify suspected environmental exposures to hazardous chemicals are doomed from the start.

The Subcommittee staff is not suggesting that ATSDR find problems where none exist or that ATSDR should or can identify the sources of a possible cancer cluster, disease or other health hazard in every instance or where the potential source of toxic exposures are ambiguous or elusive. Yet time and time again ATSDR appears to avoid clearly and directly confronting the most obvious toxic culprits that harm the health of local communities throughout the Nation. Instead, they deny, delay, minimize, trivialize or ignore legitimate concerns and health considerations of local communities and well respected scientists and medical professionals.

Many independent scientists, medical professionals, local environmental groups and public health advocates believe that rather than objectively and aggressively trying to identify the source of reported health problems, ATSDR often seeks ways to avoid linking local health problems to specific sources of hazardous chemicals. Instead, says one current ATSDR scientist who spoke to the Committee on the condition of anonymity: "It seems like the goal is to disprove the communities' concerns rather than actually trying to prove exposures." None of these problems are new to ATSDR but it will require a new will and desire to fix them on the part of ATSDR's leadership.

Background

In 1980 Congress created the Agency for Toxic Substances and Disease Registry (ATSDR) through the enactment of the *Comprehensive Environmental Response, Compensation, and Liability Act of 1980* (CERCLA) (Public Law 96–510) commonly referred to as "Superfund." CERCLA authorized the Environmental Protection Agency (EPA) to clean up nationally identified toxic waste (Superfund) sites and Section 104(i) required the Department of Health and Human Services' (HHS) Public Health Service to establish a new agency to carry out health-related activities at these waste sites.[5] Thus, ATSDR was created to help determine the potential human health consequences of releases of toxic chemicals at these sites.

Although ATSDR was created with the best of intentions, it had an extremely difficult birth and has struggled ever since. The EPA and HHS provided it with little support and at times tried to subvert it. It took three years after enactment of the law that authorized the creation of ATSDR for the Agency to actually emerge. By June 1983 the HHS' Public Health Service "had developed few detailed procedures concerning the new agency and how the Superfund responsibilities would be carried out," according to a report from Congress's investigative arm, the U.S. General Accounting Office (GAO).[6] "HHS objected to establishing a separate agency to carry out its Superfund responsibilities, contending it was not necessary."[7] In fact, HHS never wanted ATSDR to have its own staff and tried to reign in the new agency's independence by detailing CDC staff to ATSDR and forcing it to use CDC's administrative and support structure.[8]

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[3] "Statement of Mission," Agency for Toxic Substances and Disease Registry, undated, available here: *http://www.atsdr.cdc.gov/about/mission.html*

[4] "What You Can Expect From ATSDR," Agency for Toxic Substances and Disease Registry, May 2002, available here: *http://www.atsdr.cdc.gov/COM/expect.pdf*

[5] "Interim Report on Establishment of the Agency for Toxic Substances and Disease Registry and the Adequacy of Superfund Staff Resources," U.S. General Accounting Office, GAO/HRD–83–81, August 10, 1983, p. 1, available here: *http://archive.gao.gov/f0302/122111.pdf*

[6] *Ibid*, p. 3, available here: *http://archive.gao.gov/f0302/122111.pdf*. The name of the General Accounting Office was changed in 2004 to the Government Accountability Office (GAO).

[7] *Ibid*, p. 2, available here: *http://archive.gao.gov/f0302/122111.pdf*

[8] *Ibid*, p. 3, available here: *http://archive.gao.gov/f0302/122111.pdf*

In addition, because the Office of Management and Budget (OMB) reduced the number of HHS requested staffing positions in 1984 to ATSDR, CDC officials told GAO's investigators that because of limited staff "they expected to eliminate virtually all [of ATSDR's planned] long-term health studies, [health] registries, and laboratory projects."[9] During this same time-frame both EPA and OMB consistently reduced ATSDR's annual budget.[10] Three years after ATSDR was physically established, a new law was passed, the *Superfund Amendments and Reauthorization Act of 1986* (SARA) that set an arbitrary deadline of December 1988 for the Agency to conduct health assessments at 951 Superfund sites. The law was necessary at the time, many believed, because ATSDR had made zero headway in accomplishing these tasks. As a result of the new law ATSDR developed "initial mandate assessments" at 950 sites within a little over two years. The Agency achieved a quantitative victory in producing so many assessments is so little time.

But Congress's desire to force the new understaffed agency to become more effective, efficient and responsive to fulfilling its initial mandate had unintended qualitative consequences. In order to prepare health assessments on 951 Superfund sites within this time period ATSDR wrote 785 assessments in 15 months and "labeled 165 previously prepared documents in its files as health assessments" even though some were several years old, according to GAO. To accomplish this massive effort, ATSDR ignored "its own guidance requiring visits to sites" and instead conducted "desk" assessments, GAO found. The Agency, for instance, labeled previously produced documents not intended to be full health assessments as "assessments." "In the rush to complete these assessments, ATSDR dropped plans to do full internal quality checks on its assessments, and no review was made by outside experts," according to GAO.[11]

When GAO reviewed the quality and usefulness of ATSDR's health assessments in 1991 they hired five independent experts to evaluate 15 of the Agency's assessments. What they found was that the initial mandate assessments "were seriously deficient overall." Although follow up assessments were improved over the earlier assessments GAO's expert reviewers "continued to find deficiencies in evidence or analysis, such as unsupported conclusions."

GAO concluded that ATSDR needed to improve its quality controls and to establish "some independent peer review." It found that ATSDR should involve local communities more in developing assessments. The GAO panel also found the reports it reviewed contained "(1) inadequate descriptions or analyses of health risks, (2) failures to indicate whether communities had been exposed to contaminants, (3) overly general recommendations, and (4) inattention to the sufficiency of data."[12] One of the GAO panel members said that "regardless of the wide diversity of sites that we studied [the assessments] come up with the same conclusion: that there is a potential problem." Incredibly out of the 951 initial assessments ATSDR conducted it found just 13 sites as posing a "significant health risk."[13]

In the rush to push out nearly 1,000 health assessments in two years time the Agency developed a check-box mentality that helped to undermine virtually everything the Agency did. Quality became an after-thought to the ability to produce public health documents quickly. The integrity of the data, assessment of the public health risks and credibility of the conclusions all suffered deeply as a result.

Unfortunately, the past problems identified by GAO have not disappeared. Reviews of the FEMA trailer health consultation on formaldehyde, as well as other health reports from ATSDR, appears to suggest the Agency has never recovered from the initial problems that overshadowed its birth. Internally, many ATSDR employees have told the Subcommittee over the past year that the Agency lacks appropriate quality controls, it conducts inadequate analyses of health risks to local communities and they often do not collect and analyze the most relevant and revealing data about potential environmental health hazards. Externally, the local communities that ATSDR was created to help protect often believe the Agency does more harm than good by offering them reassuring but unfounded and unsound advice and analysis which simply creates an artificial perception of safety to the public that is not supported by scientific inquiry or independent examination.

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[9] *Ibid*, p. 7, available here: *http://archive.gao.gov/f0302/122111.pdf*

[10] "SUPERFUND: Funding for the Agency for Toxic Substances and Disease Registry," U.S. General Accounting Office, GAO/RCED–87–112BR, March 1987, p. 2. available here: *http://archive.gao.gov/t2pbat22/132595.pdf*

[11] "Superfund: Public Health Assessments Incomplete and of Questionable Value," General Accounting Office, RCED–91–178, August 1, 1991, p. 13, available here: *http://archive.gao.gov/t2pbat7/144755.pdf*

[12] *Ibid*, p. 18, available here: *http://archive.gao.gov/t2pbat7/144755.pdf*

[13] *Ibid*, p. 28, available here: *http://archive.gao.gov/t2pbat7/144755.pdf*

Investigating environmental public health issues is a difficult and daunting task. Local communities *expect* State or federal public health agencies to identify the cause of their specific health concerns, provide medical or other support and eradicate the environmental hazard. In some cases it is exceedingly difficult to establish a definitive link between specific toxic exposures and health problems. In other cases it may be difficult to quantify an actual health problem and in some instances the scientific evidence may not identify *any* problem let alone the specific *cause* of a health problem. But in many, many cases ATSDR seems to get the science wrong, ignores community complaints or both.

Midlothian, Texas—Cement Kilns

Mr. Sal Mier is a local resident of Midlothian, Texas and former official at the Centers for Disease Control and Prevention (CDC). Midlothian is known as the cement capital of the world and is home to three cement plants and one steel mill. These plants have released nearly one billion pounds of toxic chemicals into the local environment since 1990. The Texas Commission on Environmental Quality (TCEQ) began environmental monitoring in Midlothian in 1991. In June 2005, the Texas Department of State Health Services (DSHS) completed a review of the Texas Birth Defects registry and found that one type of birth defect related to urinary tract development (hypospadias or epispadias) was statistically elevated. The previous month DSHS completed a cancer cluster investigation that found no elevation in cancers when it examined residents in three zip codes in Midlothian and two other towns.[14] But by expanding the pool of individuals in this investigation to those outside of Midlothian, critics say the study diminished the ability to specifically identify increased rates of cancers among Midlothian residents.

In 2005, Mr. Mier petitioned ATSDR to look into health issues in Midlothian. In August 2005, ATSDR agreed to conduct a health assessment on the potential health effects of toxic substances released from Midlothian's cement kilns. Under a cooperative agreement with ATSDR, DSHS would conduct the health investigation along with some support, review and final concurrence by ATSDR. In December 2005, DSHS said that the health consultation would be completed and reviewed by ATSDR and released for public comment by "the first part of February 2006."[15] In February 2006 the document's release date was pushed back to March 2006 "due to the large volume of information to be reviewed."[16]

In December 2007, 27 months after ATSDR began their investigation, the Agency finally released a "draft" health consultation for "public comment." The report found that for the vast majority of chemicals they examined there was no public health hazard. They concluded, for instance, that there was "no evidence to suggest that adverse health effects would be anticipated as a result of any of the short-term or peak exposures to VOCs [Volatile Organic Compounds] or Metals" being emitted from the plants in Midlothian. The Agency's overall conclusion was that the air in Midlothian posed an "Indeterminate Public Health Hazard."[17] A "final" version of that study is planned to be released in the next couple of months—more than three and one half years after the investigation began.

Mr. Mier received comments on this document from several independent scientists who concluded it was deeply flawed. Dr. Stuart Batterman, Associate Chairman of the Department of Environmental Health Sciences, School of Public Health at the University of Michigan, wrote: "The Health Consultation is biased. It contains overarching statements that discount all indications that emissions from local industry and environmental conditions might or do pose a health concern in the community." Dr. Peter L. deFur, a Research Associate Professor in the Center for Environmental Studies at Virginia Commonwealth University agreed. "Throughout the document, ATSDR attempts to marginalize or disregard data that indicate that compounds produce human health risks. ATSDR has more than enough data to classify the site as a "Public Health Hazard." For the past fifteen months ATSDR has been reviewing these and many other public comments they received on their draft health con-

[14] "Birth Defects Monitoring 2005 Report Summary," Texas Department of State Health Services and "Cancer Registry 2005 Report Summary," Texas Department of State Health Services both available here: *http://www.dshs.state.tx.us/epitox/midlothian/reports.shtml*

[15] "Midlothian Petition Community Site Update, Texas Department of State Health Services, December 2005, available here: *http://www.dshs.state.tx.us/epitox/midlothian/december_update.pdf*

[16] "Midlothian Petition Community Site Update, Texas Department of State Health Services, February 2006, available here: *http://www.dshs.state.tx.us/epitox/midlothian/update206.pdf*

[17] "Health Consultation: Public Comment Release, Midlothian Area Air Quality Part 1: Volatile Organic Compounds & Metals, Midlothian, Ellis County, Texas, December 11, 2007, available here: *http://www.dshs.state.tx.us/epitox/midlothian/updates.shtm*

sultation and intend to release the final version of their report in the next couple of months.

It is clear that the release of toxic material from the three cement plants and steel mill in Midlothian has been enormous over the years. Using State and federal records from the Environmental Protection Agency's (EPA) Toxics Release Inventory (TRI) and TCEQ's Emission Inventory two graduate students at the University of North Texas, Amanda Caldwell and Susan Waskey, conducted a study of the local emissions from Midlothian for the local environmental non-profit group Downwinders At Risk. The study found that between 1990 and 2006 these four industrial plants released more than *one billion pounds* of toxic emissions to the environment. The emissions were a brew of toxic substances, including millions of pounds of manganese, lead and sulfuric acid, as well as hundreds of thousands of pounds of trichloroethylene, zinc compounds, mercury, benzene, hydrochloric acid, formaldehyde, toluene and other hazardous chemicals.[18] Tying down specific health effects to individual industrial plants in Midlothian would be a difficult undertaking. But Midlothian residents are frustrated that ATSDR has ignored critical signs of potential health problems in the community and has essentially given the community a clean bill of health despite many indications that the community may be suffering from health problems due to exposures to industrial pollutants.

Sue Pope, a Midlothian resident and one of the creators of Downwinders At Risk, had hair samples of 55 people living in or near Midlothian, many of them infants and young children, analyzed for toxic substances between 1988 and 1993. What the tests revealed was that many of the residents had high levels of aluminum, lead, cadmium and nickel. She turned over copies of these documents to Texas State authorities who were investigating health issues in Midlothian, but she says nothing ever came of it.

Other residents and independent scientists have chronicled health problems in Midlothian too. In 1998, scientists led by Dr. Marvin Legator at the University of Texas Medical Branch, Division of Environmental Toxicology published a peer-reviewed paper in the journal *Toxicology and Industrial Health* titled: "The Health Effects of Living Near Cement Kilns; A Symptom Survey in Midlothian, Texas." The study found that respiratory illnesses in Midlothian were three times more common than in neighboring Waxahatchie.[19]

Two years earlier, Legator published an editorial in the *Archives of Environmental Health,* titled: "A Deliberate Smokescreen," which criticized the scientific integrity of ATSDR's studies and the methods ATSDR uses in an attempt to investigate potential environmental exposures. In the article Legator and a colleague recommended "that careful evaluation be made of a significant number of ATSDR or ATSDR-sponsored studies to determine how well the victims of chemical exposure and our taxpayers have been served by this agency."[20]

Last December *USA Today* ran an in-depth special report titled "The Smokestack Effect: Toxic Air and America's Schools," that used the same EPA data as the report on Midlothian's toxic emissions by Caldwell and Waskey to track the path of industrial pollution and then mapped the locations of almost 128,000 schools to determine the levels of toxic chemicals in their path. The *USA Today* report's interactive map of the United States shows that of the nine schools located in Midlothian, Texas, two of them were ranked in the 1st percentile of the schools exposed to the most toxic chemicals in the Nation, three of the schools were ranked in the third percentile and each of the others were ranked in the 6th, 14th, 21st and 32nd percentiles. According to the *USA Today* report only 174 of the Nation's 127,809 schools they ranked had worse toxic air exposures than the Mt. Peak Elementary School in Midlothian, for instance.[21]

Anecdotally, many Midlothian children apparently have severe cases of asthma, cancer cases are wide-ranging among the population and there has been a history of poor health problems among cattle, horses and other animals in the area. Debra Markwardt, a local Midlothian dog breeder, recently suggested to ATSDR's Director, Dr. Howard Frumkin, that his agency examine her dogs as an indicator of what is happening to the human population in Midlothian. Markwardt moved to Midlothian in 1988. Her dogs soon started experiencing a wide-range of disturbing health prob-

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[18] Amanda Caldwell and Susan Waskey, "Midlothian Industrial Plant: Emission Data," Geography Special Problems, University of North Texas, July 25, 2008.

[19] Marvin Legator, et al., "The Health Effects of Living Near Cement Kilns; A Symptom Survey in Midlothian, Texas," *Toxicology and Industrial Health,* Vol. 14, No. 6, 1998.

[20] Marvin S. Legator and Amanda M. Howells-Daniel, "A Deliberate Smokescreen," *Archives of Environmental Health,* Vol. 49 (No. 3), May/June 1994.

[21] *USA Today* Special Report, "The Smokestack Effect: Toxic Air and America's Schools," December 8, 2008, *http://content.usatoday.com/news/nation/environment/smokestack/index?loc=interstitialskip*

lems. The photos of her dogs are troubling. Some were born with missing limbs, many had skin problems, and others were born with organs outside of their bodies and entire litters died shortly after birth. Most surprisingly, dogs that were sold and moved off of her property with severe skin problems began to regain their health within months but those that stayed continued to suffer from ill-health effects. (*See photos of Markwardt's dogs in attachment*).

Recently, Markwardt had herself and some of her dogs tested for heavy metals. Over the past few years, veterinarians have found high levels of aluminum in her animals, she says. In May 2007, Ms. Markwardt's own doctor wrote: "She has lived in a home that has very high levels of aluminum in the soil and in the dust that is found in the home. She has had a urinalysis that shows her aluminum level to be markedly elevated and it should be zero," wrote her doctor. Last July, her veterinarian wrote: "It is my opinion that these dogs need to be moved off of the property. Since nothing medical has helped, it is highly probable that this is an environmental problem."

On December 19, 2008, Dr. William Cibulas, the Director of ATSDR's Division of Health Assessment & Consultation (DHAC) wrote to Ms. Markwardt on behalf of Dr. Frumkin. "ATSDR is sympathetic toward the plight of your animals, however, veterinary and animal issues are outside of our mandated domain," he wrote. Clearly frustrated by this response Ms. Markwardt exchanged some more e-mails with ATSDR.

On January 22, 2009, Markwardt wrote back to ATSDR and copied Dr. Frumkin on the e-mail. "Please do not tell me again that veterinary and animal issues are outside of [your] mandated domain. You know full well (or should) that the potential impact on people is the issue that I raised," wrote Markwardt. "All that we have asked you to do is to provide trusted health information. Do you feel that an honest conclusion in the Midlothian Public Health Consultation can be reached by pretending what is happening to these animals is not happening; therefore, it cannot be an indicator of what is happening to human health?"

The next day, on January 23, 2009, a technical officer in DHAC, Alan Yarbrough, responded. "Again, ATSDR is sympathetic to the plight of your animals," he wrote, "but studies involving animals, even as sentinels for human health issues, are not activities engaged in or funded by our agency."

In 1991, however, the National Academies of Sciences' Committee on Animals as Monitors of Environmental Hazards was *charged by ATSDR* "to review and evaluate the usefulness of animal epidemiologic studies for human risk assessment and to recommend types of data that should be collected to perform risk assessments for human populations." In their final 176-page report for ATSDR, the academy wrote that animals can be "used to monitor concentrations of pollutants" and "can yield a better evaluation of hazard to humans" than "mechanical devices can." In fact, the academy concluded: "An investigator planning an environmental assessment should always consider using an animal sentinel system, when it is practicable, as an adjunct to conventional assessment procedures. Animal sentinel data are likely to be especially useful in circumstances where the conventional procedures are most prone to uncertainty, including assessing accumulated chemicals, complex mixtures, complex exposures, uncertain bioavailability, and poorly characterized agents." [22]

Since then ATSDR has published numerous health consultations involving animals. In April 2003 under a cooperative agreement with the California Department of Health Services, ATSDR released a health consultation regarding contamination in the private water wells of residents near the Pacific Gas and Electric Facility in Hinkley, California, made famous by environmental investigator and activist Erin Brockovich. In that instance, the health consultation did examine the potential health impact on horses, cows, dogs and cats from the exposures to Nitrate, Lead, Thallium and Chromium.[23] In March 2005, ATSDR released a health consultation that investigated potential exposures from TCE in private well water of both humans and animals in the City of Cliff Village, Missouri. The investigation began after several residents and domestic animals in the Cliff Village area experienced

[22] "Animals as Sentinels of Environmental Health Hazards," Committee on Animals as Monitors of Environmental Hazards, National Research Council, National Academy Press, Washington, D.C., 1991, available here: *http://www.nap.edu/catalog.php?record_id=1351*

[23] "HEALTH CONSULTATION: Response to Community Inquires Regarding Nitrate, Lead, Thallium and Chromium Levels in Water from Private Domestic Wells near the Pacific Gas and Electric Facility in Hinkley, California—Pacific Gas and Electric Facility, Hinkley, San Bernardino County, California," Prepared By: California Department of Health Services, Under a Cooperative Agreement with the Agency for Toxic Substances and Disease Registry, April 25, 2003, available here: *http://www.atsdr.cdc.gov/HAC/pha/pganderesp/pge_toc.html*

unusual health problems that resulted in the death of a domestic animal.[24] In December, 2005, ATSDR issued a health consultation that investigated the poisoning of a 97-pound Siberian Husky in Des Moines, Iowa.[25]

The above cases were gleaned from a cursory search of ATSDR's web-page by the Subcommittee. Why ATSDR refused Debra Markwardt's request is unclear, but there is certainly precedent for ATSDR to examine animals, particularly when there health and safety are closely tied to the health and safety of people.

On February 6, 2009, ATSDR's Yarbrough responded again to Ms. Markwardt. But this time, the Agency's rationale for refusing to investigate the health of Markwardt's dogs changed slightly. Originally, Markwardt was told "veterinary and animal issues are outside of our mandated domain," wrote ATSDR. This time, Yarbrough wrote: "ATSDR's enabling legislation does not prohibit our conduct of animal studies; however, ATSDR and the Texas Department of State Health Services do not have the expertise to conduct the appropriate animal studies," he wrote. Instead, ATSDR told Markwardt that they referred her case to two veterinarians with Texas A&M. But the researchers do not yet have any funding to support an investigation and they have not yet contacted her.

Polycythemia Vera Cancer Cluster in Eastern Pennsylvania

Dr. Ronald Hoffman, MD, is Professor of Medicine, Hematology/Oncology Section, at the Tisch Cancer Institute and Professor of Gene and Cell Medicine at Mt. Sinai School of Medicine in New York. He is also the former President of the American Society of Hematology. Dr. Hoffman is a leading expert on a rare cancer called polycythemia vera (PV). He had never heard of ATSDR before being called by ATSDR staff in 2006 to lend his expertise to an investigation it was conducting in eastern Pennsylvania examining a potential cluster of PV cases.

In October 2006, ATSDR began assisting the Pennsylvania Department of Health in investigating the high number of reported PV cases in three counties in Pennsylvania—Carbon, Luzerne and Schuylkill counties. The area ATSDR investigated is home to seven Superfund hazardous waste sites that are either closed or in the process of being remediated and seven waste coal burning power plants, which emit polycyclic aromatic hydrocarbons (PAHs). Recent research has suggested PAHs may potentially contribute to polycythemia vera.

The local community has suspected that environmental pollution in the area has a contributor to health problems there for a long time. By the fall of 2007, ATSDR had confirmed more than three dozen cases of PV in the area, more than four times the level outside the region. The Agency also discovered four cases of PV on one two-mile stretch of road not far from the former McAdoo superfund site. None of the PV patients on Ben Titus Road in Northeast Schuylkill County were blood relatives. Two of them, who both passed away last year, were husband and wife. The environmental significance of this tight grouping of PV cases on a single road and the proximity to a hazardous waste site seemed obvious to many, including Dr. Ronald Hoffman.

But that connection did not appear so obvious to ATSDR. The lead ATSDR official in charge of the investigation, Dr. Steven Dearwent, described it to Subcommittee staff as "compelling" information, but nothing more. On October 24, 2007, ATSDR released a "media announcement" regarding their PV investigation. The Agency confirmed more than three dozen cases of PV in Schuylkill, Luzerne and Carbon counties in Pennsylvania but assured the public: "ATSDR found no link between environmental factors and PV in this area."[26] The Agency also failed to mention in the media announcement the four PV cases it found along Ben Titus Road near a former Superfund site, although they had already confirmed these cases at the time.

So, when Dr. Hoffman presented an abstract of the PV investigation at the annual meeting of the American Society of Hematology in Atlanta in December 2007 titled: "Evidence for an Environmental Influence Leading to the Development of JAK2V617F–Positive Polycythemia Vera: A Molecular Epidemiological Study," this apparent contradiction did not sit well with some ATSDR officials. The Agency says

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[24] "HEALTH CONSULTATION: Cliff Village Wells Site, City of Cliff Village, Newton, Missouri, March 21, 2005, Agency for Toxic Substances and Disease Registry, available here: *http://www.atsdr.cdc.gov/HAC/pha/CliffVillageWellsSite/CliffVillageWellsHC.pdf*

[25] "HEALTH CONSULTATION: Pesticide Contamination of Residential Soil—Des Moines, Polk County, Iowa," December 8, 2005, U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, available here: *www.atsdr.cdc.gov/HAC/pha/PesticideContamination120805/PesticideContaminationSoilHC120805.pdf*

[26] "Federal Agency Releases Results of Polycythemia Vera Investigation," ATSDR Media Announcement, Agency for Toxic Substances and Disease Registry, October 24, 2007, available here: *http://www.atsdr.cdc.gov/NEWS/schuykillpa102407.html*

the paper, which included the names of ATSDR scientists, did not go through ATSDR's "clearance process."

In December 2007, the Associated Press reported that ATSDR was distancing itself from Dr. Hoffman and his paper. Dr. Dearwent, the senior ATSDR official in charge of the PV cluster investigation told the AP: "We're going to have to retract the abstract to correct the record because it is erroneous information." Dr. Dearwent claimed that the abstract had been written early in the summer and that subsequent analysis of the data did not support the conclusion of an environmental link.[27] In fact, it seems nothing had actually changed regarding the data but that ATSDR did not feel comfortable drawing any connection between the PV cluster and potential chemical exposures in the environment. Dr. Dearwent told Subcommittee staff that because Dr. Hoffman is a "clinician" and not an epidemiologist he may have viewed the PV cluster differently than the Agency. Dr. Dearwent said that "we had nothing telling us at the time nor do we now" that this cluster is somehow linked to environmental exposures.

To his credit, Dr. Hoffman presented his abstract at the American Society of Hematology conference despite efforts by ATSDR to interfere with his presentation. Last year, ATSDR posted an oddly worded statement about the abstract on its website. The Agency said that the conclusions in the abstract differed from what ATSDR told the public in October 2007 and that it "prematurely" inferred certain conclusions about the PV cluster. Yet, it concluded: "The presentation made at the American Hematology Society meeting accurately reflected ATSDR's current assessment of the data."[28]

In January 2008 Dr. Hoffman e-mailed Dr. Howard Frumkin, the director of ATSDR, about his experience with the PV investigation. "I believe that some members of your staff are unable, incapable or unwilling to objectively looking [sic] at this data," wrote Hoffman. "This nonscientific approach has led to a state of denial and paralysis in you [sic] organization which has resulted in the present confusion about this matter in the community and the press. There are important issues here and objectivity is required," wrote Hoffman. "I hope that the cynical and nihilistic behavior of some of your staff is not a reflection of the scientific veracity of the Agency[.]"

In this case, ATSDR finally acknowledged that a cancer cluster existed in the area of Eastern Pennsylvania they investigated. The Agency released the final results of their investigation last August and found residents in the three counties in Pennsylvania that they assessed were more than four times more likely to develop polycythemia vera than people living outside those counties. And while ATSDR said "There were potential environmental exposure sources common to some of the high-rate areas," they concluded that: "It is not known whether a relationship exists between any of these sources and the PV cases."[29] The Agency said future studies may attempt to investigate the environmental connection further. Dr. Hoffman says that ATSDR continually sought to downplay and minimize any links between the PV cases and the environment suggesting it was just an unusual circumstance. He described their behavior as "very odd and counter-intuitive."

Interestingly, in 1993 ATSDR conducted a public health assessment on the McAdoo Associates Superfund site. That site had ceased operations in 1979, was remediated and taken off of the Superfund list in 2001. The 1993 ATSDR public health assessment of the site found: "Site-related contamination poses *no public health hazard* because there is no evidence of current or past *exposures*, and future exposures to *contaminants* at levels of public health concern are unlikely."[30] Ben Titus Road where ATSDR investigators discovered four unrelated PV cases is close to this site. But conceding that there may be an environmental health hazard present in this community today could put ATSDR in the awkward position of acknowledging mistakes with their past public health conclusions.

In the wake of internal disagreements between Dr. Hoffman and ATSDR regarding the potential link between environmental contamination and the PV cluster, Dr.

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[27] Mike Stobbe and Michael Rubinkam, "Feds hedge on environmental link to Pennsylvania illnesses," Associated Press (AP), December 7, 2007, available here: *http://www1.phillyburbs.com/pb-dyn/articlePrint.cfm?id=1452897*

[28] "Response to the American Hematology Society Abstract," Agency for Toxic Substances and Disease Registry, available here: *http://www.atsdr.cdc.gov/sites/polycythemia—vera/abstract.html*

[29] Polycythemia Vera Investigation, Agency for Toxic Substances and Disease Registry, *http://www.atsdr.cdc.gov/sites/polycythemia_vera/*

[30] "Public Health Assessment, McAdoo Associates, McAdoo, Schuylkill County, Pennsylvania," Prepared By: Pennsylvania Department of Health Under Cooperative Agreement with the Agency for Toxic Substances and Disease Registry, September 29, 1993, available here: *http://www.atsdr.cdc.gov/HAC/pha/mcadoo/mca_p1.html#SUMMARY*

Hoffman says he pushed to publish a peer-reviewed article of the PV investigation's findings, fearing that ATSDR was not willing or able to acknowledge the significance of the PV cluster in Pennsylvania. Last month the work of Dr. Hoffman, ATSDR scientists and other colleagues at the University of Illinois College of Medicine, published their findings in the journal *Cancer, Epidemiology, Biomarkers and Prevention*. The paper reported that the risk of developing PV was 4.3 times greater for the residents living inside the three Pennsylvania counties they examined than for those living outside the area. The article concluded: "The close proximity of this cluster to known areas of hazardous material exposure raises concern that such environmental factors might play a role in the origin of polycythemia vera."[31] Dr. Dearwent, who was not an author on the paper, contends that "some of the language in the manuscript that we opposed made it back in to the paper." Dr. Hoffman and other authors of the paper deny that.

Asbestos Beach—Illinois State Beach Park in Chicago

Mr. Jeffery Camplin is President of Camplin Environmental Services and technical consultant to the Dunesland Preservation Society in Illinois. Since 2003 he has been investigating asbestos contamination on the Illinois shoreline of Lake Michigan and has filed several complaints with ATSDR regarding the inadequacies of their studies of asbestos contamination at the Illinois State Beach Park in Chicago. He is a certified safety professional (C.S.P.), certified professional environmental auditor (C.P.E.A.) and has been an accredited instructor in asbestos abatement by the Environmental Protection Agency (EPA) for more than 20 years. In 2006 he was named Environmental Safety Professional of the year by the American Society of Safety Engineers (ASSE). He is also the lead safety volunteer for the Illinois Medical Emergency Response Team (IMERT).

In Illinois there has been a long history of asbestos containing materials and fibers washing up on the shoreline of Lake Michigan for more than one decade. The Johns-Manville Corporation built a large plant on the shore of Lake Michigan that produced insulation products containing asbestos beginning in the 1920s. The plant, which included a 150-acre asbestos disposal area containing approximately three million cubic yards of asbestos-containing waste, was declared a Superfund site in 1983 and ceased operations in 1998. The asbestos disposal area was covered with soil to prevent its spread. But since then seven areas containing asbestos-containing material from the plant were discovered off-site.[32]

Around the same time as the plant's closure, asbestos debris began washing up along the shoreline at the Illinois Beach State Park, the state's most popular park at two to three million visitors per year.[33] In May 2000, the Illinois Department of Public Health under a cooperative agreement with ATSDR released a public health assessment regarding asbestos contamination at the State park. The report did find that asbestos containing material had been found scattered along the beach at the park and that material containing "low asbestos levels" had been discovered, but not at levels that would be expected to cause adverse health effects in Park workers or visitors," it said. The report concluded: "no apparent public health hazard exists related to asbestos contamination at Illinois Beach State Park."[34]

But the discovery of asbestos material on the public beach at the State park never ceased. Portions of the State park were cleared of asbestos in March 2006. In the summer of 2006 ATSDR used grading equipment to churn up the sand and air filters to capture and measure any potential asbestos fibers. The tests discovered fibers of amphibole asbestos, the most toxic kind of asbestos.

In 2007 ATSDR wrote a draft health consultation based on their findings which said there was no health hazard from the asbestos. In April 2007, local EPA officials submitted written comments of the report to ATSDR. The letter, written by Brad Bradley, the EPA's Remedial Project Manager in the Agency's Region 5 section and

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[31] Dr. Vincent Seaman, et. al., "Use of Molecular Testing to Identify a Cluster of Patients with Polycythemia Vera in Eastern Pennsylvania," *Cancer Epidemiology Biomarkers & Prevention*, 18(2), February 2009, available here, *http://cebp.aacrjournals.org/cgi/content/abstract/18/2/534*

[32] "Region 5 Superfund (SF) National Priorities List Fact Sheet: Johns-Manville Corp.," Environmental Protection Agency, Last Updated: June, 2008, available here: *http://www.epa.gov/region5superfund/npl/illinois/ILD005443544.htm*

[33] See: "Asbestos washes up on beach at state's most popular park," Associated Press, February 3, 1998; and Charles Nicodemus, "State moves in on asbestos//4 agencies study danger to beach," *Chicago Sun-Times*, February 4, 1998.

[34] "Public Health Assessment: Asbestos Contamination at Illinois Beach State Park," Prepared by: Illinois Department of Public Health Under Cooperative Agreement with the Agency for Toxic Substances and Disease Registry, May 23, 2000, available here: *http://www.atsdr.cdc.gov/HAC/pha/illinoisbeach/ibp_toc.html*

the EPA's lead asbestos expert covering Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin, was written to Mark Johnson, ATSDR's regional representative in Chicago, on behalf of the entire EPA Region 5 staff. The letter identified 13 items they believed needed clarification or correction. Many of them were not subtle editorial fixes but significant issues revolving around safety and health issues and the scientific integrity of the ATSDR report. The letter said many of the statements by ATSDR were "misleading," "questionable" and contained "inconsistencies."[35]

"The paragraph on page 12, which states that "Based on the bulk analysis of sand samples collected, the sand in [and] of itself does not appear to pose a significant source of asbestos fibers" is a little misleading," wrote Bradley. "The air samples near the beach grading equipment were significantly elevated; therefore, this would indicate that there might be a problem with this statement," he wrote. But the final ATSDR health consultation read: "Based on the bulk analysis of sand samples collected, the sand does not appear to pose a significant source of asbestos fibers." The public health agency ignored the EPA's concerns about the public's health.

The EPA noted other problems that ATSDR also simply chose to ignore. In his April 2007 letter, Bradley wrote: "13) Regarding the human health safety statements in the Report, the Executive Summary states that it is within the acceptable risk range under certain conditions to use the IBSP [Illinois Beach State Park] beaches for the general public BUT for maintenance activities they should be conducted when sand surface is wet or closed to the public. It is also stated that the IDNR [Illinois Department of Natural Resources] should continue asbestos removal from the beach. These inconsistencies and the actual air monitoring results raise concerns regarding the safety of human use of the beaches. There is ACM [Asbestos Containing Material] on the beach and it should be removed, the maintenance workers should take precautions but it is OK for the public and especially children to play with and on the beach. What is going on here, either the beach is safe or the safety is questionable," Bradley wrote. But ATSDR cleared up the answer to that question in their final report. "What are the conclusions of the EI [Environmental Exposure Investigation]?" asked ATSDR. "The activities simulated at the beaches at IBSP pose no apparent public health hazard," they declared.

In an interview with Subcommittee staff ATSDR's Mark Johnson acknowledged that his agency did not include all of the suggestions submitted by the EPA officials. It is an ATSDR document, he said, and the ultimate decision of what is in the health consultation rests with the Agency for Toxic Substances and Disease Registry. ATSDR is now in the process of reviewing new sampling data of the beaches and expects to release their new health consultation any day, according to ATSDR.

Depleted Uranium (DU) Contamination in Colonie, New York

Professor Randall R. Parrish, Ph.D., is the head of the British Geologic Survey's Natural Environment Research Council's (NERC) Isotope Geoscience Laboratories in Nottingham, England and Professor of Isotope Geology at the University of Leicester. In 2007 he was the lead author of a peer-reviewed journal article that investigated depleted uranium (DU) inhalation exposures in Colonie, New York, home to National Lead, Inc., which produced depleted uranium for U.S. military munitions from 1958 to 1984, when the site was closed due to violations of environmental emission standards.[36] In 2006, the Federal Government completed a $190 million cleanup of the site.

A 2004 ATSDR health consultation found that past emissions from the site "could have increased the risk of health effects—especially kidney disease—for people living near the plant" and found that "the combination of inhaling DU dust and cigarette smoke could have increased the risk of lung cancer." But because the plant had ceased operating, ATSDR concluded that there was "no apparent public health hazard." In addition, they rejected a request to conduct a health survey because they said it would not "answer the community's questions about whether or not the NL plant impacted their health."[37] In 2007, however, Professor Parrish and researchers at the University of Albany—using a newly developed method—detected

[35] Letter from Brad Bradley, Remedial Project Manager, Environmental Protection Agency, Region 5, to Mark Johnson, Regional Representative, Agency for Toxic Substances and Disease Registry, April 24 2007.

[36] Randall R. Parrish, et al., "Depleted uranium contamination by inhalation exposure and its detection after ~20 years: Implications for human health assessment," Society of the Total Environment, September 2007, available here: *http://www.albany.edu/news/pdf_files/Depleted_Uranium_Article.pdf*

[37] "Health Consultation: Colonie Site (Aliases: Colonie Interim Storage Site and Formerly National Lead Industries) Colonie, Albany County, New York, Agency for Toxic Substances and Disease Registry, October 5, 2004, available here: *http://www.atsdr.cdc.gov/HAC/pha/ColonieSite100504-NY/ColonieSite100504HC-NY.pdf*

DU exposures in 100 percent of the former workers at the site they tested and 20 percent of the residents they tested, in addition to DU in the soil found miles away from the site.

Parrish's paper said that the "ATSDR Health Consultation concluded that further investigations were unjustified because it would be impossible to determine the incidence of DU contamination after such a long period of time since the inhalation hazard no longer existed." But Parrish's paper showed it was possible and the authors recommended that ATSDR do a follow-up study with a larger group of nearby residents to access their "potential health outcomes." Although ATSDR's mission statement says it "serves the public by using the best science," scientists at ATSDR told Subcommittee staff that they are unswayed by Professor Parrish's findings and say they do not see a need to re-examine the Colonie, New York residents for potential DU exposures. They say that the amount of depleted uranium detected in the residents was so small that it would not result in any health hazard, thereby confirming the conclusions of their earlier health consultation. Professor Parrish says this argument does not take into account what these individuals were exposed to in the past. Parrish says that with further analysis of his work scientists can attempt to calculate the cumulative exposures of individuals to help determine what their exposures were in the past and what the health risk to them might be today.

Vieques Island, Puerto Rico

For years, ATSDR has investigated potential environmental hazards on and off the coast of the island of Vieques in Puerto Rico. The U.S. Navy engaged in live bombing practice activities on and off the coast of Vieques from 1941 to 2003 spreading munitions containing depleted uranium and other toxic chemicals into the sea and local ecosystem. In November 2003, ATSDR issued a summary of its work on the island. "Residents of Vieques have not been exposed to harmful levels of chemicals resulting from Navy training activities at the former Live Impact Area," ATSDR concluded. "It is safe to eat seafood from the coastal waters and near-shore lands on Vieques," they said.[38]

Many independent scientists and health experts question those findings. Most recently, Professor James Porter, Associate Dean at the Odum School of Ecology, University of Georgia, presented findings at a conference last month that found unexploded munitions from the U.S. Navy around the island were, in fact, leaking toxic cancer causing substances into the ocean endangering sea life. Professor Porter found that sea urchins and "feather duster worms" closest to unexploded bombs or bomb fragments off the coast of Vieques had extraordinarily high toxic levels of various chemicals. Some of the materials were nearly 100,000 times over established safe limits. Professor Porter cautioned that he performed a "point source study," meaning he took measurements close to the residual bomb materials and that ATSDR has performed "broad spectrum" tests that measure toxic chemicals in a much wider arena.

That explains the discrepancies in what Professor Porter found and what ATSDR discovered. Although Professor Porter cautioned that it is still unclear what sort of impact these toxins have had on the dinner plate some studies have shown that residents on Vieques Island have a 23 percent higher cancer rate than those on the main island of Puerto Rico.[39] Other studies have found that plants on the island have high concentrations of lead, mercury, cadmium, uranium, cobalt, manganese and aluminum.[40] Vieques residents question the integrity of the studies conducted by ATSDR, as do many Puerto Rican and other independent scientists.

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[38] "A Summary of ATSDR's Environmental Health Evaluations for the Isla de Vieques Bombing Range, Vieques, Puerto Rico," Agency for Toxic Substances and Disease Registry (ATSDR), November 2003, available here: *http://www.atsdr.cdc.gov/sites/vieques/vieques_profile.pdf*

[39] See: "Link between unexploded munitions in oceans and cancer-causing toxins determined," the University of Georgia, News Release, February 18, 2009, available here: *http://www.uga.edu/aboutUGA/research-bombs.html*; Maria Miranda Sierra, "Carcinogens found in marine life in island of Vieques in Puerto Rico," Caribbean Net News, February 21, 2009, available here: *http://www.caribbeannetnews.com/news-14429_21-21_.html*; John Lindsay-Poland, "Health and the Navy in Vieques," Fellowship of Reconciliation, Puerto Rico Update, Number 32, Spring 2001, available here: *http://www.forusa.org/programs/puertorico/archives/0401healthnavy.html*; Azadeh Ansari, "Undersea bombs threaten marine life," CNN, February 26, 2009, available here: *http://www.cnn.com/2009/TECH/science/02/26/undersea.munitions.cleanup/index.html*

[40] Dr. Arturo Massol-Deya, et. al., "Trace Elements Analysis in Forage Samples from a U.S. Navy Bombing Range (Vieques, Puerto Rico), *International Journal of Environmental Research and Public Health*, August 14, 2005; available here: *http://www.mdpi.com/1660-4601/2/2/263*

Kelly Air Force Base, San Antonio, Texas

Issuing public health documents that fail to include relevant information, are based on incomplete or deficient investigations, or omit critical public health data can contribute to the environmental exposure of the public. In 1999 an ATSDR report that examined cancer incidence around the Kelly Air Force Base in San Antonio, Texas, found increased levels of liver and kidney cancer as well as leukemia.[41] But none of ATSDR's studies on the former Air Force Base linked the illnesses to the toxins from the base that have leached into these neighborhoods.

In a critique of the ATSDR report, Dr. Katherine Squibb, a toxicologist at the University of Maryland, found that the Agency's conclusions were based on minimal information, some Air Force studies ATSDR relied on for its conclusions failed to measure important exposure pathways, and ATSDR failed to conduct an adequate assessment of whether or not some chemicals migrated off-base. "It is questionable as to whether ATSDR's conclusion that no public exposure to contaminants occurred through the domestic use of groundwater in the past is correct," wrote Squibb.[42]

In a 2002 critique of another ATSDR report on the Kelly Air Force Base, Squibb found that ATSDR did not evaluate cumulative risks of exposure for certain chemicals.[43] She also told a local reporter that ATSDR examined health risks from exposure to soil from a part of the base only after the site had been cleaned up and remediated. "It does not appear that ATSDR has considered health risks associated with soil that migrated from this site prior to remediation," said Squibb.[44]

Seven years after Dr. Squibb's comments, the issues of off-site contamination at Kelly Air Force Base were still swirling around the local community. "I don't know much about science," San Miguel, one local resident said last month, "but there are 13 homes on this block and 11 of those families have had someone die from cancer. That is what is bothering me," he said. "Where did that come from?"[45]

Trichloroethylene (TCE) Groundwater Contamination in Elkhart, Indiana

Earlier this month, ATSDR released a draft Public Health Assessment (PHA) on groundwater contamination from trichloroethylene (TCE) and other chemicals at what is known as the Lusher Avenue Site in Elkhart, Indiana. Contamination in the area has stretched back to the mid-1980s and last year EPA designated it a Superfund site and placed it on the National Priorities List (NPL). There are a number of potential sources of environmental pollution in the area including a rail yard, pharmaceutical manufacturer, plastic and metal fabrication plants and a musical instrument fabrication facility. The area has a population of 2,597 people, including 286 children six years old or younger.[46]

In 1989, EPA established a drinking water standard or Maximum Contaminant Level (MCL) for TCE of five parts-per-billion (5 ppb). Municipal water systems are required to test water for TCE concentrations every three months. If any levels exceed the MCL, they are required to notify the public via newspapers, radio, TV networks and other means and to provide alternative drinking water supplies to the public.[47] In the past, TCE contamination in the drinking water systems in Lusher were discovered in many of the several hundred private wells in the area. Residents were provided with alternative water supplies or filtration systems were installed.

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[41] "Public Health Assessment, Kelly Air Force Base, San Antonio, Bexar County, Texas," Prepared by Agency for Toxic Substances and Disease Registry, September 9, 1999, available here: *http://www.atsdr.cdc.gov/HAC/pha/kelly/kel_toc.html*

[42] "Technical Review of the Public Health Assessment, Phase I for Kelly Air Force Base, San Antonio, Bexar County, Texas, Conducted by Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry (ATSDR), Released for Public Comment, September, 1999," Prepared by Katherine S. Squibb, Ph.D., Program in Toxicology, University of Maryland, Baltimore (undated), available here: *https://afrpaar.lackland.af.mil/ar/getdoc/KELLY/KELLY_AR_3299.pdf*

[43] "Review of ATSDR Petitioned Public Health Assessment, Kelly Air Force Base," Conducted by Katherine S. Squibb, Ph.D., Program in Toxicology, University of Maryland, Baltimore, June 11, 2002, available here: *https://afrpaar.lackland.af.mil/ar/getdoc/KELLY/KELLY_AR_3278.pdf*

[44] Roddy Stinson, "Round on the Kelly-toxins mystery trail: 'dioxins and furans,'" *San Antonio Express-News*, March 26, 2002.

[45] Anton Caputo, "Kelly area homes retested by EPA," *San Antonio Express-News*, February 6, 2009, available here: *http://www.mysanantonio.com/news/environment/39182822.html*

[46] "Public Health Assessment for Lusher Avenue Groundwater Contamination, Elkhart, Elkhart County, Indiana," Public Comment Release, Prepared by: U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, March 1, 2009, p. 21, (hereafter referred to as ATSDR Lusher Site PHA, available here: *http://www.atsdr.cdc.gov/NEWS/lusher_03022009.html*

[47] "Consumer Factsheet on: TRICHLOROETHYLENE," U.S. Environmental Protection Agency, available here: *http://www.epa.gov/OGWDW/dwh/c-voc/trichlor.html*

A new round of sampling in 2005 and 2006 found some wells had TCE levels of up to 700 ppb, exposing an estimated 200 people to these contaminants.

The recent ATSDR health assessment concluded that: "Most adverse health outcomes are not anticipated at Lusher because the TCE concentration in most private wells is less than 100 ppb."[48] However, ATSDR's own 1997 Toxicological Profile on trichloroethylene cites several studies showing associations between exposures to much lower levels of TCE exposure and health effects, such as neural tube defects, for instance.[49] In addition, it cites another study of residents in Tucson, Arizona that were exposed to TCE levels between six and 239 ppb. The study found that the children of mothers who lived in this area in their first trimester of pregnancy were two and one-half times more likely to develop congenital heart defects than children of mothers not exposed to TCE during pregnancy.[50] Yet, the ATSDR health assessment says that there have been exposures at the Lusher site as high as 700 ppb, "*However, most TCE exposures at Lusher were and are less than 100 ppb and indicate little to no risk for heart defects in newborns.*" [Emphasis in the original].[51]

The ATSDR assessment does say: "People drinking well water which contains TCE at levels greater than 300 ppb have an increased risk of developing cancer." It bases this assertion on another ATSDR study that examined a cancer cluster in Woburn, Massachusetts in 1986 and found that there were more than twice as many childhood cases of leukemia as expected while the TCE contamination in the water was only 267 ppb. How ATSDR now justifies asserting that there is no increased risk of cancer below 300 ppb or that there is no risk of heart defects in newborns from the exposures in Lusher appears to be scientifically unfounded and misleading.[52]

The Public Health Assessment also failed to mention a 1994 study cited in ATSDR's own Toxicological Profile of trichloroethylene. The study found that in a review of 1.5 million residents in 75 towns monitored for TCE levels between 1979 and 1987, females exposed to drinking water in excess of the EPA maximum contaminant level (MCL) of five ppb had a significant elevation of total leukemias, including childhood leukemias, acute lymphatic leukemias, and non-Hodgkin's lymphoma. The recent ATSDR report also failed to mention that a 1996 study by the Massachusetts Department of Health found that the risk of leukemia in the group of Woburn, Massachusetts women exposed to TCE in utero were eight times higher than a control group.[53]

While none of these studies in and of themselves are conclusive evidence of clear links between TCE exposures and these specific health problems, they are part of the scientific public health record on these issues. Omitting them from a public health document that is trying to assess the public health threats from TCE to the community in and around the Lusher site appears short-sighted at best and scientifically misleading.

In the end, ATSDR's conclusions on the Lusher site seem fuzzy at best. Inconsistencies in other ATSDR reports have been a long standing frustration by both local communities and other federal agencies, particularly EPA. In its conclusions on the Lusher site, for instance, ATSDR wrote: "ATSDR categorizes the site as a past public health hazard. Due to uncertainties concerning sources, continuing migration of contaminants, and private well use, the site could pose a future public health hazard. Currently, exposure has been mitigated or lessened through provision of alternate water and filter systems for private well users with contaminated water. However, there may be private wells that still need to be tested."[54] Until ATSDR begins to focus on the scientific integrity and basic clarity of its public health documents with renewed energy, care and focus the Agency will continue to be mired down in problems and garner distrust from the local communities it is supposed to serve.

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[48] ATSDR Lusher Site PHA, p. 12.

[49] "Toxicological Profile for Trichloroethylene," U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, September 1997, p. 84, (hereafter referred to as ATSDR TCE Tox Profile) available here: *http://www.atsdr.cdc.gov/toxprofiles/tp19.pdf*

[50] ATSDR TCE Tox Profile, p. 85.

[51] ATSDR Lusher Site PHA, p. 13.

[52] ATSDR Lusher Site PHA, pp. 14–15.

[53] ATSDR TCE Tox Profile, pp. 90–91.

[54] "Public Health Assessment for Lusher Avenue Groundwater Contamination, Elkhart, Elkhart County, Indiana," Public Comment Release, Prepared by: U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, March 1, 2009, p. 21, available here: *http://www.atsdr.cdc.gov/NEWS/lusher_03022009.html*

Dr. Frumkin's National Conversation

In recent weeks Dr. Frumkin has unveiled an NCEH/ATSDR initiative he calls: "The National Conversation on Public Health and Chemical Exposures." He has grand plans. "[N]ow is an opportune time to revitalize the public health approach to chemical exposures," he wrote recently in the *Journal of Environmental Health.*[55] As part of this effort he wants to have a broad dialogue that aims to identify gaps in the public health approach to chemical exposures and identify solutions for strengthening the public health approach to chemical exposures.

Dr. Frumkin has held several internal ATSDR "all hands meetings" where he has briefed agency employees on his initiative and he organized a small meeting in Washington, D.C. on Friday, March 6th with environmental organizations. He has personally met with many public health and environmental groups in an attempt to drum up support for his initiative.

A few weeks ago he met with Stephen Lester, Science Director of the Center for Health, Environment and Justice and its Executive Director, Lois Gibbs, the local activist from Love Canal in New York who spearheaded an environmental investigation when she discovered her children's elementary school was built on a toxic waste dump. Dr. Frumkin was apparently seeking advice on how to help reorganize or reform ATSDR to make it more responsive to the concerns of local communities. Lester told him that all he needed to do was follow the recommendations he and other local community groups gave to ATSDR back in 1990. Virtually nothing has changed, Lester says. The problems, as well as many of the solutions, remain the same. Lester had been through this once before and is not very hopeful that any real change will come to the Agency.

For a twelve-year period from 1986 to 1998, Dr. Barry Johnson served as the Assistant Administrator of ATSDR and by all accounts he was a deeply dedicated and compassionate public servant. In 1990 he attempted to reach out to local community groups to begin a dialogue in order to help rectify the Agency's poor image and to move the Agency into a new direction, producing scientifically valid studies, identifying causes of environmental contamination causing harm to human health and obtaining the respect and trust of the local communities ATSDR is supposed to protect. Dr. Johnson had contacted the Center for Health, Environment and Justice (then called the Citizen's Clearinghouse for Hazardous Wastes). Because of Lois Gibbs' presence, the organization had clout with many local environmental groups and communities.

There were several meetings between ATSDR and local community groups as a result of Barry Johnson's organizing efforts. The groups produced a long-list of problems, observations and recommendations. Many of them seem to have withstood the test of time and are equally relevant and significant today. "Health officials look for every possible reason other than the obvious as the causative factor in evaluating health problems." "Studies do not address problems and do not lead to action; instead they seem to look for ways to dismiss problems." One asked: "Is there a need for ATSDR? Should ATSDR exist given that it is not providing what citizens want and need."[56]

The momentum from those meetings soon faded. Four years later Lester wrote: "Today we continue to see many of the same investigation strategies that ATSDR and CDC has been using for years—investigating health problems with scientific methods that are highly questionable and inappropriate. They consistently ask the wrong questions, use inappropriate comparison groups, dilute exposed populations with unexposed populations, eliminate exposed people from their studies and use other ill-conceived scientific methods to evaluate health problems in communities. In the end, they find no health problems because they used methods destined to fail from the beginning and because their studies are often "inconclusive by design."[57]

The integrity of the data ATSDR produces is critical to gaining the public's trust and successfully addressing important environmental public health issues. These flawed reports have very direct impacts on the safety and health of the public. The public health documents emanating from ATSDR should adhere to a clear, consistent and scientifically credible and defensible standard. Yet, in far too many instances that is not the case.

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[55] Howard Frumkin, M.D., M.P.H., Dr.P.H., "The Public Health Approach to Chemical Exposures: A National Conversation," *Journal of Environmental Health,* Volume 71, Number 7, March 2009.

[56] "Report on a Meeting Between ATSDR and Community Representatives," Citizen's Clearinghouse for Hazardous Wastes, June 30, 1990, Washington, D.C.

[57] "Promises, Promises: ASTDR . . . Don't Ask . . . Don't Tell . . . Don't Pursue," Stephen Lester, Science Director, Citizens Clearinghouse for Hazardous Waste (renamed Center for Health, Environment and Justice), *Everyone's Backyard Newsletter,* March/April 1994, p. 15–16.

ATSDR's Leadership Today

Many of the challenges that ATSDR faces every day are not simple. Accurately assessing public health implications from environmental contamination is difficult. The state of the science may not be able to determine the exact cause of a cluster of illnesses no matter how many hours are invested or how high a priority investigating the issue is to ATSDR, a local community or anyone else. But these are not now, nor have they ever been the criticisms that have been leveled against the Agency. The criticisms swirl around the simple mistakes, the careless research, the critical scientific omissions, the poorly contrived methods used by the Agency to identify the cause of a community's public health concerns and the lack of appropriate fundamental agency policies, such as having a thorough and independent review of ATSDR's public health documents *before* they are released to the public.

None of these problems will ever evaporate or disappear until ATSDR has strong leaders who are committed to ensuring that the Agency fulfills its mission and at the same time creates a public health culture that is bolstered by sound science, careful review and an eagerness to actually identify the potential environmental causes of illnesses, ailments or diseases that impact local communities and affect their health and safety. The problems that embroil ATSDR have been present for many years and did not simply emerge under the leadership of Dr. Frumkin.

However, it is apparent from both Dr. Frumkin's handling of the formaldehyde issue as well as other incidents that Dr. Frumkin's actions have contributed to a culture where scientific integrity appears to take a back seat to political expediency and uncomplicated conclusions regardless of their accuracy or potential impact upon the public's health. As the Subcommittee said in its staff report on formaldehyde last year: "It seems unlikely that ATSDR will be capable of fulfilling its core mission of protecting the public health until they have capable leaders willing and able to lead the Agency and serve the public." The cases below all reveal the approach taken by the current leadership and their commitment to scientific integrity.

Camp Lejeune, North Carolina

In 1990 ATSDR published a public health assessment that showed a dry-cleaning facility just outside of Camp Lejeune in North Carolina had inappropriately disposed of trichloroethylene (TCE) which contaminated the base's water supply.[58] In 1997 ATSDR wrote a public health assessment on the potential environmental exposures of U.S. military personnel and veterans who had served at Camp Lejeune in North Carolina and were potentially exposed to TCEs and a host of other toxic substances.[59] The report, based on flawed data that was available at the time, showed that the levels of exposures believed to have occurred would not pose a health hazard for adults. But it did recommend a follow-up study to evaluate potential health effects to mothers exposed during pregnancy and their children.[60] ATSDR has conducted numerous health studies on Camp Lejeune since then.[61]

In 2003 a Camp Lejeune veteran wrote to the Department of Health and Human Services requesting records referenced in ATSDR's 1997 public health assessment on Camp Lejeunne under a *Freedom of Information Act* (FOIA) request. The response he got back said the records "are no longer in CDC's possession. Specifically, the records were lost during a 1998 office move," an HHS official wrote. "As a result, CDC no longer has records that would respond to your request, other than the public health assessment itself."[62] However, an ATSDR FOIA officer offered a slightly different explanation. On June 2, 2003, she wrote, "A search of our record failed to reveal any documents pertaining to your request. Program staff stated that the ref-

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[58] "Public Health Assessment for ABC One Hour Cleaners, Jacksonville, Onslow County, North Carolina," Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, 1990.

[59] "Public Health Assessment for U.S. Marine Corps Base at Camp Lejeune, Military Reservation, Camp Lejeune, Onslow County, North Carolina," Agency for Toxic Substances and Disease Registry, 1997, available here: *http://www.atsdr.cdc.gov/HAC/pha/usmclejeune/clej_toc.html*

[60] For a good summary of the environmental issues at Camp Lejeune see: J. Wang, et. al., "Camp Lejeune (NC) Environmental Contamination and Management," Multimedia Environmental Simulations Laboratory, Georgia Institute of Technology, available here: *http://mesl.ce.gatech.edu/RESEARCH/CampL_GW.htm*

[61] "Camp Lejeune, North Carolina: Home," Agency for Toxic Substances and Disease Registry, available here: *http://www.atsdr.cdc.gov/sites/lejeune*

[62] Letter from William A. Pierce, Deputy Assistant Secretary for Public Affairs/Media, Department of Health and Human Services to Mr. Thomas Townsend, November 25, 2003.

erenced material was either destroyed or misplaced during an agency physical move this past October [2002]."[63]

Finally, Dr. Frumkin responded to Camp Lejeunne veteran and activist Jerry Ensminger about the FOIA responses and the validity of the 1997 Public Health Assessment on May 4, 2007. "As a scientific public health agency, it is important to us that our reports contain the most current and scientifically correct information available at the time," wrote Dr. Frumkin. "We acknowledge that the references used for the development of the 1997 public health assessment are no longer available in the Agency for Toxic Substances and Disease Registry's (ATSDR) files. A move of ATSDR staff resulted in our files of Camp Lejeune-related documents being temporarily relocated. A private contractor mistakenly disposed of the documents," said Dr. Frumkin. "Although unfortunate that the material referenced in the public health assessment is no longer available in ATSDR's files, the original information and data, with the exception of original ATSDR references, may still be available from their original sources."

Mr. Ensminger legitimately questions how the leader of a federal scientific public health agency can stand behind a document which contains no supporting information or data. He is particularly perturbed by how cavalier Dr. Frumkin has been to this and other critical public health issues. The impact of ATSDR's work has real-world implications for U.S. Veterans and other members of the public. In this instance, the U.S. Veterans Administration has specifically cited the flawed ATSDR public health assessment to deny at least one veteran medical benefit's for illnesses they believe were due to toxic exposures while based at Camp Lejeune on several occasions.[64]

Brush Wellman, Elmore, Ohio—Beryllium Tests

However, in some instances it is clear that Dr. Frumkin and his deputy Dr. Tom Sinks have intentionally tried to diminish the scope and integrity of some of the Agency's health consultations. In one investigation that examined potential exposures to beryllium in Elmore, Ohio, Dr. Frumkin and Dr. Sinks clearly prevented ATSDR staff from more adequately informing the local community about the availability of free blood tests in order to test them for potential exposure. Publicly, ATSDR said that it offered up to 200 free tests but that only about 20 individuals responded. But internally, e-mails obtained by the Subcommittee show that Dr. Frumkin and Dr. Sinks intentionally limited advertising the availability of the tests despite strong and repeated arguments from some ATSDR staff scientists.

In February 2006, Dr. Dan Middleton was finally at wits end. In an e-mail to Dr. Sinks, in which Dr. Frumkin and others were copied he wrote: "After a prolonged struggle to bring this investigation forward and innumerable revisions, I find myself at a loss as to how to proceed—I cannot in good conscience lead an investigation that has little chance of success." Middleton said he would like to resolve the issue constructively and suggested a meeting with Dr. Frumkin and Dr. Sinks.[65]

But Dr. Frumkin's reply to Dr. Sinks about the e-mail was less than encouraging. "Tom: Dan is probably right. We need a meeting. This is because he clearly hasn't gotten the message. This study is OFF. There will not be a study along the lines Dan has contemplated. There will be a limited clinical service offered to those (probably few) members of the community who want it. That service will consist of a blood test to look for beryllium sensitization among eligible persons. The outcome will be this: people who are sensitized will be informed of that fact (as will those who are not sensitized), and if they wish their doctors will also be informed. We will provide information to local doctors to help them interpret and act on the results. With that we will be done. Period. Howie."[66]

In mid-June, 2006 Dr. Middleton attempted to gain permission from Dr. Sinks to specifically inform workers in one local machine shop about the beryllium tests. "Isn't it the right thing to do?" Dr. Middleton asked.[67] In his e-mail response, Dr.

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[63] Letter from Lynn Armstrong, CDC/ATSDR FOIA Officer, Office of Communication, Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) to Thomas Townsend, June 2, 2003.

[64] Denita L. McCall, Represented by Disabled American Veterans before Department of Veterans Affairs, Rating Decision, January 17, 2007.

[65] E-mail from Dr. Dan Middleton to Dr. Tom Sinks (cc'd to Dr. Howard Frumkin and other ATSDR officials), Tuesday, February 7, 2006, 9:38 a.m.

[66] E-mail from Dr. Howard Frumkin to Dr. Tom Sinks, Tuesday, February 7, 2006 11:15 a.m.

[67] E-mail from Dr. Dan Middleton to Dr. Tom Sinks, Subject: machine shop workers, Wednesday, June 14, 2006, 4:54 p.m.

Sinks wrote: "good try—no. Let's run the advertisement. It will include machinists and they may call us."[68]

In the end, only a small number of individuals asked to be tested. A week later, Dr. Sinks was informed by Dr. Middleton that they had completed 27 interviews for the test and that 21 people are eligible.[69] Dr. Sinks then forwarded the e-mail to Dr. Frumkin with the subject line: "beryllium testing" saying "pretty good guess!" Dr. Frumkin's reply to Dr. Sinks, "Wow. I think 20 was our estimate, no?"[70] The Subcommittee investigated the beryllium issue last year.[71]

The design of any scientific study is a critical element in determining the validity of its outcome and ability of the study to identify a problem. Until ATSDR has strong dedicated leaders who are more concerned about the integrity of the reports the Agency produces than the potential backlash the Agency may receive from corporations, federal agencies or local environmental groups unhappy or dissatisfied with the results of their work ATSDR will never gain the public's trust or the confidence of independent scientists and public health professionals.

Lead in Washington, D.C.'s Drinking Water

Based on almost two years of work, it is the Subcommittee's staff's conclusion that Dr. Frumkin has shown a laissez-faire attitude towards the scientific integrity of the documents and data his agency relies upon to make critical public health decisions. In several instances he has appeared to be more inclined to defend the agencies he directs, the Agency for Toxic Substances and Disease Registry (ATSDR) as well as the CDC's National Center for Environmental Health (NCEH), than protecting the public's health by diligently investigating and analyzing potential public health threats based upon sound scientific procedures and methods. His inexcusable defense of the Agency's actions in the formaldehyde issue is perhaps the most glaring example, but there have been others.

In 2002 a change in the drinking water filtration system in Washington, D.C. led to a sharp increase in the levels of lead in the city's drinking water. This spike which may have presented a health hazard to city residents was not reported by the Washington D.C. Water and Sewer Authority (WASA) or the Environmental Protection Agency (EPA). By early 2004 tests indicated that most homes tested had water lead levels above EPA's recommended level of 15 parts per billion (ppb). The public first became aware of the high lead levels in a 2004 story in *The Washington Post*.[72]

In March 2004, scientists at the CDC's National Center for Environmental Health, which Dr. Frumkin came to lead the following year, reported that of 201 residents from 98 homes with high water lead levels they tested, none of them had lead levels in their blood that reached a "level of concern."[73] Most people interpreted this CDC report as claiming that there was no health threat from drinking Washington, D.C.'s water. A WASA fact-sheet in February 2008, for instance, said: "According to the CDC report, there were no children, from a sample group of 201, identified with blood lead levels above the CDC *level of concern* (>10 micrograms/deciliter) that were not explained by other sources, primarily the conditions of the household paint."[74]

But last month a peer-reviewed paper was released by Marc Edward, a civil and environmental engineering professor at Virginia Tech and collaborators at Children's National Medical Center that showed, in fact, children in D.C. clearly had high levels of lead in there blood as a result of the D.C. water crisis. They also found that 50 percent of the data CDC relied on from the D.C. Department of Health re-

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[68] E-mail from Dr. Tom Sinks to Dr. Dan Middleton, Subject: RE: machine shop workers, Thursday, June 15, 2006, 5:02 p.m.

[69] E-mail from Dr. Dan Middleton to Dr. Tom Sinks, Friday, June 23, 2006, 3:01 p.m.

[70] E-mail from Dr. Howard Frumkin to Dr. Tom Sinks, Saturday, June 24, 2006, 11:49 a.m.

[71] "Subcommittee Investigates CDC's Handling of Beryllium Exposure Investigation," April 11, 2008, available here: *http://science.house.gov/press/PRArticle.aspx?NewsID=2154*

[72] David Nakamura, "Water in D.C. Exceeds EPA Lead Limit; Random Tests Last Summer Found High Levels in 4,000 Homes Throughout City," *The Washington Post*, January 31, 2004, p. A1.

[73] "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water—District of Columbia, 2004," Morbidity and Mortality Weekly Report, MMWR Dispatch, Vol. 53/March 30, 2004, Department of Health and Human Services, Centers for Disease Control and Prevention, available here: *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm*

[74] "Important Facts For Lead Service Replacement: Program Review," District of Columbia Water and Sewer Authority, February 2008, available here: *http://www.dcwasa.com/site_archive/news/documents/LSR%20Program%20Facts.pdf*

garding the blood tests and water lead levels was flawed.[75] In addition, it was discovered that more than 6,500 blood tests for a critical period in 2003 and 2004 were lost. Still, Dr. Frumkin told a reporter for *Environmental Science & Technology*, the journal where the article was published, that even if the data used for the CDC analysis was deeply flawed it would not impact the CDC's conclusions. "No public-health database is perfect," he said. "But this database is not so flawed that it fails. We did a sensitivity analysis to see what happens if data are misclassified. That sensitivity analysis shows that there would need to be a very large amount of data misclassification to alter the conclusions of the study," argued Frumkin.[76]

Dr. Frumkin's statement that a "sensitivity analysis" showed that even flawed data would not change the conclusions of the CDC report struck Professor Marc Edwards as incredible for the leader of a public health agency. Professor Edwards says considering half of the data had flaws in it, it seems highly unlikely that those flaws did not impact the CDC's findings. He says his new report clearly shows that the data and therefore CDC's conclusions were wrong. Dr. Frumkin and the CDC began to back away from their initial claims that were widely interpreted to mean the drinking water was safe.

In the aftermath of the criticism of the CDC report, Dr. Frumkin said the report had a "clear message," that "there is no threshold for lead exposure." Edwards, a civil and environmental engineering Professor was named a MacArthur Fellow last summer by the John D. and Catherine T. MacArthur Foundation and granted $500,000 (often called a "Genius Grant") to study drinking water safety issues. Edwards has written several letters to the CDC alleging "possible scientific misconduct by CDC Scientists and Officials" regarding the D.C. lead—drinking water issue. He has not named Dr. Frumkin in these complaints.

But Dr. Frumkin's public response to his involvement in the D.C. lead drinking water issue is remarkably similar to his actions and inactions undertaken during ATSDR's response to the formaldehyde issue. In that instance, he argued, after being confronted by Congress that it was not his agency's fault for issuing a deeply flawed health consultation, but FEMA's fault for "misinterpreting" the data in the undeniably flawed report. On the D.C. lead issue, Dr. Frumkin e-mailed Ralph Scott, the Community Project Director for the Alliance for Healthy Homes, on Monday, February 16, 2009 and said: "In the *Post* article of February 11, WASA General Manager Jerry Johnson attributed to CDC the view that "residents' health had not been affected" by elevated lead levels in DC's water supply from 2001 to 2004. As I am sure you agree, this persistent misstatement by WASA is regrettable," wrote Dr. Frumkin. He then went on to defend the CDC report on D.C.'s lead level in drinking water saying the report actually said no levels of lead are safe for children.

Like the formaldehyde report, the CDC report was simply "misinterpreted" by the public and apparently officials at the D.C. Water and Sewer Authority, according to Dr. Frumkin. And like the formaldehyde report, the CDC report on lead levels in D.C.'s drinking water has had health related consequences. School officials in New York and Seattle have cited the flawed CDC report as justification for not appropriately responding to high levels of lead in their water, for instance. Congress's investigative arm, the Government Accountability Office (GAO) also cited the flawed CDC report and the Congressional Research Service (CRS) used the flawed data in the CDC report because they believed it was scientifically sound and accurate. "None of the 201 persons tested who live in homes with the highest levels of lead in drinking water (i.e., above 300 ppb) had blood lead levels above CDC's levels of concern," the CRS report said.[77] But Professor Edwards' paper now shows that that conclusion was based on flawed data and is wrong.

Scientific Integrity?

For a public health agency whose mission is to protect the health of the public from toxic chemicals, the integrity of the science upon which ATSDR bases their decisions and the scientific integrity of the public health documents they release to the public should be sacrosanct. But in its investigations of how ATSDR's leadership handled its health consultation on formaldehyde for FEMA last year the Sub-

[75] Marc Edwards, et. al., "Elevated Blood Lead in Young Children Due to Lead-Contaminated Drinking Water: Washington, DC, 2001–2004," *Environmental Science & Technology*, January 27, 2009.

[76] Rebecca Renner, "Mapping out lead's legacy," *Environmental Science & Technology*, February 11, 2009, available here: *http://pubs.acs.org/doi/full/10.1021/es8037017*

[77] "CRS Report for Congress: Lead in Drinking Water: Washington, DC; Issues and Broader Regulatory Implications," Mary Tiemann, Specialist in Environmental Policy, Resources, Science, and Industry Division, Congressional Research Service, Updated January 19, 2005, available here: *http://ncseonline.org/NLE/CRSreports/05jan/RS21831.pdf*

committee found a haphazard approach to clearing, vetting and approving the release of its public health documents. In addition, there was an astounding absence of independent scientific review of documents that are supposed to play a critical role in protecting the public's health and in establishing an appropriate federal response to environmentally threatened communities.[78] Largely in response to the Subcommittee's investigation Dr. Frumkin asked ATSDR's Board of Scientific Counselors to examine the Agency's "Peer Review and Clearance Policies and Practices." The board issued a draft report last October.

The Agency's Office of Science, in charge of clearing agency documents for public release, has a small staff and an enormous volume of documents it is supposed to clear, the board's report said. As a result, it lacks the ability to provide in depth scientific expertise to review many documents. Several people told the board that they were concerned that the reviews that took place above the division level were "cursory." In addition, the board wrote that "scientists expressed concern that in trying to achieve its objectives, the Office of Communication Science's wordsmithing can change the intended scientific message in a document." The board also found that there is no clearly written guidance on what documents should be submitted for external peer-review.

But the Board of Scientific Counselors was severely hampered in its review. Interviews were conducted with groups not individuals, for instance. "[S]ome participants may have felt constrained in offering their frank opinions," the board acknowledged. The board also recognized that it received "primarily a management perspective" and did not gather much insight into the concerns or worries of staff scientists. "Approximately 24 managers/team leaders and seven staff scientists were interviewed across the three panels," according to the board's report. "Moreover, only one agency employee attended the open session for walk-in comments," the report says.

In fact, it seems to the Subcommittee staff that the major focus of the board's review, initiated at the direction of Dr. Howard Frumkin, received an inevitably skewed assessment of these issues. It is unclear if the board received an accurate portrayal of how ATSDR's public health documents are vetted and released to the public by not hearing from the staff scientists and other ATSDR employees who have expressed deep and wide-ranging concerns about this issue for a long time. The fact that a single employee showed up for the board's "open session" suggests that a large cadre of these scientists remains fearful about raising critical issues with ATSDR's leadership involving the scientific integrity of the Agency's public health documents and perceived flaws in the scientific design and methodology used to investigate potential public health hazards. In the past year, for instance, the Subcommittee has received numerous communications from ATSDR staff scientists who have raised serious concerns about the willingness, ability and desire of ATSDR's leaders to ensure that only well vetted public health documents based on scientifically defensible positions and assumptions are released to the public.

Conclusion

Protecting the public's health from potential exposures to toxic substances is not an easy task. It can be scientifically challenging, time consuming and resource intensive. The Subcommittee staff suggests that legislative fixes may be necessary to address long-standing structural, procedural and technical issues that appear to have hampered ATSDR's effectiveness and harmed the communities it is supposed to protect.

But more than anything, it is apparent that no fundamental changes will occur until the nearly thousand employees at the NCEH and ATSDR, the vast majority of whom are truly dedicated and committed to protecting the public's health, have leadership that they can follow. The longer ATSDR continues to pursue its role in protecting the public's health as it has for the past three decades, issuing deeply flawed scientific reports, not responding to the concerns of local communities and approaching potential environmental exposures with a mindset that endeavors to disprove any link between the public's ill-health effects and potential exposures to environmental contaminants or toxins, the more people will suffer. After four years leading ATSDR, not only has Dr. Frumkin taken no effective steps to confront those issues, on some specific cases he has contributed to the problems detailed in this staff report. In many instances, ATSDR seems to represent a clear and present danger to the public's health rather than a strong advocate and sound scientific body

[78] "Toxic Trailers—Toxic Lethargy: How the Centers for Disease Control and Prevention Has Failed to Protect the Public Health," Majority Staff Report, Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives, September 2008, available here: *http://democrats.science.house.gov/Media/File/Commdocs/ATSDR_Staff_Report_9.22.08.pdf*

that endeavors to protect it. Without a leader able and willing to confront those issues, the public's health will continue to be harmed.

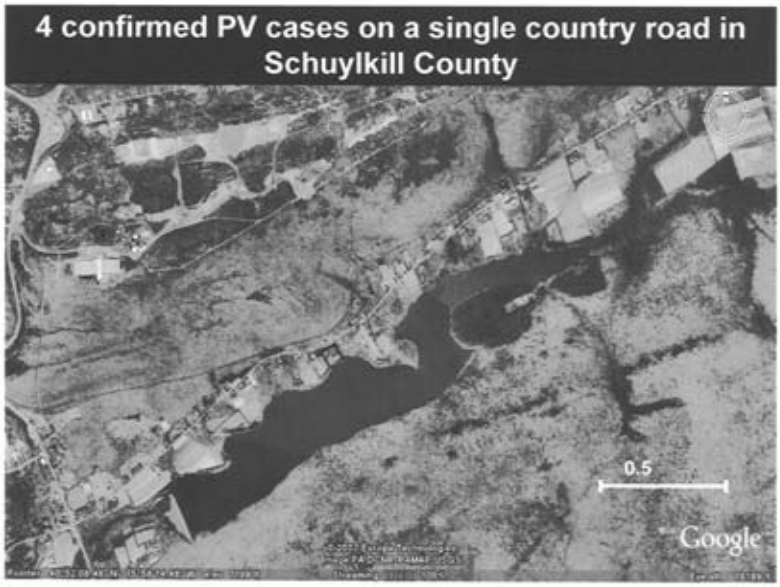
- Debra Markwardt's Dogs -

Birth Defect – Deformed Head and Face - Intestines Outside of Body
- Debra Markwardt's dogs -

Hole on Side of Body
- Debra Markwardt's dogs -

Above -- Jake living on my property in Midlothian

Below - Jake 6-Months Later -- After Living in Another Town



Chair MILLER. Dr. Broun, the Ranking Member.

Mr. BROUN. I thank the Chair.

Good morning. I want to welcome the witnesses here today and thank the Chair for holding this hearing. I share the Chair's concern with public health and safety issues not only as a legislator but also as a physician and a scientist. Our constituents deserve to know whether their families are being exposed to harmful levels of toxic chemicals.

As the Chair noted, ATSDR is no stranger to this committee. The Subcommittee's previous inquiry into the health consultation report for FEMA regarding formaldehyde in trailers and the Agency's work regarding toxic releases into the Great Lakes region pointed to weaknesses in ATSDR's scientific review process as well as how they convey information to the public. Because of these concerns, ATSDR initiated several internal reviews of these efforts and the Committee asked GAO to review the Agency's processes. Dr. Frumkin will update us on his agency's efforts today, but we will have to wait for GAO's results for a few months. Until then, I hope the witnesses here today can help this committee and the general public better understand the Agency's original mandate and how it has evolved since its inception, the public's expectations for the Agency and the effects of an increasing number of petitions to the Agency.

Understanding and communicating these fundamental points are the first steps in evaluating the effectiveness of ATSDR. While the work of the Agency is critically important, it is also very difficult. Determining causation and making health risk determinations is not always black and white. Despite the complexity of their work,

the public deserves to have an agency that they can trust. The issues that we discuss today are not simply academic.

Much like the witnesses on the first panel today, many of my constituents turn to ATSDR for answers about the effects on their local environment and on their families' health. Recently, Jill McElheney, a constituent of mine, contacted me regarding her experiences with ATSDR, the EPA and the State of Georgia. The heartbreaking story of her son's battle with childhood leukemia and the possibility that chemicals from a nearby industrial facility could have influenced his condition is cause enough for all of us to take notice.

I hope this hearing will help us shed light not only on how the Agency can better protect public health and safety but also how it can adapt to its evolving mission and the appropriateness of this evolution. Additionally, I hope the witnesses can help us understand how the Agency can better coordinate with community organizations, other executive branch agencies and State and local departments of health as well as other government facilities on the State and local level. Aside from assuring the science is always at the center of the Agency's work, understanding expectations and effectively communicating with the public is key to making sure that ATSDR is an effective agency in the future.

In closing, I want to thank our witnesses for appearing here today as well as all the hardworking folks at ATSDR.

Thank you, Mr. Chair, and I yield back the rest of my time.

[The prepared statement of Mr. Broun follows:]

PREPARED STATEMENT OF REPRESENTATIVE PAUL C. BROUN

Good morning. I want to welcome our witnesses here today, and thank the Chairman for holding this hearing. I share the Chairman's concern with public health and safety issues, not only as a legislator, but also as a physician. Our constituents deserve to know whether their families are being exposed to harmful levels of toxic chemicals.

As the Chairman noted, Agency for Toxic Substances and Disease Registry (ATSDR) is no stranger to this committee. The Subcommittee's previous inquiry into the health consultation report for the Federal Emergency Management Agency (FEMA) regarding formaldehyde in trailers, and the Agency's work regarding toxic releases in the Great Lakes Region, pointed to weaknesses in ATSDR's scientific review process as well as how they convey information to the public.

Because of these concerns, ATSDR initiated internal reviews of these efforts and the Committee tasked GAO to review the Agency's processes. Dr. Frumkin will update us on his Agency's efforts today, but we will have to wait for GAO's results for a few more months.

Until then, I hope the witnesses here today can help this committee, and the general public, better understand:

- the Agency's original mandate and how that has evolved since it's inception,
- the public's expectations for the Agency, and
- the effects of increasing numbers of petitions to the Agency.

Understanding and communicating these fundamental points are the first steps in evaluating the effectiveness of ATSDR. While the work the Agency does is crucially important, it is also very difficult. Determining causation and making health risk determinations is not always black-and-white. Despite the complexity of their work, the public deserves to have an agency they trust.

The issues we discuss today are not simply academic. Much like the witnesses on the first panel today, many of my constituents turn to ATSDR for answers about the effects of their local environment on their family's health. Recently, Jill McElheney, a constituent of mine, contacted me regarding her experiences with ATSDR, the EPA, and the State of Georgia. The heartbreaking story of her son's battle with childhood leukemia and the possibility that chemicals from a nearby in-

dustrial facility could have influenced his condition is cause enough for all of us to take notice.

I hope this hearing will help us shed light not only on how the Agency can better protect public health and safety, but also how it can adapt to its evolving mission, and the appropriateness of this evolution. Additionally, I hope the witnesses can help us understand how the Agency can better coordinate with community organizations, other Executive Branch Agencies, and State and local health departments. Aside from ensuring that science is always at the center of the Agency's work, understanding expectations and effectively communicating with the public is key to making sure ATSDR is an effective agency in the future.

In closing, I want to thank our witnesses for appearing here today, as well as all the hard-working folks at ATSDR. Thank you Mr. Chairman, I yield back the rest of my time.

Chair MILLER. Thank you, and I look forward to working with Dr. Broun on this committee. I welcome his expertise, his scientific expertise, and if I was able to get along with Mr. Sensenbrenner, I certainly think I can get along with Dr. Broun.

Mr. BROUN. I look forward to working with the Chair. There are some theoretical scientists on our scientific committee that don't think that physicians are scientists but I will take exception to that because we do scientific theory, et cetera, and I appreciate the opportunity of working with the Chair.

Chair MILLER. As a recovering lawyer, I am certainly in no position to sneer at your scientific credentials. I will certainly accept you as a scientist.

I understand Mr. Wilson has no opening statement but we will accept opening statements for the record without objection that may be included later.

[The prepared statement of Chair Gordon follows:]

PREPARED STATEMENT OF CHAIR BART GORDON

I want to thank Mr. Miller for calling this hearing. This subcommittee has done good work in keeping the pressure on the Centers for Disease Control and the Agency for Toxic Substances and Disease Registry (ATSDR) to get the science right when protecting the public's health.

Chemicals of all kinds pollute our water, our air, our soil, and also enter the food chain. Some are benign and some are dangerous.

For a community that has had a toxic spill or long-standing pollution issues, worrying that you or your family may get sick because of something they eat or breath or drink is a part of your everyday existence. If you live in such a place, you live with worry and fear and maybe even a sense of guilt that by choosing to live there you are exposing your family to something that could make them sick or even kill them.

When Congress established ATSDR in the 1980s, we hoped that it would be like the cavalry riding over the horizon to come and tell a community that everything was alright, or at least to let you know how bad the situation is. We expected them to use the best science and develop ever more innovative ways to establish whether some environmental problem was becoming a public health problem.

Unfortunately, ATSDR seems to be the gang that can't shoot straight. They come into local communities, often ignore the health complaints of local citizens, seem to ignore obvious ways to determine what might be happening, and more often than not go away saying there is nothing to worry about because they couldn't find anything. As witnesses today will testify, ATSDR seems to resist developing new scientific methods for doing their work.

The American public deserves better than this for their $74 million a year—that is ATSDR's budget—and I believe this agency can do better.

There are many, many dedicated public health professionals at ATSDR who would love to call it as they see it.

There is ample room to improve the Agency's scientific methods, and to be more creative in how they do science, so that the public is better served.

It is past time that we hold this agency to higher standards.

Panel I:

Chair MILLER. It is now my pleasure to introduce our first panel of witnesses. Dr. Salvador Mier is the former Director of Prevention for the Centers for Disease Control and a local resident of Midlothian, Texas. Professor Randall Parrish is the head of the British Geologic Survey's Natural Environmental Research Council's Isotope Geoscience Laboratories in Nottingham, England. I hope he doesn't repeat all that at every cocktail party. He participated in an innovative study of community exposure to depleted uranium in Colonie, New York. Mr. Jeffery Camplin is the President of Camplin Environmental Services Incorporated, a safety and environmental consulting firm in Rosemont, Illinois, and is a licensed asbestos consultant for the Illinois Dunesland Preservation Society. Dr. Ronald Hoffman is the Albert A. and Vera G. List Professor of Medicine at the Mount Sinai School of Medicine, the Director of Myeloproliferative Disorders——

Mr. BROUN. If you need some help with that, I will——

Chair MILLER. Perhaps Dr. Broun could introduce Dr. Hoffman. I think it is easier now. Programs at the Tisch Cancer Institute at Mount Sinai and formerly the President of the American Society of Hematology.

It is the practice of the Subcommittee to take testimony under oath. Do any of you have any objection to being sworn in? We also provide that you may be represented by counsel. Are any of you represented by counsel today? We ask you these questions to put you at ease.

If you would now all rise and raise your right hand. Do you swear to tell the truth and nothing but the truth? Let the record reflect that each of the witnesses responded in the affirmative. You now have five minutes each for your spoken testimony. Your full written testimony will be included in the record of the hearing. When you complete your testimony, we will begin with questions and each Member will have five minutes to question the panel.

Mr. Mier, please begin.

STATEMENT OF MR. SALVADOR MIER, LOCAL RESIDENT, MIDLOTHIAN, TEXAS; FORMER DIRECTOR OF PREVENTION, CENTERS FOR DISEASE CONTROL

Mr. MIER. Thank you, Chair Miller, Dr. Broun and other Committee Members. Because other Midlothian residents, Midlothian, Texas, were not able to be here today at this hearing, they asked me to bring a short video that depicts some of the animal and dog health issues that we have had concern with, and I would like to request your permission, sir, to show that brief video.

Chair MILLER. Thank you. I believe that we have talked about this at the staff level but the video is only a little more than three minutes, three and one-half minutes.

Mr. MIER. Three minutes.

Chair MILLER. And what I propose is to allow Mr. Mier to show the video and have that not counted against his five minutes for testimony. Without objection, Mr. Mier.

[Video.]

Mr. MIER. Our community is on a treadmill to nowhere. Our human and animal health issues have been festering for years. Our environmental agency declares industrial emissions are harmless and our health agency uses this as a refuge to look no further. In my 40-year public health career, mostly with CDC, I never experienced such a lack of will to determine sources of illnesses. There was never a quarrel about finding a cause caused by a bacteria or a virus, but when a potential source is involved in industry, dynamics change drastically.

For answers I look toward my former employer, CDC. Thus we petitioned ATSDR for a public health assessment in July 2005. But instead of getting the trusted health information promised by ATSDR in their mission statement, we ended up further from the truth. ATSDR has demonstrated they are not committed to the responsibilities inherent in their mission statement or they are not willing to overcome external pressures and act independently to abide by the commitments of this mission statement.

Midlothian, Texas, is a small town with one of the largest steel mills in the United States and the highest concentration of cement manufacturing in the Nation with three plants, one of which is the largest in the United States. These industries, in addition to traditional fuel and other refuse, incinerate whole and shredded tires and hazardous waste, tons of hazardous waste, in kilns never designed for burning hazardous waste. Daily, tons of toxic emissions pour out of 10 cement kilns and two steel industry stacks. Using an EPA screening model in 2005, Toxic Release Inventory, USA Today in collaboration with researchers and scientists at the University of Massachusetts, Johns Hopkins and the University of Maryland ranked all schools in Midlothian in the upper third percentile of the Nation's most toxic schools. Two ranked in the first percentile and two ranked in the third. After hazardous waste became a fuel source in Midlothian, physicians began seeing more patients complaining of upper respiratory problems. Ranchers reported breeding problems, aborted fetuses and deformed offspring in both horses and cattle. A statistically significant cluster of Down Syndrome babies was identified in 1995. A study of respiratory illnesses in Midlothian performed by the University of Texas surfaced a 35 percent higher incidence of respiratory problems in Midlothian as compared to a control group. A study in 2005 found the prevalence of overall birth defects for Midlothian was one and a half times that of Texas, and the prevalence of hypospadias and epispadias, congenital defects in which the urinary outlet opens above or below the penis or on the perineum, was three and a half times that of the State of Texas. A local dog breeder experiences in her animals large number of immune-deficiency illnesses, deformed offspring, litters born dead, cancers and failure to thrive. Questions about a suspect air monitoring system were dismissed. What about all of the empirical evidence that was surfacing? No answers came.

When ATSDR agreed to do the assessment, they said they would ask the State health department to help. Once the state became involved, the assessment morphed into a consultation and the responsibility for making the decision was relegated to the state. The same individuals who had for years declared our environment

posed no health problems were going to look at once more. Furthermore, the decision was to be based on State monitoring data, the same questionable data. By morphing the assessment to a consultation and using the same data, the same folks could pretend not to see or totally ignore health problems and empirical evidence by using the same familiar refuge. Air monitoring does not support any one being sick. ATSDR never intended to be an active participant with this consultation. We were never going to get off that treadmill, at least not with ATSDR's help.

The consultation was finally released for public comment December 11, 2007. Scientists who reviewed it made the following comments. Dr. Stewart Batterman, University of Michigan, states, "The health consultation is biased. It contains overarching statements that discount all indications that emissions from local industry and environmental conditions might or do pose a health concern in our community. It should not be issued by ATSDR." Dr. Peter deFur, of Virginia Commonwealth University, states, "ATSDR's classification of this site as an indeterminate public health hazard is in direct contradiction with the data the Agency presents in the report. Throughout the document ATSDR attempts to marginalize or disregard data that indicate that compounds produce human health risk. ATSDR has more than enough data to classify the site as a public health hazard." Dr. Neil Carman, a scientist who formally worked at the Texas State Environmental Agency, states, "It fails to seriously acknowledge the numerous gaps in the ambient air monitoring in the Midlothian area."

We naively expected an objective and scientific evaluation that would provide trusted health information. We were wrong. Instead, ATSDR abdicated its responsibilities to the state and never questioned the science behind the collection of the data and the reliability for making public health determinations. If ATSDR does not have commitment or capacity to objectively temper and counter external forces that dissuade them from their mission to serve the public by using the best science and provided trusted health information, then ATSDR needs to get out of the public health and consultation business. To maintain the status quo will only continue to risk the public health of many U.S. communities.

[The prepared statement of Mr. Mier follows:]

PREPARED STATEMENT OF SALVADOR MIER

We are on a treadmill to nowhere. Our community's human and animal health issues have been "festering" for a long time. Time and time again the Texas Department of State Health Services (TDSHS) tell citizens of Midlothian the Texas Commission on Environmental Quality (TCEQ) affirms toxic emissions from industries are too low to endanger public health—hence there is no point in looking at their health issues. **Pleas for help die at EPA, TDSHS and TCEQ doorsteps.**

In my 37-year public health career—most of which was with the Centers of Disease Control (CDC)—I never experienced such a reluctance or lack of will to determine sources of illnesses. There was never a quarrel about finding the source when you were dealing with a bacteria or a virus. But when the potential source involves an industry, dynamics change drastically. This is why I decided to look back towards my prior employer (CDC) for answers. Thus, we turned to ATSDR, the purported ultimate environmental public health agency, for help.

Instead of getting help promised by ATSDR in their mission statement, we found ourselves catapulted right back on to that treadmill and further from the truth.

ATSDR has demonstrated they either do not want the responsibilities inherent in their mission statement or they do not have the will and commitment to overcome

external pressures and act independently to abide by the promises of this mission statement.

The Industries

Midlothian, Texas, has the largest concentration of cement manufacturing in the United States. The town and schools are nestled amid three cement manufacturers—Dallas-based TXI's Midlothian cement plant, with five kilns, boasts to be the biggest in the U.S.; Ash Grove of Kansas, with three older wet kilns and Swiss company Holcim, with two kilns, are nearby. Limestone, cement's main component, is mined locally. Cement kiln dust is buried in local unlined quarries. These industries incinerate, among traditional fuels and other refuse, petroleum coke, whole and shredded tires, and hazardous waste—tons of hazardous waste—in kilns never designed to burn hazardous waste.

Adjacent to TXI, Brazilian-owned Gerdau Ameristeel, one of the largest steel mills in North America, melts trainloads of scrap metal and crushed cars into new structural steel.

Daily, tons of toxic emissions pour out of ten cement kilns and two steel industry stacks.

In late 1980 TXI became one of the Nation's largest hazardous-waste-combustion facilities accepting commercial hazardous waste. Cement kilns were authorized by EPA in a 1996 MACT rule to operate under *weaker, less protective* MACT standards for Hazardous Waste Combustors (HWC) compared to hazardous waste incinerators.

In a statement (attached) Dr. Neil Carman, Ph.D., comments:

> "Cement kilns burn up to 1,000 degrees hotter than incinerators and a concern is they may burn too hot for metals causing higher mass emissions due to greater metal volatility at higher temperatures. . . . Exposure to toxic metals is consistent with some health problems reported at Midlothian."

Contradictions in Data

In a report "Midlothian Industrial Plant Emission Data," Amanda Caldwell and Susan Waskey, two University of North Texas (UNT) graduate students added up all emission reports submitted to State and Federal Government by the three cement plants and adjacent steel mill in Midlothian. They spotlighted differences in reported volumes of air pollution when industry submits emissions reports to the State versus the Federal Government. These students discovered:

> "A cursory examination of EPA air release data in Figure 56 (Total Air Releases per Firm 1990–2006) and TCEQ air release data in Figure 60 (Total Hazardous Air Pollutants per Firm 1990–2006), show strikingly different results. For this reporting period, the EPA data shows TXI to be the firm with the largest amount of toxic chemicals released to the air (5,287,384 lbs.), while the state's data show Holcim to be the largest emitter of hazardous air pollutants (1,507,663 lbs).
>
> According to the plants' TRI [Toxic Release Inventory] reports, there were almost **48,000 pounds of lead** air pollution released by all four facilities over the entire 16 years, versus the over **90,000 pounds of lead** the same plants reported sending up their stacks to the TCEQ and its predecessors during the same period.
>
> According to the plant's TRI reports, there were approximately **5,000 pounds of Mercury** air pollution released by all four facilities from 1990 to 2006 **versus** the approximately **10,000 pounds of Mercury** air pollution reported to the state over the same time."

EPA has recently acknowledged total mercury emissions from cement plants in the U.S. are twice as high as reported to the TRI. Based on the two UNT students report, TRI emissions appear not to match State records. Differences like these should give rise to questions.

Midlothian Schools

Approximately 7,000 students attend nine schools situated in Midlothian.

USA Today in collaboration with the University of Massachusetts, the University of Maryland and Johns Hopkins University employed EPA Model, "Risk Screening Environmental Indicators," in an attempt to measure the extent of chemicals children were being exposed to while attending school. This model relied on EPA TRI data for calendar year 2005. In this analysis, *all schools rated in Midlothian* ranked in the *upper third percentile of the Nation's most toxic schools.* Two ranked in the *first percentile* of the Nation's most toxic schools, two ranked in the *third percentile.*

Their findings "Toxic Air and America's Schools" were published in the *USA Today* December 2008.

Risk Assessments

In order to allay community anxiety caused by the burning of hazardous waste, in November 1995, the TNRCC (now TCEQ) prepared the *Screening Risk Analysis for the Texas Industries (TXI) Facility in Midlothian, Texas* and the *Critical Evaluation of the Potential Impact of Emissions From Midlothian Industries: A Summary Report*.

The American Lung Association contracted with Dr. Stuart Batterman, Ph.D., Environmental and Industrial Health, University of Michigan, to do an evaluation of this risk analysis. In Dr. Batterman's 70-page de novo analyses he warns:

> ". . . Based on risk assessment techniques, other environmental impact assessment methodologies, and an assessment of existing environmental monitoring data, we conclude that the environmental and health impacts have and are likely to occur in the Midlothian area from industrial activity, including the combustion of hazardous waste at TXI. **That TXI, the other cement kilns and steel smelter in Midlothian cause impacts is inescapable."** [emphasis mine]

Dr. Batterman further states:

> ". . . Some of the monitoring programs appear entirely reasonable. . .. Others, however, are highly deficient with respect to study design, execution, data quality and data analysis. Overall, the monitoring program is not impressive given the scale of industry and waste combustion in Midlothian and the degree of public concern."

> ". . . The serious deficiencies in the Screening Risk Analysis and Summary Report indicate that **the ability of the TNRCC to conduct an objective assessment is compromised,** and the record demonstrates significant concerns regarding the effectiveness of the TNRCC in regulating the combustion of hazardous waste at TXI."

Illness Surfacing

Beginning in the late 1980's and early 1990's, shortly after TXI started burning hazardous waste:

- Physicians began observing increases in office visits from patients complaining of upper respiratory problems.
- Ranchers started reporting breeding problems, aborted fetuses and deformed offspring in both horses and cattle.
- A Statistically Significant cluster of Down syndrome babies was identified in 1995.
- A peer-reviewed study of respiratory illnesses in Midlothian, conducted by University of Texas Medical Branch and authored by Dr. Marvin Legator in 1996, concluded a 35 percent higher incidence of respiratory problems in Midlothian than the control group.
- Based on a study completed in 2005, the prevalence of overall birth defects from 1999 through 2003 for Midlothian was 150 percent that of Texas and the prevalence of hypospadias/epispadias (congenital defects in which the urinary outlet opens above or below the penis or on the perineum) in Midlothian was 350 percent that of the State.
- Since 1990 and continuing, Ms. Debra Markwardt, a local dog breeder experiences large numbers of illness in her animals that are related to immune system deficiency issues, aborted fetuses, failure to thrive, cancers and deformed offspring. Local veterinarians have attributed these problems to environmental factors. (*See addendum for her statement.*)
- In 1994 a group of mothers concerned for their children and the community pleaded with EPA that EPA at least do an animal health study. Poorly planned and based on a questionable methodology of execution, EPA initiated an animal health survey. Ultimately, the survey was abandoned and no conclusions drawn. The study did, however, identify an apparent high level of animal health problems in the study area in horses at one ranch. This rancher had seven to ten horses in any given year and reported between 50–88 percent of the animals had reproductive health problems during the survey period. The majority of these horses had estrous/cyclic problems. One mare re-

peatedly had problems giving birth or keeping the foals after birth. This horse died shortly before the survey was conducted and a necropsy was performed. An inflamed ovary and a cyst on the ovary were discovered. There was also chronic enlargement of the lymph glands in the head, neck and under the throat. The mare exhibited a muscular line on the side of the abdomen indicative of labored breathing problems. (Note: Problems experienced by this rancher are similar to problems experienced by Ms. Markwardt and other livestock owners.)

ATSDR, TDSHS, TCEQ refuse to look at or even acknowledge the existence of any empirical evidence for fear a link may be related to industrial emissions and some responsibility may ensue. They instead take refuge in theoretical mathematical computations based on questionable air monitoring data.

Seeking Answers

For years, citizens turned to TDSHS for help. TCEQ eagerly and staunchly declared emissions from industries were safe and TDSHS used this as a refuge to look no further. **No answers came.**

Questions about a suspect air monitoring system and how air monitors not placed in predominant wind patterns could produce valid readings went unanswered. What about all the empirical evidence that was surfacing? No answers came. **Year after year this cycle kept repeating. The search for a scientifically validated response could not get off the treadmill.**

To many in the community, TCEQ's methodology for collecting air monitoring data appeared to be designed to avoid major emissions and to create an illusion of ambient air purity. Could this data's reliability to assess community impact and public health withstand the scrutiny of objective unbiased scientists? We thought we would find that objectivity when we turned to ATSDR.

ATSDR Involvement

In July 2005, our petition went before an ATSDR panel. The panel deemed it met the criteria for a public health assessment.

On August 10, 2005, we received a letter from ATSDR stating that **"they"** would be doing a Public Health **Assessment** as authorized under the CERCLA. ATSDR indicated that they planned **"to ask TDSHS for help"** responding to our concerns. This was disconcerting; however, ATSDR was a federal health-based agency with a mission statement that promised the use of the best science and to provide trusted health information—and they would be in control. "So, maybe," we thought, "there was hope."

Sadly, as the assessment started to slowly roll out, objectives began to morph into paths that dodged addressing critical issues such as the need for a scientific assessment of the monitoring data and an evaluation of the empirical evidence. Example:

1. Initially ATSDR promised to do a Public Health **Assessment** "to more fully characterize the emissions from multiple large industries in the area and evaluate potential health risks resulting from individual and aggregate chemical exposures."

2. Once the State became involved, things started to morph. The **"Public Health Assessment"** changed to something new. On Sept. 12, 2005, we received a letter from ATSDR stating that because of **"*community health concerns"** they would be conducting instead a health **consultation.** They further implied that a health consultation would allow for a **"timely response (early 2006)."** In this letter ATSDR indicated that they were deferring the decision back to the State. ATSDR would review and certify it. In addition (**even though one major concern we expressed was the inadequacy of the State monitoring data for evaluating public health issues**) they stated they would rely on State monitoring data to make conclusions. **It was at this point I realized we were catapulted right back on to that treadmill going nowhere.**

   (*Note: I am still puzzled about what ATSDR meant by "community health concerns." The community was concerned that no one was looking at their health issues and asking the question, "Could something by awry with the monitoring data in which TDSHS and TCEQ take refuge to declare there were no public health issues?" Obviously the community's "health concerns" and ATSDR's health concern did not run a parallel path.)

   An **assessment** requires a closer examination of community health issues and may even entail some epidemiological activities; whereas, theoretically

a **consultation** is done when time is of essence and a rapid decision is necessary. The value of a **consultation** from ATSDR's/TDSHS' perspective would be that if air-monitoring data did not support any adverse health effects, the job ends there. **All empirical evidence and epidemiological data can then be ignored.** All other red flags indicating health problems such as high birth defects, immune system deficiencies, animal issues, UTMB Study on Upper Respiratory illness, etc., can be dismissed as irrelevant. Since ATSDR/TDSHS were going to accept monitoring data at face value and if this monitoring data is purported to reflect the cleanest air in Texas, the simplicity of the conclusions was promising.

3. To further simplify the task, the scope of the consultation narrows to looking at **air data only.**
4. Toxins in the air can be tricky—entering a body in more ways than one. So to avoid any possible complications, the scope must now be further narrowed to the **"inhalation" pathway only.**

Empirical evidence and epidemiological data has been deemed non-relevant for this consultation. It has been treated like an untouchable pariah. To include it would mean someone would have to address whether something is awry. This is a challenge that apparently ATSDR nor the State want to face.

I finally realized that regardless of what arguments are made or regardless of what empirical evidence is presented, the bottom line on this public health consultation was determined before it even began. The entire process would just be a matter of making documentation support the bottom line.

We needed input from objective unbiased reputable scientists. Shortly before the consultation was due to be released, I reached out begging for help. Six scientists responded and offered their time and skills to critique the draft consultation report.

A draft decision with an "Indeterminate Public Health Hazard" was finally posted for comments on December 11, 2007.

What the Scientists Said

The scientists who reviewed the draft were all highly critical of the product.

Dr. Stuart Batterman, Ph.D., Professor of Environmental Health in the School of Public Health and Professor of Civil and Environmental Engineering at the College of Engineering, both at the University of Michigan, comments: *". . . This Health Consultation has so many omissions, inconsistencies, and inadequate, flawed, or misleading analyses and language that my best suggestion, given in advance of my comments, is that it should not be issued by ATSDR. . . . The Health Consultation is biased. It contains overarching statements that discount all indications that emissions from local industry and environmental conditions might or do pose a health concern in the community. The Health Consultation should be objective yet maintain the health-protective stance which is appropriate for health-based agencies like ATSDR. . . . The Health Consultation relies exclusively on air quality monitoring results measured at four monitors. It does not discuss, in any coherent way, the adequacy of the spatial and temporal coverage of this network. This includes, for example, the ability to identify hotspots, the appropriateness of the network, the adequacy of the monitored parameters, the quality of the data, and the need for additional monitoring sites. . . . There is little mention of meteorology. The area shows very persistent and directional winds, which means that monitors that are not directly downwind are likely to not show impacts from local sources. The Health Consultation should include appropriate wind roses and other analyses that indicate the likely impact areas vis-á-vis monitoring sites. . . . In its present form, however, I find so many biases and deficiencies that I do not believe that the Health Consultation achieves its aims and, as stated above, I would urge that ATSDR reconsider its issuance.*

I do hope that ATSDR sponsorship and oversight provides a means to correct these problems . . .."

Dr. Peter L. deFur, Ph.D., and **Kyle Newman,** Environmental Stewardship Concepts, comment: *". . . ATSDR's classification of this site as an "Indeterminate Public Health Hazard" is in direct contradiction with the data the Agency presents in the report. Throughout the document, ATSDR attempts to marginalize or disregard data that indicate that compounds produce human health risks. ATSDR has more than enough data to classify the site as a "Public Health Hazard. . . . The problems with this assessment are numerous, and the most serious problem with the interpretation is that ATSDR discounts their own metrics of health effects, ignoring the data that exceed health levels.*

For a number of chemicals, the air concentrations are in excess of the health levels, but ATSDR dismisses the excess toxic chemicals as not a problem because the number or people harmed is small, despite the fact that the risks exceed the levels used to protect people from environmental threats (i.e., one in a million) . . ."

Dr. Neil Carman, Ph.D., Program Director, Lone Star Chapter of Sierra Club and former employee of the Texas State environmental agency, comments: "*I find the report highly inadequate for a variety of reasons* [listed in full in comments] *and fails to seriously acknowledge the numerous gaps in the ambient air monitoring in the Midlothian area. . . . A basic concern here is that asthma, allergies, immune system deficiencies, and other health problems in adults and children are not being evaluated and yet these kinds of adverse health effects are being reported by Midlothian residents . . .*"

Dr. Dennis Cesarotti, Ph.D., Northern Illinois University, comments: "*It appears that the DSHS (State Public Health) set out to prove that there were no health issues in Midlothian, Texas.*"

Dr. Al Armendariz, Ph.D., Environmental Engineer, Southern Methodist University comments: "*The report lacks an analysis of the impact of dioxin and furan emissions from local industry to the public health of the community . . . however, dioxin and furan emissions are an extremely significant component of the emissions from the local industry. . . . a significant fraction of the mercury emitted by the industrial sources in the area is likely to be emitted in gaseous form, given the volatile nature of mercury, and the temperatures of the stack gases. The gaseous mercury* will not *be collected in the particulate filters, leading to further underestimates of the true atmospheric concentrations of mercury. In addition, the gaseous mercury will not be detected by the techniques used to identify the VOC compounds.*"

Debra L. Morris, Ph.D., Adjunct Assistant Professor in the Department of Preventive Medicine and Community at the University of Texas Medical Branch in Galveston, comments: "*A symptom survey of residents in the geographical area that this document covers has been conducted and published (Legator et al., 1998). The results of this study showed that residents in this area had more respiratory symptoms than individuals in a control region. However, I am unaware that any attempt has been made to follow up on the results of the study using methodology that directly addresses and measures the health concerns of the community. Because the individuals in this area are exposed to a combination of chemicals, studies of health effects in this population would be much more revealing than an approach that makes mathematical approximations of the health risks based on measurements of individual chemicals.*" [Dr. Morris was a participant in this study.]

TCEQ Response

The Texas environmental agency (TCEQ) was highly critical of the "Indeterminate" finding. In comments to EPA, posted on their website TCEQ complains:

> **"POTENTIAL IMPACT ON TCEQ:** *The Indeterminate Public Health Hazard finding regarding air toxics in Midlothian may lead citizens and elected officials to believe the air quality is causing health impacts when air toxics monitoring in the Midlothian area not only indicates acceptable air quality but also better air quality than most monitored areas of the country. This concern could lead to pressure on TCEQ to shift resources from areas of concern in order to expend more resources in the Midlothian area.*"

As of this date (March 12, 2009), the public health consultation has not been finalized.

Due to this Administration's proposed strategy to rebuild the Nation's infrastructure, the steel and cement industries are in a position to boom. In the last year, however, all local industries in Midlothian have severely cut back on production of concrete and steel. As of October 2008, TXI has temporarily, idled its four older wet kilns and has temporarily suspended burning hazardous waste. What is coming out of the industries now does not represent what the community has been exposed to or what they will be exposed to once production accelerates and once burning of hazardous waste resumes. **If you want a less than adequate picture of emissions to which the public has been exposed and to which they will be exposed—now is the time to monitor.**

In an effort to get the "Indeterminate Public Health Hazard" lifted, TCEQ embarked on a $349,000 project purportedly to "answer some of the community's questions" and determine the percent of chromium-6 in the identified chromium emissions (a major unknown factor that lead to the indeterminate finding).

The first of four five-day monitoring periods scheduled over a year took place in December 2008—**right after TXI temporarily idled its four older wet kilns and temporarily suspended incineration of hazardous waste.** "*TXI's status*

might affect the chromium's numbers depending on whether the older kilns are operating during any testing," TCEQ officials conceded to a reporter from the *Dallas Morning News.*

Any monitoring during the time hazardous waste is not being incinerated would skew more than just the chromium numbers. It would also not capture emissions with the highest levels of concern—those resulting from the incineration of hazardous waste. What information will this data provide? Perhaps it will provide a baseline for comparison when hazardous waste incineration is revived.

The fact that this data will not be representative of actual emissions to which the public was exposed, or will be exposed, appears not to be a material consideration in the scheduling of air monitoring. **How ATSDR/TDSHS plan to retrofit this data into the conclusions of the public health consultation remains questionable.**

When ATSDR was questioned about the reliability of any data collected during the idling of these kilns, during decline in production, and during the temporary suspension of hazardous waste incineration, the response was, "We have no control over changes in plant operations due to economic conditions. Couple this with the fact that State agencies often have a limited window within which funds made available for a project must be spent." **Spending funds seemed more important than the quality of the data and evaluating public health impact to real exposures. What appears to be important is that the money be spent now.**

ATSDR critically missed the boat at step one. They failed to validate the science behind the methodology used to determine the placement of the air monitors. If they could not validate the data at the initial step, of what value are any ensuing conclusions? **The deficiencies in this consultation indicate ATSDR's ability to conduct an objective assessment is compromised.**

We never asked anyone to find a problem if one did not exist. We just wanted an unbiased objective assessment. We expected an assessment incorporating the most recent science, logic, common sense and objectivity. We did not get this.

Instead of exercising due diligence by becoming an active participant in the evaluation, ATSDR relegated their responsibility without question back to the State. The assessment of Midlothian's public health ended up back in the hands of the same decision-makers who over the years staunchly and flagrantly turned a deaf ear and blind eye to the empirical evidence handed them. **Science was not going to be factored in.**

It appears ATSDR divorced themselves from their mission statement. There was no value added to ATSDR's involvement. ATSDR's involvement only served to keep the public at bay for another four years. It was a costly waste of taxpayers' money. This involvement only elongated a process to nowhere and gave credence to impediments in the system that block science and truth.

If ATSDR does not have the **commitment or capacity** to objectively temper and counter external forces that dissuade them from their mission to serve the public by using the best science and providing trusted health information—then ATSDR needs to get out of the Public Health Assessment and Consultation business. Maintaining the status quo will only continue risking the public health of many U.S. communities.

U.S. communities desperately need an external environmental public health entity able to carry out the mission assigned to ATSDR. Perhaps contracting with a University or a School of Public Health would be a better alternative. We need an entity that is proactive and not just merely an acquiescing observer.

Addendum

1. March 17, 2009: Letter from Mr. Mier to the Honorable Brad Miller, Subcommittee Chairman, Subcommittee on Investigations and Oversight.
2. Comments and photos of animals as sentinels for environmental health hazards, from Ms. Debbie Markwardt, dog breeder and local resident of Midlothian, TX.
3. January–February 2009: E-mails between Debbie Markwardt, Alan Yarbrough, ATSDR, and John Villinaci, Texas Department of State health Services, carbon copied to Dr. Howard Frumkin, Director, ATSDR.
4. March 11, 2008 letter: Sierra Club, Lonestar Chapter to Texas Department of State Health Services, Re: Comments on 2007 Public Health Consultation for Midlothian, Texas.
5. May 1, 1996 Risk Analysis: Executive Summary extracted from evaluation of the Screening Risk Analysis for the Texas Industries (TXI Facility) In Midlothian, Texas, released November 1995. Written by the Texas Natural Resource Conservation Commission, And Other Materials Related to the Texas In-

dustries Facility by Stuart A. Batterman, Ph.D., Yuli Huang, M.S., Environmental and Industrial Health, The University of Michigan.

6. March 9, 2009: Comments on ATSDR December 11, 2007 report, Health Consultation—Midlothian Area Air Quality Park 1: Volatile Organic Compounds and Metals" from Stuart Batterman, Ph.D., Professor of Environmental Health in the School of Public Health and of Civil and Environmental Engineering, University of Michigan.
7. March 11, 2008: Comments on ATSDR Public Health Consultation of Midlothian, Texas. Prepared by: Peter L. deFur, Ph.D., and Kyle Newman, Environmental Stewardship Concepts, Richmond, VA.
8. March 2009: Written Testimony of Neil J. Carman, Ph.D., Former State of Texas Air Pollution Control Agency Regional Field Investigator of Industrial Plants Including Portland Cement Kilns and Waste Incinerators in 1980s–90s: The EPA's Sham (Bifurcated) Hazardous Waste Combustor MACT Rule and Enforcement Failures by EPA and State of Texas are Related to Health Hazards from Toxic Waste Incineration in Cement Kilns at Midlothian, Texas.
9. February 3, 2008: Sal and Grace Mier, Midlothian TX, response to ATSDR/DSHS study on Midlothian Area Air Quality Park I: Volatile Organ Compounds and Metals, December 11, 2007.
10. September 9, 2008: Not "Just Steam": A Review of "Emissions Data from Midlothian Industry" for the Texas State Natural Resources Committee.
11. June 29, 2005: Texas Department of State Health Services Birth Defects Investigation Report—Birth Defects Among Deliveries to Residents of Midlothian, Venus, & Cedar Hill, Texas, 1997–2001. Prepared by Mary Ethen, Epidemiologist, Birth Defects Epidemiology and Surveillance Branch, DSHS.
12. May 19, 2005: Midlothian Cancer Cluster Report #05026—Summary of Investigation into the Occurrence of Cancer, Zip Codes 76065, 75104, and 76084, Midlothian, Cedar Hill, and Venus, TX in Ellis, Dallas, and Johnson Counties, Texas, from 1993–2002.

Addendum #1

March 17, 2009

Honorable Brad Miller
Chair, Subcommittee on Investigations and Oversight
Committee on Science and Technology
U.S. House of Representatives
2321 Rayburn House Office Building
Washington, D.C. 20515

Congressman Miller:

I want to thank you for the opportunity to testify before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology regarding ATSDR. I submit the following suggestions.

Communities Desperately Need What ATSDR's Mission Statement Promises

There is a void in this country when it comes to protecting the health of the people when the potential source of the problem is industry---especially if the industry (s) is still active and a viable economic part of the community. One would be in denial and out of tune with reality to believe political pressure does not play a major role at federal, state and local levels.

There is an institutionalized culture that has weakened the ATSDR's **commitment** to objectively temper and counter external forces that dissuade the agency from fulfilling its mission. **Changes in institutionalized leadership at the top(that go deeper than that of the Director's position) are critical if this culture is to change**. At a minimum this includes the position of Director, Deputy Director and Director, Division of Health Assessments and Consultations.

Peer Review

Peer reviews are vitally essential. A mandate should be issued that all Public Health Assessment/Consultations be peer reviewed by a panel of internal and external experts experienced in evaluating the situations being assessed. Knowing that the work will be scrutinized (particularly by external experts) will encourage a better product.

The Co-operative Agreement between ATSDR and the States needs to be closely scrutinized.

During the hearing the question, "Can State and local levels be relied upon to provide reliable trusted health information?" was asked.

If, one would assume that environmental and public health issues could and would be adequately addressed by State and local entities, then one would ask, "Why would a community need to turn to ATSDR?" **Normally, communities turn to ATSDR after all local and State avenues have been exhausted**.

Where there is a State Co-operative Agreement between ATSDR and the State, ATSDR abdicates the investigative and decision-making responsibility back to the State – the same institutions that previously failed the community. Here lies a problem. This is a costly waste of taxpayers' money and a frustrating exercise in futility.

Public Health Assessments/Consultations should not be performed under State Co-operative Agreements -- particularly when all avenues within the State have already been exhausted and the communities are turning to ATSDR as the last resort. The resources that are wasted under these co-operative agreements can be channeled back to the ATSDR components and used more effectively for peer reviews.

Also see comment below regarding possible conflict of interest that could result under State Co-operative Agreements.

Possible Conflict of Interest

The following observation made by Dr. Al Armendariz, School of Engineering at Southern Methodist University (SMU) in Dallas, Texas, should be considered.

> "There is an obvious potential for a conflict of interest when the ATSDR contracts with state regulatory agencies to perform health assessments or to conduct follow-up environmental sampling. [Example] In Texas, the TCEQ is the state agency that grants permission to facilities (in the form of "permits") to emit pollutants to the atmosphere. In the permit writing process, the state agency is making a legal statement that a facility will not adversely impact public health. There is a very obvious potential conflict of interest when the same agency later goes into the community to do follow-up sampling in response to an ATSDR investigation. A state agency is essentially examining whether the facilities to which it granted permission to emit pollutants at an earlier date are now in fact causing an adverse public health impact. If ATSDR is going to work with other organizations to conduct assessments or do follow-up sampling, ATSDR should work with independent third parties with no obvious conflict of interest, such as state universities or schools of public health, a federal government contractor, the American Lung Association, etc."

Divisions of Regional Operations

The Regional ATSDR Office played absolutely no apparent meaningful role in our community's Consultation. Closer examination of the need for these functions should be performed. The resources dedicated to these positions could be better invested in research or in the assessment/consultation peer-review process.

Sincerely,

Sal Mier
Midlothian, Texas

Addendum #2

STATEMENT OF DEBRA MARKWARDT
MIDLOTHIAN, TEXAS
AREA DOG BREEDER

I am Debra Markwardt, a professional dog breeder since 1982. When I moved my home and business to Midlothian in 1988 my animals were all thriving. Over the years my animals started manifesting health issues. They did not seem to thrive as well. Entire litters were dying. (Last year I lost 75 percent of my litters.) Pups were being born with strange birth defects that I had not previously seen in my animals. Birth defects such as large domed heads, external intestines, extra or missing limbs, blindness, missing testicles, distorted genitalia, no visible signs of urinary outlet, etc., became common.

Hair analysis for me and for some of my animals was done. Varying degrees of heavy metals have been identified in all of these tests. Every one of these tests reflected extremely high levels of aluminum. High aluminum in their systems causes extreme mineral imbalances depleting their body of essential nutrients. Aluminum, lead, and mercury go to the brain and nervous system, thereby poisoning every organ of the body. As the immune systems deteriorate diseases manifest.

My animals also started manifesting severe problems with their coats. They were becoming emaciated and failing to thrive. Problems were more evident in the very young and in the older animals. Pups were born with heavy metals in their system and weaker immune systems. If a pup survived past six to eight months it survived relatively well. My vet explained that some pups had stronger immune systems than others. If their survival passed that critical period, it was an indicator of a stronger immune system. I have lost about 75 young adult dogs since I moved to Midlothian.

Ranchers in the community were having similar problems with their livestock. Efforts to get these issues addressed died at the doorsteps of EPA, Texas Department of State Health Services (TDSHS), and the Texas Commission on Environmental Quality (TCEQ). TCEQ said our environment in no way posed a problem and this was the reason TDSHS could comfortably walk away.

When ATSDR became involved we had hopes that we finally had an agency that would look at our problems and give us a scientific answer.

Midlothian is experiencing birth defects in their children at a rate 150 percent that of the state. They are experiencing hypospadia/epispadias at a rate 350 percent that of the state. I believe birth defects in my animals parallel birth defects seen in children born in Midlothian. I also felt that immune system deficiencies documented in my dogs parallel problems people in the community were alleging.

I cannot understand why ATSDR and TDSHS do not believe what is happening to my animals is relevant to the assessment of this community's public health. What is happening to my animals could be happening to the people of Midlothian. I keep getting a brush-off from ATSDR with comments like ". . . veterinary and animal issues are outside of our mandated domain" and ". . . studies involving animals, even as sentinels for human health issues, are not activities engaged in or funded by our agency" and ultimately ". . . ATSDR and the Texas Department of State Health Services do not have the expertise to conduct the appropriate animal studies."

I was not asking them to do an animal study. I offered my data for use in the ATSDR public health consultation as possible sentinels to what could and may be happening to the community. ATSDR firmly stated that there would be no association of these animals with the public health consultation they were doing for Midlothian. There are children who are waiting to be born. **These animals could be a key to their future. Who will help these children?**

Below, are examples of what I have been experiencing—different birth defects, results of immune system deficiencies, and examples of how animals with weakened immune system respond when raised away or removed from Midlothian. I too am experiencing health problems. On the last page is a statement from my doctor.

Willow Brook Animal Hospital & Willow Run Kennels

Harry Moore, DVM, DAC VPM
W. E. Guthrie, DVM

Willow Run Kennels
Animal Clinic

December 12, 2008

To Whom It May Concern:

Enclosed is a picture of two young dogs. These dogs are litter mates. At weaning they were similar in weight and condition. The difference is that the dog on the right is housed at the home of Debra Markwardt in Midlothian, Texas. Over the last several years I have seen several of her dogs with similar coat conditions and posture. Some have been diagnosed with demodecosis (a mite infestation) seen in dogs with impaired immune systems and secondary pyodermas–bacteria skin infections). The susceptibility to this disease is in blood lines. In Ms. Markwardt's case, the condition is not limited to a specific blood line. She has also had other instances of having the only dog out of a litter have skin disorders.

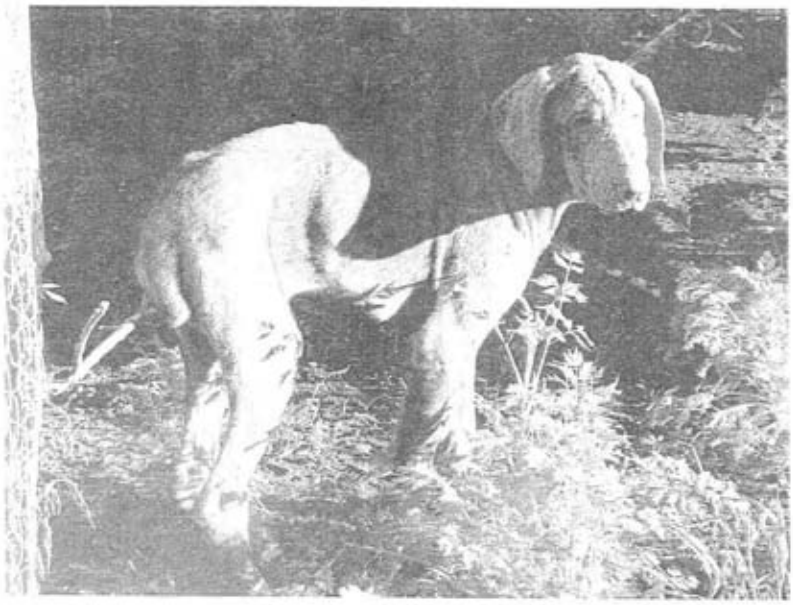
My conclusion from treating her animals over the last few years is that there is an environmental cause to the problems.

Sincerely yours,

W. E. Guthrie, Jr. DVM

W. E. Guthrie, Jr., DVM

These 2 animals are littermates. The one on your left was purchased and moved away shortly after weaning. The one on the right remained on my property. The picture speaks for itself. However since the 4 wet kilns were temporarily idled and are temporarily not burning hazardous waste, I have seen a significant improvement on this animal.



Above - Jake living on my property in Midlothian

Below - Jake 6-Months Later
After Living in Another Town

Severe immune system deficiency

Enlarged Lymph Nodes Due to Possible Hazardous Waste

Englarged Lymph Nodes Below Jaw and Along the Neck

Male Born With No Testicles

Birth Defect – Deformed Head and Face - Intestines Outside of Body

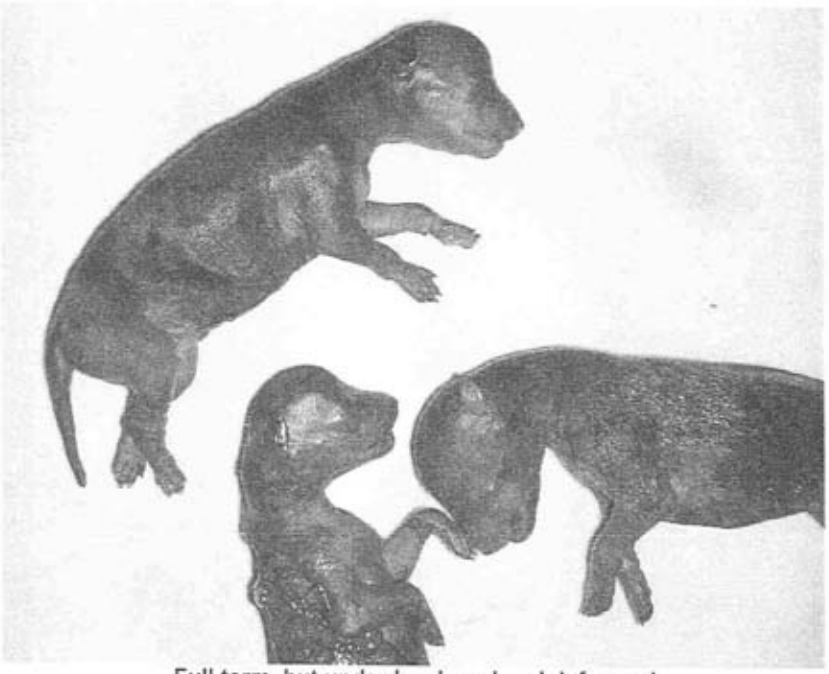
Hole on Side of Body

No Visible Urinary Outlet

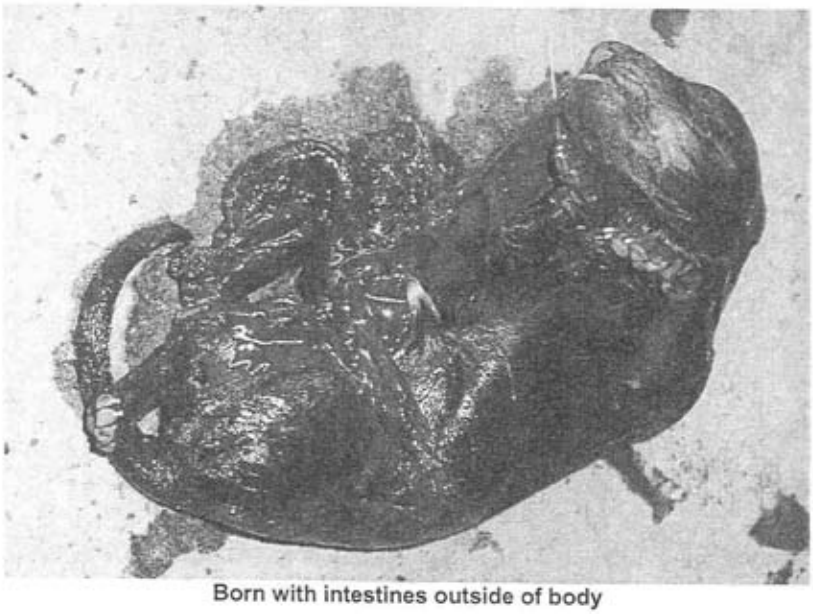
Deformed Head and Face, Deformed Genitalia

Extra Paw on Right - Deformed on Left

Large Domed Head & Other Skeletal Deformities



Full term, but underdeveloped and deformed



Born with intestines outside of body

BAYLOR
Family Medical Center
at Hills County
A Baylor Health Care Affiliate

May 24, 2007

Re: **Deborah Markwardt**
Date of birth: January 10, 1962

To Whom It May Concern:

Ms. Markwardt is a long-term patient of mine who has battled significant health issues over the last five years. She has had abdominal pain, she has had neuromuscular symptoms, fatigue, headaches, nausea, most recently profound fatigue. She has had two recent CAT scans that show nonspecific granulomatous disease. She has lived in a home that has very high levels of aluminum in the soil and in the dust that is found in the home. She has had a urinalysis that shows her aluminum level to be markedly elevated and it should be zero. She also is a professional dog breeder who has noted significant skin and hair problems in the dogs that she has at her home. The veterinarian that has treated these animals has confirmed this is likely on the basis of aluminum toxicity. Today I have referred her to Dr. Craig Glazer at UT Southwestern who is a pulmonary specialist who has special interest in environmental heavy metal poisoning. I anticipate that he will confirm that Ms. Markwardt's symptoms are in fact due to aluminum toxicity. I have strongly recommended that she immediately move from her current property to minimize the health damage that has already occurred.

Sincerely

Thomas G. Ledbetter, M.D.

TGL/gm

Waxahachie
Thomas G. Ledbetter, M.D.
John A. Bossinger III, M.D.
Thomas Wilson, M.D.
Eddie F. Joffe, M.D.
David Langston, M.D.
Peggy Langston, M.D.
Deborah Fang, M.D.
Travis Henry, M.D.
Suzanne Bond, M.D.
Paul Powell, M.D.
Ruth Ann Adell, D.O.
Yolanda Brady, M.D.
Kimberly Swart, M.D.
Donna Howard, FNP
Chelsey Beasley, A.N.P.
Sara Moreland, FNP

Midlothian
Jeffrey A. Anthony, M.D.
Shirley C. Joffe, M.D.
Karen Yeh, M.D.
Chad Coleman, M.D.
Leigh Nordstrom, M.D.
Matthew Moreland, D.O.
Judy Davis, FNP

Red Oak
Alexander Hallah, M.D.
James L. Thomlinson II, M.D.
Jason Nordstrom, M.D.
Haley Wagner, D.O.

305 N. Hwy 77, Suite 200, Waxahachie, Texas 75165 • (972) 923-1686 Fax (972) 937-7731
1441 Midlothian Parkway, Suite 100, Midlothian, Texas 76065 • (972) 723-1474 Fax (972) 723-9423
273 E. Ovilla Rd., Suite 4, Red Oak, Texas 75154 • (972) 617-5225 Fax (972) 617-7932

Addendum #3

Wise, Jane

From: Debra Markwardt [markwardt.d@aircanopy.net]
Sent: Saturday, March 07, 2009 7:44 PM
To: Pasternak, Doug
Subject: FW: Midlothian, TX - Air Emission Issues
Attachments: IMG_1361.jpg; Ty.jpg; Dr. Ledbetter.jpg

From: Debra Markwardt [mailto:markwardt.d@aircanopy.net]
Sent: Monday, December 15, 2008 10:28 AM
To: 'Kenneth Jacobson'; 'David.'; 'Dr. Howard Frumkin'; 'John Villanacci'; 'bheath@usatoday.com'; 'Richard Greene'; 'Michael Honeycutt'
Cc: 'Mier Mier'
Subject: Midlothian, TX - Air Emission Issues

I live in Midlothian close to TXI and Gerdau AmeriSteel. I have lived here approximately twenty years. I have tried to surface problems related to the emissions from the local industries and potential damage to human health. It has become evident that we have no one in a position of power willing to assess the situation objectively and scientifically.

For several years I have been concerned about health problems surfacing in my dogs and the impact that local air pollution has had on their development. My dogs are like "the canaries in the coal mine." I had hoped that the Public Health Consultation (not yet finalized) conducted by ATSDR/TDSHS could see the correlation between animal health and human health but apparently the ATSDR/TDSHS staff did not seem interested in pursuing this issue (as evidenced by their comments in the draft Consultation Report)

I am attaching a picture of two dogs I raised (as part of my dog breeding business) to show how one thrived away from my property and the other that remained on my property did not. I am also attaching a letter from a veterinarian (who I have gone to for years) and his opinion on what he feels is causing the problems with my dogs.

Like my dogs, I too am experiencing health problems. I am also attaching a recent letter from my primary care physician and his observations and recommendations regarding my health status.

I have reached the point of just walking away and saying to the community, "Just wait a lower quality of health is coming to you too." But because of the young and the innocent my conscience won't let me do it. I have done all I can do, therefore am turning to you. **Maybe your voice can make a difference.**

Thank You

Debra Markwardt
972-775-2562
markwardt.d@att.net

Wise, Jane

From: Debra Markwardt [markwardt.d@aircanopy.net]
Sent: Saturday, March 07, 2009 7:50 PM
To: Pasternak, Doug
Subject: FW: Midlothian, TX - Air Emission Issues

-----Original Message-----
From: Casso.Ruben@epamail.epa.gov [mailto:Casso.Ruben@epamail.epa.gov]
Sent: Tuesday, January 13, 2009 7:34 AM
To: Debra Markwardt
Subject: RE: Midlothian, TX - Air Emission Issues

Dear Ms. Markwardt:

This is in response to your email dated December 15, 2008 that was received by the U.S. Environmental Protection Agency (EPA) Region 6 office about your own health concerns and health problems in your dogs and possible air quality impacts on their development. Your email has been forwarded to me for response. We understand that your email was also received by the Center for Disease Control, the Agency for Toxic Substances (ATSDR) and the Texas Department of State Health Services (TDSHS) and that one or more of these public health agencies will be providing you a separate response to your email.

Since EPA is not itself a public health agency and does not have direct expertise or authority on canine health issues we consulted with the Agency for Toxics Substances and Disease Registry for information. We also consulted with the Texas Commission on Environmental Quality (TCEQ) since it is the primary implementing agency for ambient air quality issues in the State of Texas, and TCEQ has been delegated the authority to implement most Federal air quality regulations in lieu of EPA.)

It is our understanding that TCEQ been investigating your concerns for some time, including conducting extensive sampling at your residence. Both TCEQ and ATSDR have indicated to us that to date, no evident or conclusive air quality impact causes for your or your pets' health condition have been found. We can report that TCEQ is working with the City of Midlothian and a focus group of citizens to conduct an ongoing air quality monitoring study in Midlothian to help address air quality monitoring data gaps identified in the draft public health assessment for that area. We are very pleased to see this cooperation and effort between TCEQ and the community to seek to address citizen concerns and the concerns raised by ATSDR/TDSHS in the draft public health assessment. We plan to keep apprised of this effort. ATSDR/TDSHS may consider the results of this TCEQ study as well as consider the public comments submitted on the draft public health assessment in their ongoing health assessment process.

We also understand that ATSDR/TDSHS contacted veterinary health experts at Texas A&M University who may be considering conducting some type of animal health study of their own. You may also wish to contact the Texas Animal Health Commission (.http://www.tahc.state.tx.us/) or the Texas Veterinary Medical Association (http://www.tvma.org/) for more information.

I hope this information is helpful.

-Ruben Casso
Air Toxics Coordinator

Wise, Jane

From: Debra Markwardt [markwardt.d@aircanopy.net]
Sent: Saturday, March 07, 2009 7:48 PM
To: Pasternak, Doug
Subject: FW: Midlothian, TX - Air Emission Issues

From: Debra Markwardt [mailto:markwardt.d@aircanopy.net]
Sent: Thursday, January 22, 2009 1:07 PM
To: 'Cibulas, William (ATSDR/DHAC/OD)'
Cc: 'John Villanacci'; 'Frumkin, Howard (CDC/CCEHIP/NCEH)'
Subject: RE: Midlothian, TX - Air Emission Issues

January 22, 2009

Dear Dr. Cibulas,

Refer to December 15 email to Dr. Frumkin below, your response dated December 19, and my questions to you dated December 20.

Can I count on a response to the questions in my December 20 email and to the comments made herein?

I would like to know specifically why you feel the immune system problems, birth defects, and a host of diseases manifesting in my animals cannot be an indicator of what could be happening to the people living near hazardous waste incineration facilities and why you so casually and readily dismiss it.

Please do not tell me again that veterinary and animal issues are outside of [your] mandated domain. You know full well (or should) that the potential impact on people is the issue that I raised. All that we have asked you to do is to provide trusted health information. Do you feel that an honest conclusion in the Midlothian Public Health Consultation can be reached by pretending what is happening to these animals is not happening; therefore, it cannot be an indicator of what is happening to human health?

I look forward to your response.

Sincerely
Debra Markwardt
Midlothian

From: Debra Markwardt [mailto:markwardt.d@aircanopy.net]
Sent: Saturday, December 20, 2008 9:19 AM
To: 'Cibulas, William (ATSDR/DHAC/OD)'
Cc: 'Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB)'; 'Yarbrough, Alan W. (ATSDR/DHAC/CAPEB)'; 'Frumkin, Howard (CDC/CCEHIP/NCEH)'; 'John Villanacci'
Subject: RE: Midlothian, TX - Air Emission Issues

Dr. Bill Cibulas,

After a more in depth review of your response, the more I am amazed about how you and your staff could have missed the point entirely.

You state, "ATSDR is sympathetic toward the plight of your animals; however, veterinary and animal issues are outside of our mandated domain." My offer to you was to permit you to use my animals as sentinels to what may be happening to the human population. Animals have served as sentinel indicators for health effects in humans and have been the basis for human research for years. It is difficult to understand how any agency charged with your mission can make such a statement.

You state: "Two veterinarians with Texas A&M are reportedly interested in your case and are planning a biomarker spatial analysis to investigate genotoxicity in animals. Since they have not secured funding yet, there is no timeframe for this activity." It sounds as if ATSDR is shrugging this responsibility. Why?

You further state, "TDSHS prepared a draft HC and released it to the public for comment; the public comment period ended on March 11, 2008" ... "TDSHS is working to finalize the HC, and ATSDR is encouraging TDSHS to complete this task by March 11, 2009."

First, what is happening to these animals and the correlation to public health should be part of this health study and should be addressed before finalizing any conclusions.

Second, so there is no funding yet? This is a public health issue that could have broad implications. Shouldn't ATSDR be obligated to fund this activity?

Debra Markwardt
Midlothian

From: Cibulas, William (ATSDR/DHAC/OD) [mailto:wic1@cdc.gov]
Sent: Friday, December 19, 2008 10:38 AM
To: markwardt.d@aircanopy.net
Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Yarbrough, Alan W. (ATSDR/DHAC/CAPEB); Frumkin, Howard (CDC/CCEHIP/NCEH)
Subject: FW: Midlothian, TX - Air Emission Issues

Dear Ms. Markwardt:

Thank-you for your December 15 email to Dr. Frumkin concerning air issues in Midlothian, Texas. I am responding for him.

In Texas, the work of the Agency for Toxic Substances and Disease Registry (ATSDR) is carried out through a Cooperative Agreement with the Texas Department of State Health Services (TDSHS). TDSHS is working to scientifically and objectively address air issues in the Midlothian area. Its findings will be presented in a document called a Health Consultation (HC). TDSHS prepared a draft HC and released it to the public for comment; the public comment period ended on March 11, 2008. ATSDR understands that TDSHS received numerous comments from community members and local industries. TDSHS is working to finalize the HC, and ATSDR is encouraging TDSHS to complete this task by March 11, 2009.

ATSDR is sympathetic toward the plight of your animals; however, veterinary and animal issues are outside of our mandated domain. Since TDSHS also does not have expertise with animals, we understand that they have referred this issue to veterinary specialists with Texas A&M University. Two veterinarians with Texas A&M are reportedly interested in your case and are planning a biomarker spatial analysis to investigate genotoxicity in animals. Since they have not secured funding yet, there is no timeframe for this activity.

TDSHS is focusing on air issues as specified in the original petition, but ATSDR is willing to support TDSHS in evaluating soil, dust, and/or urine data if you are willing to share that information.

If you have any questions, please feel free to contact Alan Yarbrough.

Regards,
Bill Cibulas

CAPT William Cibulas, Ph.D.
Director, Division of Health Assessment & Consultation
NCEH/ATSDR
4770 Buford Highway NE / MS F59
Atlanta, GA 30341-3717

E-mail: wic1@cdc.gov

Wise, Jane

From: Debra Markwardt [markwardt.d@aircanopy.net]
Sent: Saturday, March 07, 2009 7:59 PM
To: Pasternak, Doug
Subject: FW: Midlothian, TX - Air Emission Issues

From: Cibulas, William (ATSDR/DHAC/OD) [mailto:wic1@cdc.gov]
Sent: Friday, December 19, 2008 11:20 AM
To: Debra Markwardt
Cc: Yarbrough, Alan W. (ATSDR/DHAC/CAPEB)
Subject: RE: Midlothian, TX - Air Emission Issues

Ms. Markwardt,

Thanks for the note. I am passing it along now to the staff working on this site.

Regards,
Bill Cibulas

CAPT William Cibulas, Ph.D.
Director, Division of Health Assessment & Consultation
NCEH/ATSDR
4770 Buford Highway NE / MS F59
Atlanta, GA 30341-3717

Telephone: 770.488.0607
E-mail: wic1@cdc.gov

From: Debra Markwardt [mailto:markwardt.d@aircanopy.net]
Sent: Friday, December 19, 2008 11:59 AM
To: Cibulas, William (ATSDR/DHAC/OD)
Subject: RE: Midlothian, TX - Air Emission Issues

One of the big concerns that I have is that they are doing air monitoring now. The problem is that TXI shut down their 4 wet kilns. We are not going to get a true record of what this plant has been emitting & affecting our health for the last 20 years. Also, Gerdau has reduced emissions.

It is my understanding that this air monitoring is going to be for the ATSDR & TDSHS to better understand our air quality concerns. But with out these plants producing anything NOW it will have a untrue reading of what is happening.

Thank you for your reply,

Debra L. Markwardt

From: Cibulas, William (ATSDR/DHAC/OD) [mailto:wic1@cdc.gov]
Sent: Friday, December 19, 2008 10:38 AM
To: markwardt.d@aircanopy.net
Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Yarbrough, Alan W. (ATSDR/DHAC/CAPEB); Frumkin, Howard (CDC/CCEHIP/NCEH)
Subject: FW: Midlothian, TX - Air Emission Issues

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ATSDR is sympathetic toward the plight of your animals; however, veterinary and animal issues are outside of our mandated domain. Since TDSHS also does not have expertise with animals, we understand that they have referred this issue to veterinary specialists with Texas A&M University. Two veterinarians with Texas A&M are reportedly interested in your case and are planning a biomarker spatial analysis to investigate genotoxicity in animals. Since they have not secured funding yet, there is no timeframe for this activity.

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If you have any questions, please feel free to contact Alan Yarbrough.

Regards,
Bill Cibulas

CAPT William Cibulas, Ph.D.
Director, Division of Health Assessment & Consultation
NCEH/ATSDR
4770 Buford Highway NE / MS F59
Atlanta, GA 30341-3717

E-mail: wic1@cdc.gov

3/11/2009

From: Cibulas, William (ATSDR/DHAC/OD) [mailto:wic1@cdc.gov]
Sent: Friday, December 19, 2008 10:38 AM
To: markwardt.d@aircanopy.net
Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Yarbrough, Alan W. (ATSDR/DHAC/CAPEB); Frumkin, Howard (CDC/CCEHIP/NCEH)
Subject: FW: Midlothian, TX - Air Emission Issues

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If you have any questions, please feel free to contact Alan Yarbrough at 770-488-3655.

Regards,

Bill Cibulas

CAPT William Cibulas, Ph.D.
Director, Division of Health Assessment & Consultation
NCEH/ATSDR
4770 Buford Highway NE / MS F59
Atlanta, GA 30341-3717

-----Original Message-----
From: Yarbrough, Alan W. (ATSDR/DHAC/CAPEB) [mailto:aby6@cdc.gov]
Sent: Friday, January 23, 2009 3:08 PM
To: Debra Markwardt; Cibulas, William (ATSDR/DHAC/OD)
Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Frumkin, Howard (CDC/CCEHIP/NCEH); John Villanacci
Subject: RE: Midlothian, TX - Air Emission Issues

Dear Ms. Markwardt,

Thank-you for your email.

Our Cooperative Agreement Partner, the Texas Department of State Health Services (TDSHS), is willing to look specifically at the soil data from your property and provide a health consultation to evaluate levels of contamination, determine what completed exposure pathways may exist, and make any needed recommendations. This health consultation will be specific to your property and will differ from the ongoing health consultation which is evaluating contaminants in air.

Again, ATSDR is sympathetic to the plight of your animals, but studies involving animals, even as sentinels for human health issues, are not activities engaged in or funded by our agency. TDSHS has been in close communication with two professors from Texas A&M Veterinary school. They are discussing a possible project in the Midlothian area to look at the dogs in the Midlothian area. If the project moves forward, staff from TDSHS will be contacting Ms Markwardt.

We will share any health consultations once they are completed. The air HC is planned to be completed by the end of March, which will allow time to evaluate the latest chromium data.

Thank-you,

Alan Yarbrough

From: Debra Markwardt [mailto:markwardt.d@aircanopy.net]
Sent: Saturday, December 20, 2008 10:19 AM
To: Cibulas, William (ATSDR/DHAC/OD)
Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Yarbrough, Alan W. (ATSDR/DHAC/CAPEB); Frumkin, Howard (CDC/CCEHIP/NCEH); 'John Villanacci'
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Dr. Bill Cibulas,

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You state, "ATSDR is sympathetic toward the plight of your animals; however, veterinary and animal issues are outside of our mandated domain." My offer to you was to permit you to use my animals as sentinels to what may be happening to the human population. Animals have served as sentinel indicators for health effects in humans <http://www.ncbi.nlm.nih.gov/pubmed/11453293> and have been the basis for human research for years. It is difficult to understand how any agency charged with your mission can make such a statement.

You state: "Two veterinarians with Texas A&M are reportedly interested in your case and are planning a biomarker spatial analysis to investigate genotoxicity in animals. Since they have not secured funding yet, there is no timeframe for this activity." It sounds as if ATSDR is shrugging this responsibility. Why?

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Second, so there is no funding yet? This is a public health issue that could have broad implications. Shouldn't ATSDR be obligated to fund this activity?

Debra Markwardt

Midlothian

From: Debra Markwardt [mailto:markwardt.d@aircanopy.net] On Behalf Of markwardt.d@att.net
Sent: Tuesday, January 27, 2009 10:27 AM
To: 'Cibulas, William (ATSDR/DHAC/OD)'
Cc: 'Frumkin, Howard (CDC/CCEHIP/NCEH)'; Villanacci, John
Subject: RE: Midlothian, TX - Air Emission Issues

TO: Dr. Howard Frumkin

Dr. William Cibulas

Dr. John Villanacci

Dear Sirs:

I am responding to the email below that I received from your office. I find

it very frustrating because there seems to be a communication barrier

between us. If it I am not communicating my message properly, I sincerely

apologize.

I do not live in a bubble. I live in the same environment as many other

inhabitants of Midlothian. I am experiencing health problems that others

are experiencing. My dogs are experiencing problems that other animals and

livestock in the community have experienced. These health effects are not

unique to me or my animals. For years citizens of Midlothian have been

attempting in vain to surface these same issues. The one common denominator

that we all have is where we live and the air we breathe.

Although I appreciate your offer to do a separate health consultation to

examine my soil, I cannot help but question the agencies' logic in excluding

what is happening to me and my animals from this current Midlothian health

consultation. Does this mean that you have already concluded the air in our

environment is in no way impacting on my health and the health of my animals

and therefore these health issues are not material to the Midlothian public

health consultation?

As Dr. Michael Honeycutt, Texas Commission on Environmental Quality, was

quoted in the Houston Chronical article, In Harms Way, "If health effects

are occurring, something is awry." If the air monitoring data you are

reviewing totally rules out the possibility of any negative health effects

occurring, but they indeed they do occur, then do you not believe it

incumbent upon you to resolve whether something is awry before you jump to

any conclusions? Is there a possibility that negative criticism that was

submitted in the comments to the draft public health consultation regarding

the shortcomings of the air monitoring data upon which the conclusions were

based has some validity? Turning a blind eye to the health effects that have

surfaced throughout the years will not give credence to any conclusions but

will only serve to undermine and further erode the public's trust in the

government agencies whose mission it is to provide reliable information. I sincerely thank the Texas Department of State Health Services offer to

do

a separate health consultation on my property by examining the soil.

However, I am debating the value this would be to anyone. I have already had

private lab tests conducted on the soil. I have consulted with

veterinarians and with my physician. I already know the health problems that

I am having. I already witnessed first-hand and documented the diseases

that have been manifested in my animals due to immune system deficiencies

and heavy metal poisoning and a host of other known and unknown chemicals.

I already know about all the birth defects, still born, the inability to

reproduce - the list goes on - that my animals have experienced. I was not

asking for anyone to tell me what was happening. I already know. What I was

offering you was an insight to valuable indicators that could give you a

clue to what may potentially be happening to human health in Midlothian.

But if I understand you correctly, none of this is within your purview and

hence ATSDR has opted to make it a non-factor in the Midlothian public

health consultation.

Would you be kind enough to answer these specific questions?

1. Can you give me a rationale for separating the current public health

consultation from the health issues my animals and I are experiencing? How

did you conclude that these negative health effects could not be related to

the air in our environment and that there are no airborne deposits contaminating my property?

2. Will you cite the specific congressional authority that prohibits ATSDR from acknowledging and addressing animal health issues that might be related to toxic air emissions?

3. Can you tell me why the date of March 2009 was set as the goal for completion of the final Midlothian public health consultation when TCEQ just started their 1-year project to gather additional air monitoring data to fill the gaps identified in the draft consultation?

4. Due to the economy, In October 2008, TXI temporarily idled their 4 antiquated environmentally unfriendly wet kilns and has temporarily suspended hazardous waste incineration. Also, due to the economy all three cement plants and Gerdau Steel have temporarily cut back production. Any air monitoring data taken during this idle period cannot reflect a true picture of the air emissions to which Midlothian's public is normally exposed. According to a recent article in Dallas Morning news: "The first of four five-day monitoring periods scheduled over a year took place in early December, when TXI's four older kilns were idle. TXI's status might affect the chromium's numbers, TCEQ officials conceded, depending on whether the older kilns are operating during any testing." Is this the data you will be using to finalize your conclusions?, If yes, why would you be

comfortable using data that is truly not representative of normal emissions

to make such a critical decision?

I am re-attaching the documents I sent with my original email just in case

they were lost in transmission and you did not have the opportunity to

review them. These attachments are:

1. A letter from my personal physician,

2. One of the letters from my veterinarian, and

3. A picture of two littermates - one that remained in Midlothian, and

one that was raised away from Midlothian.

I await your response to my questions.

Sincerely,

Debra Markwardt

Midlothian, Texas

-----Original Message-----

From: Yarbrough, Alan W. (ATSDR/DHAC/CAPEB) [mailto:aby6@cdc.gov]

Sent: Friday, January 23, 2009 3:08 PM

To: Debra Markwardt; Cibulas, William (ATSDR/DHAC/OD)

Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Frumkin, Howard

(CDC/CCEHIP/NCEH); John Villanacci

Subject: RE: Midlothian, TX - Air Emission Issues

Dear Ms. Markwardt,

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Our Cooperative Agreement Partner, the Texas Department of State Health Services (TDSHS), is willing to look specifically at the soil data from your property and provide a health consultation to evaluate levels of contamination, determine what completed exposure pathways may exist, and make any needed recommendations. This health consultation will be specific to your property and will differ from the ongoing health consultation which is evaluating contaminants in air.

Again, ATSDR is sympathetic to the plight of your animals, but studies involving animals, even as sentinels for human health issues, are not activities engaged in or funded by our agency. TDSHS has been in close communication with two professors from Texas A&M Veterinary school. They are discussing a possible project in the Midlothian area to look at the dogs in the Midlothian area. If the project moves forward, staff from TDSHS will be contacting Ms Markwardt.

We will share any health consultations once they are completed. The air HC is planned to be completed by the end of March, which will allow time

to evaluate the latest chromium data.

Thank-you,

Alan Yarbrough

(770) 488-3655

From: Debra Markwardt [mailto:markwardt.d@aircanopy.net]

Sent: Saturday, December 20, 2008 10:19 AM

To: Cibulas, William (ATSDR/DHAC/OD)

Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Yarbrough, Alan W. (ATSDR/DHAC/CAPEB); Frumkin, Howard (CDC/CCEHIP/NCEH); 'John Villanacci'

Subject: RE: Midlothian, TX - Air Emission Issues

Dr. Bill Cibulas,

After a more in depth review of your response, the more I am amazed about how you and your staff could have missed the point entirely.

You state, "ATSDR is sympathetic toward the plight of your animals; however, veterinary and animal issues are outside of our mandated domain." My offer to you was to permit you to use my animals as sentinels to what may be happening to the human population. Animals have served as sentinel indicators for health effects in humans <http://www.ncbi.nlm.nih.gov/pubmed/11453293> and have been the basis for human research for years. It is difficult to understand how any agency charged with your mission can make such a statement.

You state: "Two veterinarians with Texas A&M are reportedly interested in your case and are planning a biomarker spatial analysis to investigate genotoxicity in animals. Since they have not secured funding yet, there is no timeframe for this activity." It sounds as if ATSDR is shrugging this responsibility. Why?

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First, what is happening to these animals and the correlation to public health should be part of this health study and should be addressed before finalizing any conclusions.

Second, so there is no funding yet? This is a public health issue that could have broad implications. Shouldn't ATSDR be obligated to fund this activity?

Debra Markwardt

Midlothian

From: Cibulas, William (ATSDR/DHAC/OD) [mailto:wic1@cdc.gov]

Sent: Friday, December 19, 2008 10:38 AM

To: markwardt.d@aircanopy.net

Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Yarbrough, Alan W.

(ATSDR/DHAC/CAPEB); Frumkin, Howard (CDC/CCEHIP/NCEH)
Subject: FW: Midlothian, TX - Air Emission Issues

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investigate genotoxicity in animals. Since they have not secured funding yet, there is no timeframe for this activity.

TDSHS is focusing on air issues as specified in the original petition, but ATSDR is willing to support TDSHS in evaluating soil, dust, and/or urine data if you are willing to share that information.

If you have any questions, please feel free to contact Alan Yarbrough at 770-488-3655.

Regards,

Bill Cibulas

CAPT William Cibulas, Ph.D.
Director, Division of Health Assessment & Consultation
NCEH/ATSDR
4770 Buford Highway NE / MS F59
Atlanta, GA 30341-3717

E-mail: wic1@cdc.gov

No virus found in this incoming message.

ATSDR
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

What You Can Expect From ATSDR

What Is ATSDR?

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency in Atlanta, Georgia. The agency's mission is **to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related to toxic substances.** ATSDR identifies communities where people might be exposed to hazardous substances in the environment. The agency also determines how hazardous a site is and recommends actions that need to be taken to safeguard the health of community residents. ATSDR works with communities, environ-mental groups, tribal governments, and local, state, and other federal agencies to protect the public health.

What Will ATSDR Do in Your Community?

- Involve communities and tribes when responding to their environmental public health concerns.
- Be independent, be objective, and make public health decisions based on current available science.
- Review and assess environmental, health, and community information and data.
- Contact the relevant federal, tribal, state, and local health and environmental agencies, and always the communities, while investigating a hazardous waste site or release.
- Collect additional data through exposure investigations, limited and targeted environmental sampling, and health studies to assess health impacts.
- Provide and explain the results of our evaluations, medical consultations, and investigations to communities and tribes.
- Provide environmental health education for health care providers, communities, and tribes.
- Provide emergency response assistance for acute hazardous materials incidents.
- Refer individuals to specialists in environmental medicine for health care followup.
- Incorporate in final ATSDR documents comments received from the public on draft documents.
- Refer public health issues or problems to other federal, tribal, state, or local governmental entities when they do not fall within ATSDR's areas of responsibility.

What Will ATSDR Not Do in Your Community?

- Conduct large-scale site- or release-related environmental sampling. The U.S. Environmental Protection Agency and state environmental agencies are responsible for these sampling activities.
- Enforce regulations. ATSDR is an advisory, nonregulatory public health agency.
- Provide medical treatment and health care services.

If you would like additional information, contact the ATSDR Community Involvement Team:

Call: 1-888-42-ATSDR (toll-free)
that is, 1-888-422-8737

E-mail: atsdric@cdc.gov

Visit: http://www.atsdr.cdc.gov

Write:
Community Involvement Team
Division of Health Assessment and Consultation, ATSDR
Mail Stop E-56
1600 Clifton Road, NE
Atlanta, GA 30333

Report-180 PM65

May 2002

----- Forwarded Message ----
From: Debra Markwardt <markwardt.d@aircanopy.net>
To: GRACE MIER <mier-sg@sbcglobal.net>
Sent: Monday, February 2, 2009 9:02:36 AM
Subject: FW: Midlothian, TX - Air Emission Issues

-----Original Message-----
From: Villanacci, John [mailto:John.Villanacci@dshs.state.tx.us]
Sent: Monday, February 02, 2009 8:51 AM
To: markwardt.d@att.net; Cibulas, William (ATSDR/DHAC/OD)
Cc: Frumkin, Howard (CDC/CCEHIP/NCEH)
Subject: RE: Midlothian, TX - Air Emission Issues

Dear Ms. Markwardt:

Thank you for your e-mail concerning environmental health issues in Midlothian, Texas. We appreciate your vigilance and the concern you have expressed for your neighbors, your pets, and yourself. Finding definitive answers to environmental concerns is never easy; however, I will try to address some of the questions that you have raised.

First, there are two primary ways that scientists try to address these types of environmental public health issues. One is by using available environmental sampling results to identify potential public health risks, and the other is by use of a well designed epidemiologic study to look at possible associations between disease rates and exposure. In most instances epidemiologic studies are preferred; unfortunately they can be very expensive both in time and money. Because of this, most governmental agencies will first examine the environmental information to establish that the exposures are of sufficient magnitude to warrant further investigation. When an environmental exposure investigation finds exposures at levels sufficient to possible cause adverse health effects we may try to seek additional funds to conduct an environmental epidemiologic study. Conducting an epidemiologic study without documenting exposures would make it difficult for investigators to make a strong argument, attributing the disease to the environmental exposure.

For several reasons, when this health consultation was initiated, its scope was limited to the potential human health risks associated with contaminants in the air. This decision was made in part due to the historic concerns with contaminants in the air and in part due to the extremely large volume of data that need to be analyzed to address those concerns. The decision also was consistent with the stated nature of a health consultation which is to be limited in scope, focusing on one

issue. The disadvantage of addressing contaminants in only one media (air) is that it only addresses potential exposures that may occur through that one media, in this case via inhalation. Thus, any conclusions that are reached can only apply to that type of exposure.

It also is important to note that because health consultations look at community exposures they cannot make any conclusions with regard to individuals. So even if the Midlothian health consultation ended up concluding that based on the available data we were not able to identify a public health hazard, it would not be able to make any conclusions regarding the health issues that either you or your animals are experiencing. Additionally, since the consultation only looked at potential health risks from airborne contaminants through inhalation, it will not be able to make any conclusions as to whether contaminants on your property came from the air. Determining whether contaminants on your property are at high enough levels to present a health risk can only be made from a direct evaluation of soil, water, or vegetation samples collected from your property.

You are correct that there are circumstances where animals might be able to serve as sentinels for human exposure; however, determining whether health effects in animals are related to exposure or whether the exposures those animals received is relevant to humans takes a certain kind of expertise; expertise that combines an understanding of veterinarian medicine, toxicology, and epidemiology. People conducting such an investigation would have to be able to evaluate the diseases in the animals, establish whether the diseases in different species are related, and whether the different diseases in the different species could have the same etiology (cause). These are skills beyond our expertise; however, my staff has been in contact with experts in this field and is trying to help facilitate such an investigation. We are very optimistic that the researchers will be able to conduct such an investigation; however, at this time the proposal is still being developed. I am fairly certain that if this project moves forward they are going to need the cooperation and/or assistance from the community; I am sure that any assistance that you could provide in this regard would be appreciated. We will try to keep you informed as progress is made in this endeavor.

You are correct again in that one of the reasons for initiating the TCEQ project was to address data gaps identified in the draft health consultation. While it may be best to wait until all those data were available before finalizing the health consultation we have been able to identify certain aspects of those data with the greatest potential to affect the conclusions reached in the health consultation. One of the biggest issues we hope to address relates to the "speciation" or form of the chromium present in ambient air. If we can determine from the new data what fraction of the total chromium is chromium VI, we can

potentially eliminate one of the major "indeterminate" conclusions in the health consultation. For this, we only need some objective data telling us what this relative fraction is in Midlothian air. We have consulted with ATSDR and have agreed to proceed with the health consultation as soon as those data are available, with the understanding that we will review the other data as soon as possible. We actually consider all health consultations to be living documents, in that as new data become available, the conclusions can change depending on what those data indicate. Thus, we will review the data when it is available and we will either prepare a new health consultation or an addendum to the original. My staff has consulted with TCEQ and the March deadline is based on when they think that those data will become available.

The last item that you raise is something that is as frustrating to us as it is to you in that we have no control over changes in plant operations due to economic conditions. Couple this with the fact that state agencies often have a limited window within which funds made available for a project must be spent. The good news is that, although the data used in the original health consultation may not have been collected near major population centers, based on their proximity to certain facilities and an analysis of wind direction data, my staff are confident that the original monitor locations should have picked up contaminants at concentrations higher than what they would have picked up if they had been collected in population centers. This means is that the samples that have already been collected should provide a reasonable estimate of maximum possible exposures - exposures higher than what might be received in the population centers.

I hope that this information is helpful; my staff is available to help if you have any other questions.

Your,

John

John F. Villanacci, Ph.D., NREMTI, Manager

Environ. & Injury Epidemiology and Toxicology Branch

Epidemiology & Disease Surveillance Unit; MC 1964

Texas Department of State Health Services

P.O. Box 149347

Austin, Texas 78714-9347

Salus populi suprema lex esto

Confidentiality Notice*****

The information in this email may be confidential and/or privileged. If you are not the intended recipient or an authorized representative of the intended recipient, you are hereby notified that any review, dissemination or copying of this email and its attachments, if any, or the information contained herein is prohibited. If you have received this email in error, please immediately notify the sender by return email and delete this email from your computer system. Thank you.

-----Original Message-----
From: Debra Markwardt [mailto:markwardt.d@aircanopy.net] On Behalf Of markwardt.d@att.net
Sent: Tuesday, January 27, 2009 10:27 AM
To: 'Cibulas, William (ATSDR/DHAC/OD)'
Cc: 'Frumkin, Howard (CDC/CCEHIP/NCEH)'; Villanacci, John
Subject: RE: Midlothian, TX - Air Emission Issues

TO: Dr. Howard Frumkin

Dr. William Cibulas

Dr. John Villanacci

Dear Sirs:

I am responding to the email below that I received from your office. I find

it very frustrating because there seems to be a communication barrier

between us. If it I am not communicating my message properly, I sincerely

apologize.

I do not live in a bubble. I live in the same environment as many other

inhabitants of Midlothian. I am experiencing health problems that others

are experiencing. My dogs are experiencing problems that other animals and

livestock in the community have experienced. These health effects are not

unique to me or my animals. For years citizens of Midlothian have been

attempting in vain to surface these same issues. The one common denominator

that we all have is where we live and the air we breathe.

Although I appreciate your offer to do a separate health consultation to

examine my soil, I cannot help but question the agencies' logic in excluding

what is happening to me and my animals from this current Midlothian health

consultation. Does this mean that you have already concluded the air in our

environment is in no way impacting on my health and the health of my animals

and therefore these health issues are not material to the Midlothian public

health consultation?

As Dr. Michael Honeycutt, Texas Commission on Environmental Quality, was

quoted in the Houston Chronical article, In Harms Way, "If health effects

are occurring, something is awry." If the air monitoring data you are

reviewing totally rules out the possibility of any negative health effects

occurring, but they indeed they do occur, then do you not believe it

incumbent upon you to resolve whether something is awry before you jump to

any conclusions? Is there a possibility that negative criticism that was

submitted in the comments to the draft public health consultation regarding

the shortcomings of the air monitoring data upon which the conclusions were

based has some validity? Turning a blind eye to the health effects that have

surfaced throughout the years will not give credence to any conclusions but

will only serve to undermine and further erode the public's trust in the

government agencies whose mission it is to provide reliable information. I sincerely thank the Texas Department of State Health Services offer to do

a separate health consultation on my property by examining the soil.

However, I am debating the value this would be to anyone. I have already had

private lab tests conducted on the soil. I have consulted with

veterinarians and with my physician. I already know the health problems that

I am having. I already witnessed first-hand and documented the diseases

that have been manifested in my animals due to immune system deficiencies

and heavy metal poisoning and a host of other known and unknown chemicals.

I already know about all the birth defects, still born, the inability to

reproduce - the list goes on - that my animals have experienced. I was not

asking for anyone to tell me what was happening. I already know. What I

was

offering you was an insight to valuable indicators that could give you a

clue to what may potentially be happening to human health in Midlothian.

But if I understand you correctly, none of this is within your purview and

hence ATSDR has opted to make it a non-factor in the Midlothian public

health consultation.

Would you be kind enough to answer these specific questions?

1. Can you give me a rationale for separating the current public health

consultation from the health issues my animals and I are experiencing? How

did you conclude that these negative health effects could not be related to

the air in our environment and that there are no airborne deposits

contaminating my property?

2. Will you cite the specific congressional authority that prohibits

ATSDR from acknowledging and addressing animal health issues that might be

related to toxic air emissions?

3. Can you tell me why the date of March 2009 was set as the goal for

completion of the final Midlothian public health consultation when TCEQ just

started their 1-year project to gather additional air monitoring data to

fill the gaps identified in the draft consultation?

4. Due to the economy, In October 2008, TXI temporarily idled their 4 antiquated environmentally unfriendly wet kilns and has temporarily suspended hazardous waste incineration. Also, due to the economy all three cement plants and Gerdau Steel have temporarily cut back production. Any air monitoring data taken during this idle period cannot reflect a true picture of the air emissions to which Midlothian's public is normally exposed. According to a recent article in Dallas Morning news: "The first of four five-day monitoring periods scheduled over a year took place in early December, when TXI's four older kilns were idle. TXI's status might affect the chromium's numbers, TCEQ officials conceded, depending on whether the older kilns are operating during any testing." Is this the data you will be using to finalize your conclusions? If yes, why would you be comfortable using data that is truly not representative of normal emissions to make such a critical decision?

I am re-attaching the documents I sent with my original email just in case they were lost in transmission and you did not have the opportunity to review them. These attachments are:

1. A letter from my personal physician,
2. One of the letters from my veterinarian, and
3. A picture of two littermates - one that remained in Midlothian, and

one that was raised away from Midlothian.

I await your response to my questions.

Sincerely,

Debra Markwardt

Midlothian, Texas

-----Original Message-----

From: Yarbrough, Alan W. (ATSDR/DHAC/CAPEB) [mailto:aby6@cdc.gov]

Sent: Friday, January 23, 2009 3:08 PM

To: Debra Markwardt; Cibulas, William (ATSDR/DHAC/OD)

Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Frumkin, Howard (CDC/CCEHIP/NCEH); John Villanacci

Subject: RE: Midlothian, TX - Air Emission Issues

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Alan Yarbrough

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Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Yarbrough, Alan W. (ATSDR/DHAC/CAPEB); Prumkin, Howard (CDC/CCEHIP/NCEH); 'John Villanacci'

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Debra Markwardt

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Sent: Friday, December 19, 2008 10:38 AM

To: markwardt.d@aircanopy.net

Cc: Gillig, Richard (Rick) (ATSDR/DHAC/CAPEB); Yarbrough, Alan W. (ATSDR/DHAC/CAPEB); Frumkin, Howard (CDC/CCEHIP/NCEH)

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If you have any questions, please feel free to contact Alan Yarbrough at 770-488-3655.

Regards,

Bill Cibulas

CAPT William Cibulas, Ph.D.

Director, Division of Health Assessment & Consultation

NCEH/ATSDR

4770 Buford Highway NE / MS F59

Atlanta, GA 30341-3717

E-mail: wic1@cdc.gov

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Checked by AVG - http://www.avg.com

Version: 8.0.176 / Virus Database: 270.10.13/1912 - Release Date: 1/23/2009

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Checked by AVG - www.avg.com
Version: 8.0.233 / Virus Database: 270 10.16/1929 - Release Date: 02/01/09 18:02:00
No virus found in this incoming message.
Checked by AVG - www.avg.com
Version: 8.0.237 / Virus Database: 270.11.8/1985 - Release Date: 03/07/09 18:43:00

-----Original Message-----
From: Yarbrough, Alan W. (ATSDR/DHAC/CAPEB) [mailto:aby6@cdc.gov]
Sent: Friday, February 06, 2009 1:25 PM
To: markwardt.d@att.net
Cc: Frumkin, Howard (CDC/CCEHIP/NCEH); Cibulas, William (ATSDR/DHAC/OD); Pettigrew, George (ATSDR/DRO); John.Villanacci@dshs.state.tx.us
Subject: FW: Midlothian, TX - Air Emission Issues

Dear Ms. Markwardt,

ATSDR agrees with the issues raised in Dr. Villanacci's February 1, 2009 e-mail response. In your January 27, 2009 email, the issue of ATSDR's statutory authority was specifically mentioned. ATSDR's enabling legislation does not prohibit our conduct of animal studies; however, ATSDR and the Texas Department of State Health Services do not have the expertise to conduct the appropriate animal studies. In this case we will rely on the Texas A&M researchers, with whom TDSHS is coordinating with, to conduct a study on the animals in the area.

Attached is a factsheet which explains what ATSDR does.

If you have any data, especially concerning aluminum that you can share with ATSDR and TDSHS, we will be willing to review such information.

Thank-you for your interest.

Alan Yarbrough

From: Villanacci, John [mailto:John.Villanacci@dshs.state.tx.us]
Sent: Monday, February 02, 2009 9:51 AM
To: markwardt.d@att.net; Cibulas, William (ATSDR/DHAC/OD)
Cc: Frumkin, Howard (CDC/CCEHIP/NCEH)
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First, there are two primary ways that scientists try to address these types of environmental public health issues. One is by using available environmental sampling results to identify potential public health risks, and the other is by use of a well designed epidemiologic study to look at possible associations between disease rates and exposure. In most instances epidemiologic studies are preferred; unfortunately they can be very expensive both in time and money. Because of this, most governmental agencies will first examine the environmental information to establish that the exposures are of sufficient magnitude to warrant further investigation. When an environmental exposure investigation finds exposures at levels sufficient to possible cause adverse health effects we may try to seek additional funds to conduct an environmental epidemiologic study. Conducting an epidemiologic study without documenting exposures would make it difficult for investigators to make a strong argument, attributing the disease to the environmental exposure.

For several reasons, when this health consultation was initiated, its scope was limited to the potential human health risks associated with contaminants in the air. This decision was made in part due to the historic concerns with contaminants in the air and in part due to the extremely large volume of data that need to be analyzed to address those concerns. The decision also was consistent with the stated nature of a health consultation which is to be limited in scope, focusing on one issue. The disadvantage of addressing contaminants in only one media (air) is that it only addresses potential exposures that may occur through that one media, in this case via inhalation. Thus, any conclusions that are reached can only apply to that type of exposure.

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You are correct that there are circumstances where animals might be able to serve as sentinels for human exposure; however, determining whether health effects in animals are related to exposure or whether the exposures those animals received is relevant to humans takes a certain kind of expertise; expertise that combines an understanding of

veterinarian medicine, toxicology, and epidemiology. People conducting such an investigation would have to be able to evaluate the diseases in the animals, establish whether the diseases in different species are related, and whether the different diseases in the different species could have the same etiology (cause). These are skills beyond our expertise; however, my staff has been in contact with experts in this field and is trying to help facilitate such an investigation. We are very optimistic that the researchers will be able to conduct such an investigation; however, at this time the proposal is still being developed. I am fairly certain that if this project moves forward they are going to need the cooperation and/or assistance from the community; I am sure that any assistance that you could provide in this regard would be appreciated. We will try to keep you informed as progress is made in this endeavor.

You are correct again in that one of the reasons for initiating the TCEQ project was to address data gaps identified in the draft health consultation. While it may be best to wait until all those data were available before finalizing the health consultation we have been able to identify certain aspects of those data with the greatest potential to affect the conclusions reached in the health consultation. One of the biggest issues we hope to address relates to the "speciation" or form of the chromium present in ambient air. If we can determine from the new data what fraction of the total chromium is chromium VI, we can potentially eliminate one of the major "indeterminate" conclusions in the health consultation. For this, we only need some objective data telling us what this relative fraction is in Midlothian air. We have consulted with ATSDR and have agreed to proceed with the health consultation as soon as those data are available, with the understanding that we will review the other data as soon as possible. We actually consider all health consultations to be living documents, in that as new data become available, the conclusions can change depending on what those data indicate. Thus, we will review the data when it is available and we will either prepare a new health consultation or an addendum to the original. My staff has consulted with TCEQ and the March deadline is based on when they think that those data will become available.

The last item that you raise is something that is as frustrating to us as it is to you in that we have no control over changes in plant operations due to economic conditions. Couple this with the fact that state agencies often have a limited window within which funds made available for a project must be spent. The good news is that, although the data used in the original health consultation may not have been collected near major population centers, based on their proximity to certain facilities and an analysis of wind direction data, my staff are confident that the original monitor locations should have picked up contaminants at concentrations higher than what they would have picked up if they had been collected in population centers. This means is that the samples that have already been collected should provide a reasonable estimate of maximum possible exposures - exposures higher than what

might be received in the population centers.

I hope that this information is helpful; my staff is available to help if you have any other questions.

Your,

John

John F. Villanacci, Ph.D., NREMTI, Manager

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Salus populi suprema lex esto

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-----Original Message-----

Addendum #4

SIERRA CLUB
Lone Star Chapter

March 11, 2008

Environmental and Injury Epidemiology and Toxicology Program
Texas Department of State Health Services
1100 West 49th Street, Room T–702
Austin, TX 78756

Re: Comments on 2007 Public Health Consultation for Midlothian, Texas

Dear Texas Department of State Health Services Consultation staff:

I am writing to share serious concerns over the gaps and inadequacies presented in the Texas Department of State Health Services (TDHS) and the Agency for Toxic Substances and Disease Registry (ATSDR) report titled *"Health Consultation—Midlothian Area Air Quality Part 1: Volatile Organic Compounds & Metals."* I find the report highly inadequate for a variety of reasons and fails to seriously acknowledge the numerous gaps in the ambient air monitoring in the Midlothian area.

Background Levels: Waste Incineration Conducted at Kaufman, TX

"We obtained background levels for many of the contaminants from TCEQ monitoring results for the town of Kaufman, TX, a town of similar population size, no large industry, and which is only rarely downwind from Midlothian."

At least one serious concern about using Kaufman, TX is the fact that relatively large-scale waste incineration has been conducted for many years in this community. Incinerators operated in Kaufman include municipal waste combustion facilities or medical waste incineration or both, which emit many of the same products of incomplete combustion (PICs) as do cement kiln hazardous waste incinerators such as Dioxins, Dibenzofurans, Polychlorinated Biphenyls, Polycyclic Aromatic Hydrocarbons and Metals. I recommend that you consult with TCEQ about how many waste incineration facilities were operated or are still operating in Kaufman, TX.

However, I have no details or information about the siting of the TCEQ's Kaufman monitor relative to the waste incineration facilities and whether the monitor was downwind or upwind of the incineration facilities. But the fact that large-scale waste incinerators may have been operating in Kaufman over many years indicates that the use of Kaufman, TX is inappropriate for any comparisons to Midlothian, TX.

PART I
Sampling every six days for VOCs & metals. May 1981–March 2005.

1. Sampling site selection for TCEO ambient air monitoring raises many issues. A number of the Midlothian and Ellis County TCEQ sampling sites are not selected for suitable sampling suits as to be downwind of the Midlothian industrial plant emissions plumes and will not provide valid downwind ambient air concentrations to measure emissions from the industrial plants. How many Midlothian and Ellis County TCEQ sampling sites are actually in the general downwind area of the plants and how far in feet are these?

2. Sampling frequency raises another set of ambient air monitoring issues. Sampling on a once in six day sample duty cycle only looks at most at 16.7 percent of the days for air pollution and excludes for analysis 83.3 percent of the time period every year.

3. Sampling—protocol of flow rate and analytical limitations also present a number of additional ambient air monitoring issues that need to be addressed. Many air contaminants are excluded from laboratory analysis and many are not detected due to minimum detection limits set above threshold where many toxic air contaminants may be present such as dioxins, dibenzofurans, polychlorinated biphenyls, polycyclic aromatic hydrocarbons, and others.

A.1. While it is true that "all the chemicals being released from cement kilns and steel mills have not been fully identified," this health consultation has evaluated 237 individual contaminants including 119 VOCs and 108 metals and other inorganic substances.

Another concern surrounds the question of whether the TDSHS scientists have any prior experience in performing an evaluation of a commercial or private hazardous waste combustion facility in Texas before this current Midlothian effort. Since this is not a responsibility typically involving the TDSHS scientists, the consultation may be partly compromised by the inability to comprehend the complex emissions hazards associated with such hazardous waste storage, treatment and disposal facilities as exist at Midlothian. For example, downwind air monitoring sites may be too far away from the hazardous waste facilities to be able to detect ground level fugitive hazardous waste emissions leaks from the transfer, storage and piping system at such a facility. However, having myself visited Midlothian many times and having been downwind of the hazardous waste facilities, I definitely noticed during each visit that there were in my opinion distinct fugitive gaseous emissions from these operations that produced instant severe headaches. While I cannot state

for certain if such fugitive gaseous emissions were associated with the hazardous waste operations, I did not notice similar fugitive gaseous emissions from the two non-hazardous waste cement kilns at Midlothian. As a result, I maintain that the fugitive gaseous emissions from the hazardous waste cement kiln were associated with its hazardous waste operations.

Hazardous waste chemistry is highly complex and may become more complex during and immediately after the incineration process. Hazardous waste consists of toxic soup mixtures of innumerable organic and inorganic chemicals, elemental chemicals, metals, acids, bases, salts, waste water and other wastes from complex industrial manufacturing processes.

Hazardous waste incineration has the potential to take the thousands of organic and inorganic chemicals and chemically transform them into thousands and thousands of incompletely burned compounds.

The consultation did not include consideration of the need to sample the air, water and food chains for known species of the following twenty groups of halogenated organic chemicals that are toxicologically known to cause adverse biological effects through the Ah-r-mediated mechanism of action:

Polychlorinated dibenzo-p-dioxins
Polychlorinated dibenzo-furans
Polychlorinated biphenyls
Polychlorinated naphthalenes
Polychlorinated diphenyltoluenes
Polychlorinated diphenyl ethers
Polychlorinated anisoles
Polychlorinated xanthenes
Polychlorinated xanthones
Polychlorinated anthracenes
Polychlorinated fluorenes
Polychlorinated dihydroanthracenes
Polychlorinated diphenylmethanes
Polychlorinated phenylxylylethanes
Polychlorinated dibenzothiophenes
Polychlorinated quarterphenyls
Polychlorinated quarterphenyl ethers
Polychlorinated biphenylenes
Polybrommated diphenyl ethers
Polychlorinated azoanthracenes

Cite: Table 4—Compounds that May, Based on Experimental Evidence or Structure, Be Expected to Have the Potential to Cause Adverse Effects through the Ah-r-mediated mechanism of action, p. 266 in Chapter 9, "Dioxins, Dibenzofurans, PCBs and Colonial, Fish-Eating Water Birds" by John P. Giesy, James P. Ludwig, and Donald E. Tillin, published in *Dioxins and Health* edited by Arnold Schecter, Plenum Press, New York, 1994.

There may be other possible organics including polybrominated aromatic compounds, polychlorinated-brominated aromatic compounds, polyfluorinated aromatic compounds, polychlorinated-fluorinated aromatic compounds, and other polycyclic aromatic hydrocarbons (all lumped together as "dioxins" here).

The large-scale hazardous waste incineration activities conducted at Midlothian for approximately twenty years create unique circumstances for producing the air emissions of a large number of exceptionally toxic substances since there is no such thing as 100 percent combustion efficiency and total organic chemical destruction in any incineration devices let alone cement kilns. A basic concern is that the consultation has seriously underestimated and downplayed the dangers of large scale incineration of hazardous waste for a local community. The large scale incineration of hazardous waste has an expected potential to create thousands of unusual byproducts of incomplete combustion (some of these organic compounds are created by partial thermal decomposition of the waste mixtures and other compounds are created by rapid "de novo synthesis" in the cooling stack gas phase) with many occurring at levels below the frequently used one part per billion detectability limit in organic analytical equipment. But most of these unusual byproducts of incomplete combustion are not measured or identified due to their difficult chemical characteristics, which need highly specialized analysis at extremely low concentrations below most VOC analyzers. Of course, dioxin and dibenzofuran analytical equipment go well below the 1.0 ppb level down in the low parts per trillion levels and parts per quadrillion range. It's not feasible to conclude if the 119 VOCs reviewed represent 50 percent of the total VOC species emitted or 25 percent or 10 percent or less. Without a more comprehensive VOC analysis of the total low part per trillion range

VOC species, highly toxic organics like the dioxins are being ignored completely in the consultation.

Some of these VOCs will be bound to the particulate matter emitted and this represents another fraction of the total VOCs in the ambient air. But VOC sampling that collects only gaseous phase organics and not the particle phase organics will miss a fraction of the VOC compounds in the air.

Reviewers need to ask: What is the range of possible types of VOCs produced from large-scale hazardous waste incineration? What is the range of the possible concentrations of the VOCs produced from large-scale hazardous waste incineration? Are these VOCs being detected? Yes, some VOC byproducts are being detected as indicated by 119 VOCs, but the concern is that many VOCs (several thousand more VOCs) are not being detected due to the high detectability limits in the analytical equipment such as 1.0 ppb and the potential for similar VOC species to overlap.

The same applies to inorganic compounds and metals, and in many monitoring sites, inorganic compounds and metals were not even collected.

The TCEQ has no laboratory facilities specifically established for conducting dioxin and dibenzofuran analyses, and due to the costs of such analyses, it's typically not required by the TCEQ on most environmental samples due to the expense of such laboratory analysis.

The EPA has recognized along with the organic chemistry science that any form of chlorine (organic and inorganic) in combination with carbon in a combustion process will produce the expected dioxins and dibenzofurans by rapid "de novo synthesis." The large-scale hazardous wastes burned at Midlothian have routinely contained numerous organic chlorinated residues and inorganic chemicals which would be expected to produce certain stack concentrations of dioxins and dibenzofurans by rapid "de novo synthesis." Some dioxins and dibenzofurans may also be present among the chlorinated hydrocarbons and inorganic chlorine compounds in the large-scale hazardous wastes burned and could be emitted as undestroyed chemicals.

A.2. It is also true that "All the chemicals currently being incinerated and released have not been tested for carcinogenicity and endocrine disrupting potential." However, based on historical reviews of cancer incidence and/or mortality rates in Midlothian and Ellis County, no individual or aggregate cancer rates were significantly elevated with respect to the rest of the state.

Several problems exist with the Texas Cancer Registry databases and the conclusion of **"no individual or aggregate cancer rates were significantly elevated with respect to the rest of the state"** seems premature and an unscientific statements. The Cancer Registry is significantly flawed itself in its omissions and tracking system. Many people do not show up in this database.

The EPA's recent Endocrine Screening, Testing Advisory Committee (EDSTAC) only recommended testing of potential endocrine disrupting chemicals for interference in three human hormonal pathways of estrogen, thyroid and androgen. All other hormones were excluded by endocrine testing and screening.

A.4., C.3., & D.3. The community was concerned about the health effects of dioxins, metals, and mixtures of compounds. Air data for dioxins are not routinely collected in Texas; therefore it was not possible to evaluate the potential adverse health effects associated with these compounds. We evaluated available VOCs and metals air contaminant data with respect to its potential for causing adverse health effects in humans due to acute, intermediate, and/or chronic exposures. Only manganese exceeded its health based screening value for chronic inhalation exposures. However, based upon a review of the toxicological data, we would not expect to see adverse health effects due to either long-term or short-term exposure to manganese. Mixtures of compounds also were evaluated in this consultation. Long-term aggregate exposures to air contaminants in Midlothian are not expected to result in adverse non-cancer or cancer health effects.

I find the conclusion on the VOC's seriously flawed and unsound since too many organic chemicals are not even monitored for in Midlothian. I don't think that TDSHS has any idea or even an intelligent guess as to how many organic chemicals were not being detected due to their presence below the detectability analytical limits of the lab equipment or were not being analyzed for at all such as all of the dioxin-related compounds. See more comments under A–1.

This conclusion is not scientific and is based on extremely limited data that cannot logically support or confirm such a broad sweeping conclusion: **"Mixtures of compounds also were evaluated in this consultation. Long-term aggregate exposures to air contaminants in Midlothian are not expected to result in**

adverse non-cancer or cancer health effects." One reason is that not all of the mixtures can possibly be determined without a great deal more ambient air monitoring and far more sophisticated laboratory analyses looking at many more products of incomplete combustion including levels in the parts per trillion where many toxic dioxin-related compounds occur or even lower levels.

A.5., A.7., & C.1. In this health consultation, DSHS has analyzed each and every individual air sampling result collected from all TCEQ sampling locations in the Midlothian area and has not relied on any TCEQ-summarized data. Also, DSHS has not relied on any of the TCEQ's effects screening levels (ESLs) for determining potential health risks associated with exposures to airborne contaminants in Midlothian.

Significant limitations exist with the sampling and analysis program in Midlothian.

A.6. & D.4. The community was concerned that the potential for adverse health effects may be underestimated due to averaging of contaminant data over time. The initial screening of the air data involved comparing the maximum concentration for each contaminant to its most conservative health-based screening value. Contaminants whose maximum concentrations exceeded the most conservative health-based screening value were evaluated for acute, intermediate, and long-term exposures. None of the compounds examined (with the exception of benzene) had a single 24-hour measurement that exceeded its acute exposure guideline. The acute inhalation MRL for benzene was exceeded three isolated times in 13 years. Consequently, after reviewing all of the available data (which includes 94,932 individual 24-hour measurements), we find no evidence to suggest that adverse health effects would be anticipated as a result of any of the short-term or peak exposures to VOCs or Metals. The potential for adverse health effects due to exposure to EPA's NAAQS compounds will be evaluated in a future health consultation.

This conclusion is totally inconsistent with the real world experiences of many Midlothian area residents as well as myself and does not recognize the serious limitations of the available data. Especially in view of the significant limitations exist with the sampling and analysis program in Midlothian.

A.8., B.4., C.4., & D.1. The community was concerned about asthma, allergies, immune system deficiencies, and other health problems in adults as well as children. Data for these health problems are not routinely collected in Texas. Therefore, we were not able to systematically assess whether the levels of these conditions in Midlothian are different than in other areas of the state.

A basic concern here is that asthma, allergies, immune system deficiencies, and other health problems in adults and children are not being evaluated and yet these kinds of adverse health effects are being reported by Midlothian residents. The TDSHS should conclude no adverse health effects are expected when so many types of health outcomes are excluded from the consultation. Hazardous emissions and toxic contaminants could certainly be contributing or causing adverse health effects based on the information about many of these pollutants. Did the consultation consider fatalities from asthmatic attacks or allergies?

B.1., B.2., & D.2. Over the years, the Texas Cancer Registry and Texas Birth Defects Registry have conducted incidence, mortality, and prevalence investigations to determine if cancer and birth defect rates were higher or lower in the Midlothian area compared to the rest of the state (Appendix D). No statistically significant elevations of specific or total cancers were found. The prevalences for a few birth defects were higher than expected and for a few other birth defects were lower than expected based on State rates. These higher prevalence rates were not unique to Midlothian/Ellis County but were also observed throughout Health Service Region 3 (which includes 18 other counties primarily north and west of Ellis County). Because of the numerous factors involved, it is not possible to determine if these increases are due to environmental exposures or differences in reporting practices in this region compared with the rest of the state. Furthermore, it should be noted that only three of the 99 compounds with health based comparison values (i.e., ethylbenzene, 2-butanone, and methyl isobutyl ketone) listed "developmental effects" as the critical effect (i.e., the first observable physiological or adverse health effect occurring at the low-

est exposure dose known to produce any effect at all). Hazard quotients for those three compounds were 0.000352, 0.0000653, and 0.00000793 respectively, levels that are far below levels that might be expected to result in an increased risk for birth defects.

This conclusion is somewhat illogical, especially in view of the significant limitations that exist with the monitoring siting, monitor distances, sampling and analysis program in Midlothian.

General Findings #1, #2, #3, and #4 are conclusions that are highly deficient for their numerous omissions and flawed considerations of data gaps.

Why am I concerned about industrial air pollution impacting the Midlothian community and rural residents?

In the 1990s I developed a recognition that the industrial air pollution at Midlothian was clearly causing significant adverse health effects to area residents and often their animals based on my previous professional experience as a State investigator for twelve years at other types of industrial facilities, based on many visits to Midlothian to investigate the conditions there, based on reviewing emissions information and permits for the Midlothian plants, based on analysis of monitoring information, and based on interviews with many citizens. I emphasize this background because during my professional experience with the Texas Air Control Board from 1980–1992, I investigated about 1,000 citizen complaints of air pollution and citizens generally complained when the industrial air pollution was so egregious that people were suffering adverse health effects from something in the air and therefore they were strongly compelled to file complaints in order to seek action to abate the problems. Once corrective measures occurred to reasonably abate the alleged air pollution events effecting their health and their residences, citizens typically complained less or no more at all. Nonetheless many residents were trying to deal with local toxic nightmares of one degree to another. In several cases, abatement of pollution events producing citizen complaints required months and even several years before the problems were reasonably abated.

In my opinion, the Midlothian toxic nightmare fits into a pattern I have encountered elsewhere in Texas. Since leaving the Texas Air Control Board in 1992 after inspecting industrial facilities for twelve years in West Texas and which included a cement manufacturing plant with two cement kilns, I have been regularly interacting with Midlothian residents regarding their health and environmental concerns with the significant toxic emissions from three local cement kilns and the steel mill. I am familiar with the locations of each of the four plant sites and have reviewed emissions associated with the facilities. Although I previously worked for the state environmental agency known as the Texas Commission on Environmental Quality (TCEQ), I have developed grave concerns about the bias that routinely creeps into the Agency's scientific efforts such as certain aspects of the ambient air monitoring activities at Midlothian and the Agency's generally egregious failure to protect public health from impacts due to exposure to a range of toxic contaminants. In addition, I have experienced severe headaches near the TXI facility during brief exposures to industrial emissions next to the TXI facility, which for me raises troubling questions about the abysmal lack of regulatory oversight by the TCEQ and a lack of concerns about the health and safety of Midlothian residents.

I have reviewed previous reports of November 2, 1995 report: *The Screening Risk Analysis for the Texas Industries (TXI) Facility in Midlothian, Texas,* by the Office of Air Quality/Toxicology and Risk Assessment Section, Texas Natural Resource Conservation Commission, and a November, 1995 report: *The Critical Evaluation of the Potential Impact of Emissions From Midlothian Industries* by the Texas Natural Resource Conservation Commission. Even the January 31, 1996 federal report was severely flawed for similar problems and errors: *Midlothian Cumulative Risk Assessment Volume 1,* by the Multimedia Planning and Permitting Division, U.S. Environmental Protection Agency, Region 6, Dallas, Texas.

Risk assessments in Texas (the TCEQ's *Screening Risk Analysis and the Summary Report,* 1995 for Midlothian, TX) are poor starting points for future studies and actions aimed at protecting public health and the environment due to the innumerable flaws, omissions, gaps, poor science and errors. However if viewed as "technical support" documents to justify EPA and State declarations of no substantial risk to public health due to pollution in Midlothian, they must be criticized due to their many serious omissions, inconsistencies and inadequate or misleading analyses. The federal and State peer review process is an abysmal failure in the Midlothian case.

Based on de novo analysis at TXI, we conclude that environmental and health impacts have and are likely to occur in the Midlothian area from industrial activity, including the combustion of hazardous waste at TXI. There is high likelihood that

the environmental and health impacts are significant, as demonstrated by exposures and risks that greatly exceed U.S. EPA target exposure levels for a variety of exposure scenarios and source assumptions at a large number of sites. Exceedances of acceptable risk levels for children at all residential locations is especially noteworthy.

Because predicted health risks exceed target levels, continued waste combustion at TXI requires more stringent controls, e.g., more effective air pollution control technology, waste feed limitations, and/or modified operating practices.

The serious deficiencies in the *Screening Risk Analysis and Summary Report* for TXI indicate that the ability of EPA Region 6 to conduct an objective assessment is compromised, and the record demonstrates significant concerns regarding the effectiveness of the EPA Regions and states like Texas in regulating combustion of hazardous waste at these cement kilns.

The EPA Region with oversight for state like Texas must be strongly criticized for the tendency to go far beyond what is scientifically supportable by the existing data in making sweeping generalizations regarding the present and future safety of waste combustion in communities. Statements with little or a frail scientific basis show a disregard for the protection of public health, and serve to diminish the EPA's and states credibility among the public.

I strongly support concerns of local residents regarding hazardous waste pollution emitted by cement kilns, which have already impacted communities in the area and surrounding water and land use. In addition, a potential for more far reaching environmental impacts to air and water quality and ecological systems is a significant concern of the Sierra Club and we support the obvious need to reduce emissions.

Respectfully yours,

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Addendum #5

Executive Summary

Extracted From

Evaluation of
The Screening Risk Analysis for the Texas Industries (TXI Facility
In Midlothian, Texas
Written by the Texas Natural Resource Conservation Commission
And Other Materials Related to the Texas Industries Facility

By
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May 1, 1996

Following are photocopies of the Executive Summary for this document

1. Executive Summary

This report critically reviews the Screening Risk Analysis for the Texas Industries (TXI) Facility in Midlothian, Texas and other materials related to the Texas Industries (TXI) facility, the most important of which is the Critical Evaluation of the Potential Impact of Emissions From Midlothian Industries: A Summary Report. Both documents were written by the Texas Natural Resources Conservation Commission (TNRCC) and released November, 1995.

TXI has been producing cement since 1960 in the town of Midlothian located 30 miles southwest of Dallas, Texas. Since the late 1980's, TXI has become one of the nation's largest hazardous waste combustion facilities accepting off-site or "commercial" hazardous waste. Midlothian also contains a steel recycler and two other large cement-producing facilities. These facilities have also burned waste and tires as fuel. Most of this report focuses on TXI, although some portions provide a broader perspective. This report also presents several de novo analyses, including dispersion modeling, risk assessment and data interpretation.

This report draws on a variety of source materials, including permits, guidance materials, the Federal Register and other regulatory and compliance information, and much of the public record including correspondence involving the public, TXI, TNRCC, and EPA obtained in several visits to TNRCC. Telephone conversations with Midlothian residents were also held.

While this report is lengthy, it is not exhaustive and not every aspect of the TNRCC's analysis could be examined in-depth. In cases, the scope of this report did not permit any coverage. Still, this report addresses many factors that affect the determination of public health and environmental impacts in the Midlothian area. In cases, a more thorough review and critique of several topics is provided than has been performed by the TNRCC in any available report. This review was made difficult due to the lack of information in the Screening Risk Analysis and the Summary Report. (This report reproduces critical data which should have been presented in the Screening Analysis and Summary Report by TNRCC, e.g., soil concentrations and emission data.)

The Screening Risk Analysis and the Summary Report are useful starting points for prioritizing future studies and actions aimed at protecting public health and the environment. However, if viewed as "technical support" documents to justify TNRCC declarations of no substantial risk to public health due to pollution in Midlothian, they must be criticized due to their many serious omissions, inconsistencies, and inadequate or misleading analyses. Substantial deficiencies include the use of inappropriately low or unreliable emission rates (especially for arsenic, benzo(a)pyrene, beryllium, dioxin/furans, and mercury), the omission of many compounds specified in EPA guidance (e.g., antimony, barium, silver and thallium in the direct exposure pathway, and cadmium and chromium in the indirect pathway), the omission of fugitive emission

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sources (e.g., cement kiln dust), the omission of the effect of documented kiln upsets (estimated to lead to upper-bound particulate emission rates 20 to 40% higher than reported), the omission of the drinking water pathway, some incorrect model parameters (e.g., omission of soil/water partition coefficient for lead), and many erroneous interpretations of model results and available data.

The omission of many hazardous compounds and the selective use of available emission data, among other reasons, mean that the Screening Risk Analysis has not evaluated or has improperly evaluated some of the potentially largest chemical causes of cancer and noncancer risks. Additionally, the TNRCC estimated, but omitted from the Screening Risk Analysis, relatively high risk estimates for on-site TXI property which is being used for agricultural purposes.

In the unequivocal conclusions drawn in the TNRCC reports, technical data and results are interpreted narrowly and sometimes incorrectly, uncertainties are given little if any consideration, US EPA guidance is incorrectly interpreted, and no mention is made of further actions and studies which could help to confirm conclusions, e.g., TXI's ongoing odor studies, health studies, etc. Statements like "*...results of these evaluations ... indicate that adverse health effects are not expected to occur in area residents, including sensitive subgroups*" (p. iv), are incorrect with respect to risks that may occur after 30 or more years of emissions. The Summary Report does not describe or estimate cumulative impacts, trends, or other details necessary to correctly estimate future risks.

Much of the environmental data monitored in Midlothian is insufficient to support the TNRCC's claims. For example, while several of the largest risks predicted in the Screening Risk Analysis resulted from eating local fish and meat, no samples of fish or meat were analyzed or reported. Contaminant concentrations in sediment or water, both important in indirect exposure pathways, were also not reported. In cases, concentrations in air and soil were compared to high impact sites in Texas and the US, not true background levels for Midlothian. Soil and air sampling techniques were not state-of-the-art, in cases US EPA-approved methods were not used, some sampling locations or sampling times were inappropriate to characterize impacts, no meteorological and other data are presented to interpret monitored data, in one case industry was inappropriately given notice prior to ambient monitoring, and significant issues of quality assurance remain for much of the data. All of this leads to the perception that the TNRCC's interpretation and actions are not protective of public health.

The body of this report presents de novo analyses of environmental impacts and health risks from the TXI facility. Based on risk assessment techniques, other environmental impact assessment methodologies, and an assessment of existing environmental monitoring data, we conclude that environmental and health impacts

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have and are likely to occur in the Midlothian area from industrial activity, including the combustion of hazardous waste at TXI. That TXI, the other cement kilns and steel smelter in Midlothian cause impacts is inescapable. For example, concentrations of arsenic, beryllium, cadmium, chromium and lead in soil show patterns associated with the major sources, and soil levels appear to be increasing. Further, there is high likelihood that the environmental and health impacts are significant, as demonstrated by exposures and risks that greatly exceed US EPA target exposure levels for a variety of exposure scenarios and source assumptions at a large number of sites. (Target levels are individual lifetime cancer risks of 10^{-6} and hazard quotients for non-cancer risks of 0.25.) Exceedences of acceptable risk levels for children at all residential locations is especially noteworthy. These risk estimates exclude impacts from other industrial facilities in Midlothian, some of which are expected to have greater impacts than the TXI facility.

The revised (de novo) risk estimates exceed the TNRCC estimates due primarily to the inclusion of the drinking water pathway, accounting for fugitive impacts, and the use of more realistic worst-case emission rates. The de novo estimates still exclude effects of upsets and other factors which would increase risks. However, the de novo analysis better represents the overall risk associated with exposure to TXI emissions, the goal in requiring the completion of risk assessments for facilities burning hazardous waste.

Because predicted health risks exceed target levels, continued waste combustion at TXI requires more stringent controls, e.g., more effective air pollution control technology, waste feed limitations, and/or modified operating practices. The EPA Maximum Available Control Technology (MACT) standards for cement kilns burning hazardous waste, just released by EPA in March 1996, would also have the effect of requiring additional controls on TXI to meet mercury, dioxin/furans and possibly other emission limitations. Additionally, the proposed MACT standards will require more restrictive limitations in TXI's permit for antimony, chromium, mercury, lead, particulate matter, hydrocarbons and dioxin/furans than currently specified. The EPA determined that the MACT standards are cost-effective, however, MACT standards are generally not very stringent and, at present, are only in draft form. When approved, however, the MACT standards will represent minimum standards which the TNRCC must adopt.

Risk assessment targets do not represent other health endpoints, nuisance impacts, ecological damage, animal impacts, etc. On nuisance, the record demonstrates numerous complaints, potential violations, Orders by TNRCC and the US EPA, etc. Ecological impacts have not been investigated. While a livestock general and reproductive health study in Midlothian was released by EPA Region VI on Jan. 31, 1996, the extremely low response rates and other issues render this study useless, thus, animal impacts are also unknown.

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Several additional factors should be stated. First, in cases, the TNRCC has made considerable efforts to monitor environmental impacts, and indications are that many TNRCC technical personnel are competent and concerned. Some of the monitoring programs appear entirely reasonable, some represent useful allocation of resources, and some involve a degree of innovation. Others, however, are highly deficient with respect to study design, execution, data quality and data analysis. Overall, the monitoring program is not impressive given the scale of industry and waste combustion in Midlothian and the degree of public concern.

Second, the TNRCC must be strongly criticized for its tendency to go far beyond what is scientifically supportable by the existing data in making sweeping generalizations regarding the present and future safety of waste combustion in Midlothian. The TNRCC seems even to capitalize on its findings, shown clearly by claiming to have performed a "comprehensive assessment," by completing "exhaustive sampling," by dismissing all risks found, by maintaining that strong odors pose no health risk to TXI employees or residents, etc. In any event, statements with little or a frail scientific basis show a disregard for the protection of public health, and serve to diminish the TNRCC's credibility among the public.

Finally, the record is deeply troubling regarding activities by the TNRCC related to inspection and enforcement, and by TXI with respect to compliance and responsiveness. This is not the focus of this report, and a comprehensive review of regulatory compliance and enforcement is not provided. Even a cursory examination, however, indicates many inspection, enforcement and compliance issues. For example, the TNRCC has not addressed many concerns raised by its technical staff, has applied different standards to cement kilns and incinerators (despite language to the contrary), has used lax emission requirements (e.g., for opacity and HCl), has not anticipated the stricter controls on waste combustion, has not resolved many historical and ongoing problems with air quality violations and nuisance complaints that have persisted for years, has not prohibited or directed other Texas agencies to prohibit agricultural uses or other high-risk uses of contaminated areas on TXI property, and has rarely pursued administrative penalties or other remedies for violations. While the regulatory situation regarding the combustion of hazardous waste in cement kilns is hardly simple, and political and economic battles are being waged over waste combustion in Texas and the nation, the resolution of even simple nuisance complaints at TXI is neither timely nor satisfactory.

The serious deficiencies in the Screening Risk Analysis and Summary Report indicate that the ability of the TNRCC to conduct an objective assessment is compromised, and the record demonstrates significant concerns regarding the effectiveness of the TNRCC in regulating the combustion of hazardous waste at TXI.

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Addendum #6

March 9, 2008

Environmental and Injury Epidemiology and Toxicology Program
Texas Department of State Health Services
1100 West 49th Street, Room T-702
Austin, Texas 78756
via email to: epitox@dshs.state.tx.us

To Whom It May Concern:

In this letter I offer some brief comments on the Agency for Toxic Substances and Disease Registry (ATSDR) report entitled "Health Consultation - Midlothian Area Air Quality Part 1: Volatile Organic Compounds & Metals," released in a public comment version dated December 11, 2007. My understanding is that this Health Consultation is an ATSDR document prepared by the Texas Department of State Health Services (TDSHS) under a cooperative agreement with ATSDR.

By way of background, I am Professor of Environmental Health in the School of Public Health and Professor of Civil and Environmental Engineering at the College of Engineering, both at the University of Michigan. I have over 25 years experience in air quality, risk assessment, environmental monitoring and assessment, environmental epidemiology, and related topics. My laboratory and field staff provide, among other research activities, field and laboratory measurements of many of the compounds in this analysis for the purpose of exposure and risk assessment, and I have broad expertise in these fields. Further, I was involved in reviewing environmental, risk and engineering data for industry in Midlothian in the mid-1990s, and am familiar with the record, local situation, and many of the public concerns that motivated this Health Consultation by ATSDR. I authored a report entitled "Evaluation of The Screening Risk Analysis for the Texas Industries (TXI) Facility in Midlothian, Texas written by the Texas Natural Resource Conservation Commission and Other Materials Related to the Texas Industries Facility," dated May 1, 1996. (I would be glad to make this report available if it has been lost.)

Although the scope of the Health Consultation is very much more limited than TNRCC's 1995 Risk Analysis (as well as the similar US EPA Risk Assessment that followed in 1996), many of the same concerns apply. This Health Consultation has so many omissions, inconsistencies, and inadequate, flawed, or misleading analyses and language that my best suggestion, given in advance of my comments, is that it should not be issued by ATSDR. Due to time constraints, I cannot provide full review, but the following list details at least some highlights.

1. ATSDR should provide a peer review on this document, and should identify the experts called upon for this purpose. The experts should include internal and external members.
2. The Health Consultation should make available all the data and calculations, including data on the background levels used for comparison. Otherwise it cannot be peer-reviewed and its archival value is extremely limited. A good example of data presentation is the recently completed Michigan Department of Environmental Quality's Detroit Air Toxics Initiative Risk Assessment, see http://www.michigan.gov/documents/DATI_-_COMPLETE_FINAL_REPORT_11-9-05_142053_7.pdf – but there are many other examples.
3. The Health Consultation is biased. It contains overarching statements that discount all indications that emissions from local industry and environmental conditions might or do pose a health concern in the community. The Health Consultation should be objective yet maintain the health-protective stance which is appropriate for health-based agencies like ATSDR. Also see point 12 below.
4. There is superfluous and misleading material in the Health Consultation concerning the number of measurements, compounds, and analyses conducted to date. As examples, if I take a single soil sample and analyze it for 300 compounds, that is 300 measurements. If I take a year of TEOM $PM_{2.5}$

measurements, that is 8760 hourly averages. This is unimportant. The bottom line is whether data are sufficient, and the Health Consultation makes clear that more data is needed to answer questions concerning risks and health impacts. Sample sizes should be discussed in the statistical analyses, and not used to exaggerate the significance of the Health Consultation.

5. The Health Consultation should make explicit at the onset that health risks from many or most of the toxics will occur via non-inhalation pathways –though ingestion, dermal contact, bioaccumulation, etc. – and that the analysis in the Health Consultation does not encompass this scope. The Health Consultation should then indicate how the analysis of these "indirect exposure pathways" is to be accomplished. This is discussed detailed in EPA's risk assessment guidance. It is unacceptable and misleading that the Health Consultation completely excludes this discussion. Note that the argument that this is irrelevant or outside the scope cannot be made as this Health Consultation considers past environmental sampling and data reviews, including soils levels (e.g., pages 15-16.) and it makes numerous calculations and references to risks.

6. The Health Consultation relies exclusively on air quality monitoring results measured at four monitors. It does not discuss, in any coherent way, the adequacy of the spatial and temporal coverage of this network. This includes, for example, the ability to identify hotspots, the appropriateness of the network, the adequacy of the monitored parameters, the quality of the data, and the need for additional monitoring sites.

7. The risk assessment guidance from EPA makes explicit recommendations to identify and analyze risks to vulnerable and susceptible individuals. This includes individuals that are highly exposed. This is not discussed in the Health Consultation, other than a short and inadequate section on children.

8. There is little mention of meteorology. The area shows very persistent and directional winds, which means that monitors that are not directly downwind are likely to not show impacts from local sources. The Health Consultation should include appropriate wind roses and other analyses that indicate the likely impact areas vis-à-vis monitoring sites. Dispersion modeling, perhaps beyond the present scope, has been completed for all of the facilities in question, e.g., in the 1995 and 1996 risk analyses mentioned, and it could provide very useful spatial information regarding locations of local source impacts.

9. There is a lot of speculation without attribution in the Health Consultation. For example, page 7 part C,4 indicates, without evidence, that human HAC values would be equally conservative in protecting animal health. This is certainly not the case when considering, for example, deposition and ingestion uptake. As a second example, page 10, item 4 states that "we do not anticipate that air pollutant levels for much of the city would be too much higher than those observed." This shows little understanding of dispersion from tall sources, trends in VOCs, and the representativeness and accuracy of (older) toxic measurements. Additionally, such vague and double negative statements should be removed.

10. The methodology for comparing ambient pollutant levels in Midlothian to background levels is flawed. On page 20, the comparison levels are stated to be taken from the National Ambient Volatile Organic Compound database which dates, I believe, from 1989. This is completely out of date given the long term declining trend in VOC levels. Similarly, the Hazardous Substance Data Base used for other purposes dates, I believe, from 1998, and is also outdated. I can not be sure as no citations are provided for these literature sources – they should be. It seems in the subsequent compound-specific analyses that other sources are used anyway. This is confusing and should be corrected.

11. Continuing the point above regarding background levels, it makes little sense to compare levels in Midlothian to urbanized areas where vehicle-related emissions dominate for VOCs and often other pollutants. In addition, the mixture of VOCs and other in Midlothian is likely to differ significantly from urban areas. Background comparisons should use a background site, which is also defined by EPA in their monitoring site guidance as a site unlikely to be affected by local sources. Typically, these are rural sites. This Health Consultation continues to make this mistake (I pointed this out in 1996). The sites used for comparison and their levels should be documented.

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12. The effect of using highly urbanized and possibly even industrial sites as background sites is to greatly diminish or even eliminate the apparent local source impact. This is a notable bias in this report.

13. The notion of a "background quotient" (page 21) seems to be novel, but is an idea to which I would give a grade of "D". The term implies that it is related to the hazard quotient, but it is not health based. The notion of background is flawed, as seen above. The background quotient number is biased by selective use of background sites and also the averaging of the Midlothian air quality data (see point 14 below).

14. The methodology for estimating "average exposures" is flawed. On page 19, it is stated that sample results from all sites are averaged together. This means that areas with high concentrations are averaged out by areas with low concentrations. Such averaging can be utilized for attainment demonstrations with the National Ambient Air Quality Standards, but is not appropriate for the determination of risks, susceptible populations, and local impacts. Indeed, EPA's risk assessment guidance discusses the importance of documenting risks to the most exposed/susceptible individuals. A notion of population risk can be valid, but is done for very different purposes. Additionally, the monitors have a very unequal balance of toxics measurements available, and since few statistics are presented, it is unclear whether even the (incorrect) aim of deriving a population average has been correctly determined.

15. The Health Consultation does not summarize any of the primary information, e.g., concentrations and concentration statistics of pollutants at each monitor. This easily fits on few pages for each monitoring site. See also point 2 above.

16. The discussion on page 20 regarding an exposure period of 30 years is anecdotal in nature (e.g., no citations provided), not in EPA's risk guidance, and should be removed.

17. The Health Consultation refers to "EPA regulatory standards for acceptable risk." There are some guidelines, but no such standards. Further, the results in the previous cumulative risk assessments are no longer valid since some of the IRIS and other toxicity factors changed, some new data has been collected, and there is no "gold" standard for comparison which would indicate whether a risk is acceptable.

18. The Health Consultation should explain that previous analyses, e.g., the EPA and TNRCC Screening Risk Analyses, considered a cancer risk of 1 E-5 as the target risk level, while this Health Consultation has elevated the level of acceptable risk by ten times to 9.99 E-5 (page 20) which is interpreted as "no apparent public health hazard." The reason for this change should be discussed. Further, this is a much higher risk level for a population (rather than for single individuals) than is typically and normally considered as a *de minimis* environmental risk for a population. This needs elaboration.

19. A silly point, but a cancer risk of 9.99 E-5 is acceptable, but 1.00 E-4 (0.1% more) is "an apparent hazard." No one can estimate these risks to one significant digit, much less than three! These statements and language should be corrected.

20. More importantly, the Health Consultation should include a discussion of risk characterization, following EPA guidance. This discussion addresses issues of uncertainty, variability, and other factors that affect the interpretation of results.

21. There should have been action by the State of Texas or ATSDR to get the key data needed to evaluate potential risks highlighted by this and earlier analysis. In 1995-6 for example, my report – and others – indicated that need to measure Cr+6, the toxic form. Dioxin/furan data remain missing. This seems inexcusable. The omission of these and other hazardous compounds is one of the key reasons why this Health Consultation is so inconclusive. It would seem to be in government and industry' interest to sponsor the funding to provide better estimates of Cr+6 content.

22. It should also be noted that air pollutant concentrations and health risk calculations in the Health Consultation do not represent nuisance impacts, ecological damage, and animal impacts. Odor, irritation-related, and breathing difficulty reports complaints are legitimate air quality issues. On this, the record over the years in Midlothian demonstrates numerous complaints, and some facilities have

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00116 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

many complaints regarding these issues each year. Some of these complaints have been classified by TNRCC and TCEQ as high priority, imminent threat events. However, Texas rules regarding criteria defining a nuisance are restrictive, and few of the complaints can be or have been investigated in a timely manner by officials and are able to corroborate the community-based complaints. Thus, documentation is incomplete and the facilities are not considered to be a nuisance. The Health Consultation should include a section on nuisance impacts and review the evidence.

23. The Health Consultation has no description of alleged violations, potential violations, assessed penalties, Orders by TNRCC and the US EPA, etc., regarding compliance with air quality emission standards, maintenance of air quality control equipment, and other permit conditions. These issues are not only in the legal domain as they indicate upsets, unaccounted emissions, and impacts on the communities that are not reflected in the permit conditions. Due to their short-term episodic impact, they may also not be reflected in the monitoring data. Again, none of this is mentioned in the Health Consultation, yet it strongly affects air quality impacts on the community.

Please note that the above list of deficiencies is not comprehensive. I did not have time to comment on the cancer and other registry information and analyses, and I also did not have time to provide detailed comments on most of the chemical-specific analyses.

I offer these comments in the hope of improving the relevance of this Health Consultation. In its present form, however, I find so many biases and deficiencies that I do not believe that the Health Consultation achieves its aims and, as stated above, I would urge that ATSDR reconsider its issuance. I do hope that ATSDR sponsorship and oversight provides a means to correct these problems.

I look forward to your response and wish you the best!

Stuart Batterman, B.S., M.S., Ph.D.
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Addendum #7

MIDLOTHIAN, TX—COMMENTS ON ATSDR PUBLIC HEALTH CONSULTATION

PREPARED BY: PETER L. DEFUR, PH.D. AND KYLE NEWMAN
ENVIRONMENTAL STEWARDSHIP CONCEPTS, RICHMOND VA 23238

MARCH 11, 2008

Personal information:

We are submitting these comments on the ATSDR Public Health Consultation for Midlothian, TX out of concern for the role of scientific data in public health assessments and how data are used in environmental management. We learned of this document from colleagues in the area and reporters who asked if we had seen the report. Environmental Stewardship Concepts (ESC) provides technical consultation to citizen groups and agencies regarding the cleanup of contaminated sites across the Nation. At present, our work includes Superfund sites, RCRA sites, State cleanups, contaminated rivers under TMDL cleanup, and operating permits for sites that handle contaminated materials. We are intimately familiar with CERCLA and the work the ATSDR has done regarding contaminated site health assessments. Biographical sketches for Dr. deFur and Mr. Newman are appended at the end of the comments.

Summary

ATSDR's classification of this site as an "Indeterminate Public Health Hazard" is in direct contradiction with the data the Agency presents in the report. Throughout the document, ATSDR attempts to marginalize or disregard data that indicate that compounds produce human health risks. ATSDR has more than enough data to classify the site as a "Public Health Hazard."

The problems with this assessment are numerous, and the most serious problem with the interpretation is that ATSDR discounts their own metrics of health effects, ignoring the data that exceed health levels. For a number of chemicals, the air concentrations are in excess of the health levels, but ATSDR dismisses the excess toxic chemicals as not a problem because the number or people harmed is small, despite the fact that the risks exceed the levels used to protect people from environmental threats (i.e., one in a million).

The most glaringly obvious example of ignoring relevant data is the disregard of aggregate exposures on cancer health effect where ATSDR claimed that even though risks exceeded the regulatory threshold, results were inconclusive since the specific species of chromium measured in the air could not be identified with any certainty. Since the cement kiln is known to utilize hazardous waste fuel in its operation, it is hardly an unreasonable assumption to assume that the more toxic forms are being released. ATSDR also provides no information to support the conclusion that if risks from chromium were excluded cancer risks would no longer exceed the regulatory threshold. ATSDR's own data do not support this attempt at marginalizing the risks.

Non-cancer health effects are dismissed just as easily. For example, when health risks for manganese were found to be unacceptable, ATSDR concluded that actual risks were low because health screening values incorporated safety margins based on uncertainties in the toxicity data. Lowering screening values based on uncertainty is common practice at EPA and other agencies responsible for public health. Does ATSDR disagree with this approach? The rational for dismissing risks from manganese certainly implies that ATSDR is prepared to replace EPA's official determination and EPA's scientific expertise with their own. What exactly what does ATSDR believe the purpose of incorporating uncertainty into screening values is? ATSDR was brought in to evaluate health risks to the community of Midlothian, not to evaluate how human health screening values are calculated. This dismissal, combined with the approach for evaluating the non-cancer effects of aggregate exposures that assumed compounds only target a single organ system provides further evidence that ATSDR's evaluation and conclusions are deeply flawed.

Background levels are inappropriately calculated and do not reflect true background conditions. Urban concentrations are not appropriate for a rural Texas community. ATSDR's decision to average these background concentrations from highly industrialized areas no doubt further inflated background concentrations. This error in methodology in turn led to the dismissal of risks from a number of toxic chemicals since they were "not significantly above background levels."

EPA did NOT conduct a cumulative risk assessment in the document cited by ATSDR, per EPA official methodology. The EPA conducted an exposure analysis as

a case study or example for the Cumulative Risk Framework. Dr. deFur chaired the peer review of the Framework document and has subsequently worked on cumulative risk assessment implementation. The analysis at Midlothian, TX did not follow the Cumulative Risk Framework, nor could it have followed the Framework because the Midlothian assessment was conducted *before* EPA finalized the Framework.

Cumulative risk assessment (see the May 2007 issue of Environmental Health Perspectives for a mini-monograph on cumulative risk) requires more than an attempt to combine the air emissions from four major sources. A proper cumulative risk assessment incorporates health status, community infra-structure evaluations, examination of the history of the sources and much more than was done for the exposure analysis done by EPA at Midlothian, TX more than a decade ago.

The report makes no attempt to deal with the chemicals for which there are no regulatory numbers, i.e., no HAL on which to base a health evaluation. This omission is not even handled in an uncertainty section that could be used to make up for the data gaps and weaknesses in quantitative evaluation. The report further indicates an ability to conduct an uncertainty analysis by using a Monte Carlo analysis, the software for which would provide a feature for conducting a quantitative uncertainty analysis. 59 organics and 28 metals or inorganic chemicals had no health based screen but 16 organics and two inorganics exceed background, per Table 3a.

The report also fails to grasp the biological basis for the action of multiple chemicals acting over many years on the same people and on the same physiological systems. The metals are mostly all neurotoxins and affect the brain, especially the developing brain in fetuses and young children. ATSDR could have sought at least a qualitative analysis of the combined effects of so many neurotoxins over long periods.

It is unclear why the conventional air pollutants were not included in the analysis. These data should be available now for the area, and for all of Texas. In particular, $PM_{2.5}$ is most significant because of the toxic chemicals associated with the particles, and because the particles themselves are deadly. Indeed, recent health investigations in the peer-reviewed literature indicate there is no threshold for $PM_{2.5}$, thus any exposure will cause such problems as increased heart attack, increased stroke, and increased asthma attacks with possible mortality.

The report has no data on dioxins, furans, PCBs, phthalates, pesticides, a number of other compounds and these are dismissed in the text on page 70, A4, C3 and D3 response. Cement kilns are known sources of dioxins and furans, according toe the most recent EPA Dioxin Reassessment (see source and exposure section). Even if ATSDR did not bother to spend the money and take air samples, the EPA database has sufficient information on sources to make an informed estimate of dioxin and furan emissions. As for the other chemicals, if ATSDR did not take fresh samples, then they should have contacted EPA for data that could be used to make an estimate.

The Monte Carlo analysis of data is not valid and is intended to skew the interpretation of the data. I doubt that this analysis was done according to EPA guidelines for probabilistic assessments, but there are no methods given, so it is not possible to assess what ATSDR did in the Monte Carlo analysis.

Specific Comments

Fig. 1 and 2: where is the wind rose? Where are the residences? ATSDR should have used wind data from the facilities, the closest weather station or airport.

Enough time has elapsed since the beginning of the investigation that ATSDR could have installed a weather station in an appropriate location in Midlothian.

Page 22: Why is there not a single list of chemicals? Code the measured, above and below diction and which no toxicology data. Present display is too hard to interpret—What are the Region III risk based air levels and the numbers from the IRIS listing? The report needs to provide these two sets of values that are commonly accepted as applicable around the county.

Page 17: There is a big difference between ATSDR MRL values and the IRIS listings. ATSDR MRL's are always higher, less protective, less conservative than the IRIS values.

Page 19: Averaging the numbers from four collecting locations is NOT conservative Taking the maximum value recorded is conservative. Taking the upper 95 percent C.I. of all values is OK. But the data are so oddly collected in time and space, and so skewed in distribution that some adjustments should have been made to account for these patterns and attempt to get some sense of representative data.

Tables 1a/1b show a sampling distribution that is skewed as to be bizarre. Of the 13 sites, one has 9,294 samples in 11 years and 22,956 for organics for six of those

years and another site had five metal samples one year. Organics were sampled and measured only at four sites and 13 years and not all the sampling was equal. The analysis must not give all samples equivalency.

The 95 percent UCL of all samples is not useful when the data are so clearly skewed in sampling distribution among locations and across time (years).

The graphical depiction of actual data in Fig. 3–23 is useful and when merged with data from Table 4b reveals the following information on detections and levels that exceed the HAL's:

Chemical	95% UCL all	HAC	ppb Max	Number exceeding HAL	HAL
Benzene	.364	.04	20.57	926	CREG
1,3 Butadiene	.00703	.0151	0.340	66	CREG
Carbon tetrachloride	. 102	.0106	4.27	711	CREG
Chloroform*	.00657	.0089	0.260	210	CREG
1,2 dibromoethane	.00138	.000217	0.12	407	CREG
1,2 dichloroethane	.00805	.0095	0.46	87	CREG
Methylene chloride	.0351	.613	1.58	3	CREG
1,1,2,2 tetrachloroethane	.00158	.00251	0.150	3	CREG
1,1,2 trichloroethane	.00101	.0115	0.150	1	CREG
1,2,4 trimethylbenzene	.0709	1.22	7.33	5	RfC
1,3,5 trimethylbenzene	.0215	1.22	2.03	2	RfC
Vinyl chloride	.00171	.0455	0.120	7	CREG
Xylene	.263	23	32.05	1	RfC
Arsenic (PM_{10})	.0116	.000233	0.012	181*	CREG
Arsenic ($PM_{2.5}$)	.0011	.000233	0.00982	157	CREG
Arsenic (TSP)	.0216	.000233	0.058	40	CREG
Beryllium (PM_{10})	.0005	.000417	0.0005	181*	CREG
Cadmium (PM_{10})	.00106	.000556	0.004	181*	CREG
Cadmium (TSP)	.0299	.000556	0.0092	57	CREG
Cadmium ($PM_{2.5}$)	.00166	.000556	0.129	27	CREG
Chlorine ($PM_{2.5}$)	.0113	.232	0.407	2	RfC
Chromium (PM_{10})	.00566	.0000833	0.025	181*	CREG
Chromium (TSP)	.00577	.0000833	0.0287	157	CREG
Chromium ($PM_{2.5}$)	.0014	.0000833	0.027	40	CREG
Lead (TSP)	.217	.375	1.51	65	RfC
Manganese (PM_{10})	.0454	.04	0.171	71	MRL
Manganese (TSP)	.0446	.04	0.076	20	MRL

*All samples measured exceeded the CREG

All of the chemicals listed above show maximum values that exceed the HAC and the HAL. Many of these chemicals had many measurements in excess of the concentration determined to be without effect—in essence the level for protecting public health. In several cases, all measurements exceeded the regulatory limit.

The interpretation by ATSDR that there is no health problem defies logic and all sense of public health assessment. Citizens are exposed to 19 chemicals at times in excess of cancer guidelines or non-cancer. No attempt to put these all together. In spite of the CDC conclusion that these is no safe lead exposure, ATSDR disagrees and is not concerned with children developing neurological problems.

The non-cancer aggregate on p. 68 is wholly unsatisfactory in method but even where found an HI greater than one, discounted because Manganese is the chemical and the MRL is less than the NOAEL (animals v. humans). So the MRL was ignored because ATSDR did not like the answer or the method, or some other thing. What about children's development?

ATSDR did not even report or measure $PM_{2.5}$ for which there is no threshold for health effects.

Cancer p. 69: This statement is dismissive at best, callous and wrong at worst. The $1x10^{-4}$ cancer threshold given by ATSDR is for Superfund sites—Does ATSDR propose the residents of Midlothian live on a Superfund site? I am sure there will be both dismay and relief that some agency has finally admitted the nature and magnitude of the problem. Now, clean it up and make the industries and EPA pay.

This Monte Carlo is a joke. Where are the cumulative probability distributions? Other data need to be displayed compared to ALL regulatory levels. Most such analyses present the probability density functions.

A8—Not measuring does not make the effect go away or diminish.

No soil sample results were presented by ATSDR, only a statement that there was nothing wrong with the soil.

p. 74 Overall At best, the risks are hard to quantify on the basis of the data presented. Most likely there are clear health effects, both cancer and non-cancer, from the air emissions. The non-cancer effects are likely neurological.

No where does ATSDR attempt to determine the effects of a lifetime of breathing contaminated air—and let's add on $PM_{2.5}$ to the toxic chemicals measured here.

Biographical Sketch for Peter L. deFur

Dr. Peter L. deFur is President of Environmental Stewardship Concepts, an independent private consulting firm, and is an Affiliate Associate Professor and Graduate Coordinator in the Center for Environmental Studies at Virginia Commonwealth University where he conducts research on environmental health and ecological risk assessment. Dr. deFur has served on numerous State and federal advisory committees.

Dr. deFur presently serves as technical advisor to citizen organizations concerning the cleanup of contaminated sites at FUDS, CERCLA and RCRA sites around the country. His projects include the Housatonic River, MA; the Delaware River; Lower Duwamish River, WA; Rayonier site in Port Angeles, WA; and the Spring Valley site in Washington, DC. Many of these sites, and others on which he has worked are contaminated with PCBs and/or dioxins.

Dr. deFur received B.S. and M.A. degrees in Biology from the College of William and Mary, in Virginia, and a Ph.D. in Biology (1980) from the University of Calgary, Alberta. He was a postdoctoral fellow in neurophysiology in the Department of Medicine at the University of Calgary, and an environmental fellow at AAAS in 1989. Dr. deFur held faculty positions at George Mason University and Southeastern Louisiana University before joining the staff of the Environmental Defense Fund (EDF) in Washington, DC. In 1996, deFur formed ESC and accepted a part-time position at VCU.

Dr. deFur has extensive experience in risk assessment and ecological risk assessment regulations, guidance and policy. He served on the NAS/NRC Risk Characterization Committee that prepared *Understanding Risk*. Dr. deFur served on a number of scientific reviews of EPA ecological and human health risk assessments, including the Framework for Cumulative Risk Assessment, the assessment for the WTI incinerator in Ohio and EPA's Ecological Risk Assessment Guidelines. deFur served on three federal advisory committees for EPA's Endocrine Disruptor Screening and Testing Program.

Kyle Newman has worked at Environmental Stewardship Concepts since 2004, where he has held the position of Environmental Scientist since 2006. He has worked in the environmental field since 1999 when he first worked for the consulting company Advent Inc., and has developed expertise in risk assessment, freshwater ecology, toxicology, soil contamination, and conservation biology.

Kyle graduated from Virginia Commonwealth University in 2003 with a B.S. in Biology. He is currently finishing his Masters of Science at VCU's Center for Environmental Studies and performing research on the relationship between ecological vulnerability and stream macro-invertebrate community structure. In addition to his work at ESC, Kyle is also the senior Recitation Leader for VCU's groundbreaking Life Science 101 course on systems biology.

Addendum #8

STATEMENT OF NEIL J. CARMAN, PH.D.

Former State of Texas Air Pollution Control Agency Regional Field Investigator of Industrial Plants Including Portland Cement Kilns and Waste Incinerators in 1980s–90s

The EPA's Sham (Bifurcated) Hazardous Waste Combustor MACT Rule and Enforcement Failures by EPA and State of Texas are Related to Health Hazards from Toxic Waste Incineration in Cement Kilns at Midlothian, Texas

The sham EPA MACT rule for toxic waste incineration has created a tragic mess for communities like Midlothian, TX. In addition, State and EPA enforcement failures have led to over a decade of unsafe air pollution and plant upsets impacting citizens close to Midlothian cement kilns that are allowed to incinerate up to 200 million pounds a year of hazardous waste. Known kiln stack air pollutants include carcinogenic metals. Result is Midlothian residents have been living a fifteen-year toxic nightmare created by broken regulatory systems at EPA and State of Texas both failing to fix dirty air problems. As a former State of Texas air pollution investigator, the Midlothian situation is as appalling as I have encountered in thirty years of environmental work in Texas and other states.

Egregious toxic air pollution is due to a bad MACT rule and laxness in fixing the upsets (24-hour baghouse failures) at Texas Industries, Inc's (TXI) four cement kilns burning hazardous waste as fuels. In 1996, EPA made a regretful decision to allow cement kilns to serve as *commercial hazardous waste incinerators and, in hindsight, EPA's decision was exceptionally poor public health policy for communities like Midlothian's.* It led to a serious failure under the *Clean Air Act* and RCRA to protect public health. Adding to bad MACT rule-making is EPA and Texas officials turned a blind eye to years of repeated citizen complaints of health problems, alleging something was rotten at TXI's plant because residents and their animals suffered serious illnesses and their animals often died prematurely. Unsafe levels of air pollution such as toxic metals and other substances from TXI's poorly regulated toxic waste incineration are the primary suspect in my opinion.

Incineration of wastes is a dangerous activity, but even more dangerous is cement kilns incinerating hazardous waste under sham MACT rules. Hazardous waste incineration is inherently dangerous, because combustion of such waste produces thousands of toxic byproducts spewed into the air. Cement kilns were not designed, built or intended for use as commercial toxic waste incinerators since EPA has a RCRA program for permitting of toxic waste incinerators. Cement kilns are designed to make cement and possess different designs and operations from dedicated hazardous waste incinerators. The EPA needs new MACT standards and strict enforcement to fix its egregious 1996 MACT mistake.

Why are Cement Kilns unsafe to communities as quasi-hazardous waste incinerators?

Cement kilns were authorized by EPA in a 1996 MACT rule to run under weaker, less protective MACT standards for Hazardous Waste Combustors (HWC) compared to hazardous waste incinerators. By bifurcating the MACT rule and adopting weaker incineration rules for cement kilns, EPA turned a small group of Cement plants (less than 20 percent in the U.S.) into dangerous toxic waste incinerators with higher mass emissions of toxic substances than more stringently regulated hazardous waste incinerators. The MACT HWC rule set standards for Hazardous Air Pollutants such as mercury, arsenic, cadmium, chromium VI, lead, dioxins, chlorine, total hydrocarbons (CO), particulate matter, DRE of 99.99 percent, opacity, etc. Cement kilns raced to get RCRA permits to burn toxic waste.

Cement kilns burn up to 1,000 degrees hotter than incinerators and a concern is they may burn too hot for metals causing higher mass emissions due to greater metal volatility at higher temperatures. Adding to this concern is TXI had several baghouse failures lasting for hours, and in my view higher toxic metal emissions would have likely occurred. Exposure to toxic metals is consistent with some health problems reported at Midlothian.

March 2009 Status of EPA's Hazardous Waste Combustor MACT rule:

(1) EPA's HWC rule is currently under review after Federal Court litigation resulted in a remand back to EPA for agency action to fix the sham HWC MACT rule;

(2) EPA having admitted that more than half the MACT emission standards that the HWC rule contains are unlawful, the Agency is now deciding whether to defend the rest or take the whole HWC rule back to fix it;

(3) One of the issues raised in the HWC MACT rule-making is whether EPA should keep the specially lenient standards that allow cement kilns to burn hazardous waste; and

(4) EPA deliberately set MACT standards at a level that would ensure new hazardous waste burning kilns would be built to keep burning hazardous waste.

In my thirty years professional experience investigating industrial plants and community health complaints from neighborhoods and downwind residents, I interacted with many communities in Texas seeing first hand how air pollution harms communities. I observed that toxic waste burning cement kilns like Midlothian's are especially dirty facilities spewing out a dangerous soup of toxins, known carcinogens, and harmful chemical mixtures that are poorly known for human health effects. Arsenic, aluminum, cadmium, chromium, lead, mercury, nickel and selenium are among toxic heavy metals emitted by TXI due to receipt of bulk hazardous waste and its incineration.

Conclusion:

As a former Texas investigator with 12 years inspecting over 200 industrial plants a year including waste incinerators and cement kilns, I regard incineration as a dangerous activity based on investigations of incinerators with problems while working for the State of Texas air pollution control agency. Even more dangerous is cement kilns incinerating toxic wastes classified as "hazardous waste" by EPA. EPA needs to set more stringent MACT rules for all Hazardous Waste Combustors, and notably cement kilns and protect public health in these badly impacted communities. Note attached list of toxic substances associated with hazardous waste incineration.

Volatile Organic Compounds, Metals and Criteria Air Pollutants Potentially Emitted by Hazardous Waste Incineration

I. 115 Volatile Organic Compounds = Products of Incomplete Combustion (PICS)

Acetone (1)
Acetonitrile (2)
Acetophenone (3)
Benzaldehyde (4)
Benzene (5)
Benzenedicarboxaldehyde (6)
Benzofuran (7)
Benzoic Acid (8)
Bis(2-ethylhexyl phthalate) (9)
1-Bromodecane (10)
Bromofluorobenzene (11)
Bromoform (12)
Bromomethane (13)
Butylbenzyl phthalate (14)

Carbon tetrachloride (15)
Chlorobenzene (16)
1-Chlorobutane (17)
Chlorocyclohexanol (18)
1-Chlorodecane (19)
Chlorodibromomethane (20)
2-Chloroethyl vinyl ether (21)
Chloroform (22)
1-Chlorohexane (23)
Chloromethane (24)
1-Chlorononane (25)
1-Chloropentane (26)
Cyclohexane (27)
Cyclohexanol (28)
Cyclohexene (29)

1-Decane (30)
Dibutyl phthalate (31)
Dichloroacetylene (32)
Dichlorobromomethane (33)
1,2-Dichlorobenzene (34)
1,4-Dichlorobenzene (35)
1,1-Dichloroethane (36)
1,2-Dichloroethane (37)
1,1-Dichloroethylene (38)
Dichlorodifluoromethane (39)
Dichloromethane (40)
2,4-Dichlorophenol (41)
Diethyl phthalate (42)
Dimethyl ether (43)
3,7-Dimethyloctanol (44)
Dioctyl adipate (45)

Ethenylethylbenzene (46)
Ethylbenzaldehyde (47)
Ethylbenzene (48)
Ethylbenzoic acid (49)
Ethylphenol (50)
(Ethylphenyl)ethanone (51)
Ethynylbenzene (52)
Formaldehyde (53)

Heptane (54)
Hexacholorbenzene (55)
Hexachlorobutadiene (56)
Hexanal (57)
1-Hexene (58)
Methane (59)
Methylcyclohexane (60)
Methyl ethyl ketone (61)
2-Methyl hexane (62)
3-Methyleneheptane (63)
3-Methylhexane (64)
5,7-Methylundecane (65)

Naphthalene (PAH) (66)
Nonane (67)
Nonanol (68)
4-Octene (69)

Pentachlorophenol (70)
Phenol (74)
Polychlorinated Biphenyls (PCBs) (71)
Polychlorinated dibenzo-p-dioxins (PCDDs) (72)
Polychlorinated dibenzofurans (PCDFs) (73)

I. 115 Volatile Organic Compounds = Products of Incomplete Combustion (PICS)

Pentanal (75)
Phenylbutenone (77)
Phenylpropenol (79)
Phenylacetylene (76)
1,1'-(1,4-Phenylene) bisethanone (78)
Propenyl methylbenzene (80)

1,1,2,2-Tetrachloroethane (81)
Tetrachloroethylene (82)
Tetradecane (83)
Tetramethyloxirane (84)
Toluene (85)
1,2,4-Trichlorobenzene (86)
1,1,1-Trichloroethane (87)
1,1,2-Trichloroethane (88)
Trichloroethylene (89)
Trichlorofluoromethane (90)
Trichlorotrifluoroethane (91)
2,3,6-Trimethyldecane (92)
Trimethylhexane (93)
2,3,5-Trichlorophenol (94)

Vinyl chloride (95)

I. 115 Volatile Organic Compounds: 20 Polycyclic Aromatic Hydrocarbons (PAHs) detected with Hazardous Waste Fuel Use:

Acenaphthylene (96)
Acenaphthene (97)
Anthracene (98)
Benz(a)anthracene (99)
Benzo(a)pyrene (100)
Benzo(b)fluoranthene (101)
Benzo(k)fluoranthene (102)
Benzo(g,h,i)perylene (103)
Chrysene (104)
Dibenzo(a,h)anthracene (105)
Fluoranthene (106)
Fluorene (107)
Indeno(1,2,3-c,d)pyrene (108)
Naphthalene (109)
Phenanthrene (110)
Pyrene (111)
Phenanthrene (112)
Perlyene (113)
2-Chloronaphthalene (114)
2-Methylnaphthalene (115)

II. 16 Metals Emitted Depending on Characteristics of the Hazardous Waste Fuel Use:

Antimony (116)
Arsenic (117)
Barium (118)
Beryllium (119)
Cadmium (120)
Chromium (121)
Cobalt (122)
Copper (123)
Lead (124)
Manganese (125)
Mercury (126)
Nickel (127)
Selenium (128)
Silver (129)
Thallium (130)
Zinc (131)

III. Criteria Pollutants Associated with Hazardous Waste Fuel Use:

Sulfur dioxide (132)
Carbon Monoxide (133)
Soot/Smoke - Fine Particulate matter PM2.5 (134)
Nitrogen oxides (135)
Volatile Organic Compounds (1 - 115 and others unidentified)

Addendum #9

Midlothian Area Air Quality Part I: Volatile Organ Compounds & Metals

December 11, 2007

Response: Sal and Grace Mier, Midlothian, Texas: February 03, 2008

Preface:

We recognize that a great deal of valuable time, energy and resources were expended in the development of this report. However, we are generally very disappointed that an effort to make such critical judgments regarding the public health of our community was based on such poor and weak air monitoring data—and even more disappointing was the fact that the primary author(s) of this Report do not appear to have made any serious effort to validate and challenge the quality of this data but nevertheless were comfortable in making sweeping generalizations as if the data were sound.

Any product, whether it be a building, a document, or a report such as this is only as good as the foundation upon which it is constructed. **Step one** of this assessment should have been to assure the base (the air monitoring data) upon which all analyses for this report would evolve was solid and contained data that accurately reflected a complete picture of emissions. Thus, it is perplexing and deeply disappointing to discover that the Texas Department of State Health Services (TDSHS) and the Agency for Toxic Substances and Disease Registry (ATSDR) have produced a Public Health document which was based on deficient air monitoring data, the collection of which was not designed to analyze community impact and not designed to adequately capture complete emissions.

It is not our intent to imply that it is ATSDR's or TDSHS' fault that the proper air monitoring data upon which to base a sound public health assessment does not exist. We assume that it was the best you had available to you. However, we would like to believe that at step one TDSHS would have attempted to verify the methodology incorporated to position air monitors to optimally capture emissions (i.e., populace, wind rose patterns, etc.) and the impact on the community before they proceeded. When you review selection of monitoring sites, history, wind rose patterns, location of major emission sources, etc., it is obvious scientific methodology to capture community exposure and impact was not a prerequisite to the placement of the Midlothian air monitors. Consequently, TDSHS' attempt (with the enabling of ATSDR) to retrofit a methodology and create the illusion of adequacy is extremely disappointing and makes a statement that the true assessment of public health in Midlothian many not have been the major priority.

We realize it is not within TDSHS' purview to dictate to TCEQ a methodology for establishing an air monitoring system. However it is TDSHS' responsibility to **properly critique its adequacy for assessing public health.** If we cannot rely on our public health agencies to do the right thing, rather than becoming a solution to the problem, they become part of the problem.

We want to emphasize, we do not want you to find a problem if one does not exist. However, it was our hope that we would get a solid, sound, unbiased decision based on solid sound data. The foundation upon which the findings of this report are based is seriously wanting and flawed.

You have already pointed out many of the inadequacies of the monitoring sites in this report.

(1) Tayman Drive: **No metals and inorganic compounds were collected** at this site. *(This is the one site that was best positioned to capture emissions from all major industries, but its data was limited.)*

(2) CAMS–52: **No metals and inorganic compounds were collected.** *(This site is capable of capturing some emissions from TXI and Chaparral Steel, but inadequately placed for capturing the majority of emissions from the other industries.)*

(3) CAMS–302: **Metals and inorganic parameters were analyzed from *PM_{10}.** *(This site is not in a prevailing wind pattern for any of the emission sources. No indication that TSP was sampled for metal speciation.)*

(4) CAMS–94: Not in a prevailing wind pattern for any of the emission sources. This site was selected as a background monitor for the DFW metroplex because it's south of and upwind from all industries. ***No speciation of met-**

als from particulate matter greater than $PM_{2.5}$. *(This may be adequate for regulatory purpose; however, this data does not present an adequate picture of local exposure.)* Monitors smaller than TSP monitors are not adequate for determining level of heavy metals in ambient air.

TSP monitors were last used in 1998.

Insufficient data available to evaluate metals—Mercury as an example: Reliable data to determine the amount of mercury in the ambient air does not exist. Note the only readings reflected in the air monitoring data for mercury were based on $PM_{2.5}$ speciation for metals. These readings are for the most part "non-detect." Given the amount of mercury that is self-reported by the industries these 'non-detect' readings are questionable. In 2004 the industries "self-reported" air release of mercury compounds per pounds as follows: Chaparral Steel—**709,** Ashgrove—**150,** Holcim—**59,** TXI—**10.** This demonstrates: 1) the inadequacy of the monitoring location to capture complete emissions, and 2) the inadequacy of relying on $PM_{2.5}$ for speciation of metals.

According to the Office of Air Quality Planning and Standards (OAQPS) final staff paper released in December, there is a distinction in TSP, $PM_{2.5}$ and PM_{10}* and the adequacy of anything less than TSP to evaluate **total *lead in ambient air. Refer to* http://www.epa.gov/ttn/naaqs/standards/pb/data/20071101_pb_staff.pdf *on page 17 (2.3) Air Monitoring.* **2.3.1.1 Inlet Design** *(last paragraph) reads:*

> *"Sampling systems employing inlets other than the TSP inlet will not collect Pb contained in the PM larger than the size cutpoint. Therefore, they do not provide an estimate of the total Pb in the ambient air. This is particularly important near sources which may emit Pb in the larger PM size fractions (e.g., fugitive dust from materials handling and storage)."*

With our petition, we submitted a document: *Evaluation of The Screening Risk Analysis for the Texas Industries Facility in Midlothian* by Dr. Stuart Batterman, et al. This document evaluates risk assessments, monitoring, soil sampling, etc., done in Midlothian and presented in this consultation as activities engaged in the assessment of the community's public health. Dr. Batterman's evaluation reflects many of our concerns regarding the quality of these activities. Therefore, we are requesting that the entire document be considered as part of our comments.

Inhalation is not the only exposure route for toxins in the air. There is no indication in the analyses that skin absorption and ingestion was factored in when evaluating impact.

Because of the critical deficiencies in the air monitoring data, to comment any further on the analyses of public health impact of the toxins would be an exercise in futility as we believe it to be a moot issue. Therefore, we will make comments on general issues.

Response to Petitioner and Community Health Concerns

A.1. While it is true that "all the chemicals being released from cement kilns and steel mills have not been fully identified," this health consultation has evaluated 237 individual contaminants including 119 VOCs and 108 metals and other inorganic substances.

Response: There are over 1,000 regulated chemicals; reviewing 237 is a start. We appreciate the fact that this report has concluded that we cannot disregard the potential impact of the unknown regarding the remainder of the chemicals. However, should this statement simply read, "Of the over 1,000 regulated chemicals, we are proud to state we have evaluated 237"?

A.2. (1) It is also true that, "All the chemicals currently being incinerated and released have not been tested for carcinogenicity and endocrine disrupting potential." (2) However, based on historical reviews of cancer incidence and/or mortality rates in Midlothian and Ellis County, no individual or aggregate cancer rates were significantly elevated with respect to the rest of the state.

Response:

(1) We appreciate your acknowledgement of the deficiency in the extent of chemical testing. We agree with you that many chemicals (as well as heavy metals) being incinerated have **not** been tested for endocrine disrupting potential; however, many **have been** tested or are in the process of being tested. Recent scientific studies have raised red flags regarding endocrine disruption potential for many of the toxins already identified and at levels significantly lower than the current "No Observed Adverse Effect Levels" used

in health risk assessments. Recent science has cast doubt on the current regulatory standards.

(2) How does the **testing** of chemicals for carcinogenicity and endocrine disrupting potential correlate solely to cancer incidence in Midlothian? There are illnesses other than cancer that are of concern. **(a)** Birth defects (BDs) have consistently been significantly higher in Ellis County than the State of Texas for the five years (1999 through 2004). Health Region 3 has the **highest overall BD** rate of all the eleven health regions in Texas—there appears to be a common denominator here—and that is air pollution. Although we cannot say that this higher rate of BDs is definitely attributed to air pollution—**we cannot definitely say that it is not. (b)** Collection of quality cancer data in the State of Texas is still in its developing stages of surveillance. Unlike the BD data collection system, Texas collection of cancer data is passive. In other words the cancer surveillance system has to depend on the good will of physicians, hospitals and treatment facilities to report and many of these providers do not yet have electronic databases to facilitate this reporting. **(c)** Major complaints involve asthmas and other respiratory problems as well as immune system deficiencies. A peer-reviewed study regarding respiratory illnesses in Midlothian, "*The Health Effects of Living Near Cement Kilns; A Symptom Survey in Midlothian*" performed by UTMB and authored by Dr. Marvin Legator, et al., was submitted as part of this petition. This study reflected a higher incidence of respiratory problems in Midlothian than the control group.

A.4., C.3., & D.3. The community was concerned about the health effects of **dioxins, metals,** and **mixtures of compounds.** (1) Air data for dioxins are not routinely collected in Texas; therefore it was not possible to evaluate the potential adverse health effects associated with these compounds. (2) We evaluated available VOCs and metals air contaminant data with respect to its potential for causing adverse health effects in humans due to acute, intermediate, and/or chronic exposures. Only manganese exceeded its health based screening value for chronic inhalation exposures. (3) However, based upon a review of the toxicological data, we would not expect to see adverse health effects due to either long-term or short-term exposure to manganese. (4) Mixtures of compounds also were evaluated in this consultation. (5) Long-term aggregate exposures to air contaminants in Midlothian are not expected to result in adverse non-cancer or cancer health effects.

(1) TCDD is considered by science to be one of the most, if not the most, toxic **man-made** substances. **No safe level has been identified.** It has been shown to disrupt multiple endocrine functions and has negative outcomes for the fetus. Although you cannot evaluate it, you cannot disregard it.

(2) Based on the placement of the air monitors, it does not appear assessing true community exposure was a factor in the collection of the data analyzed. There are too many deficiencies and weaknesses in the air monitoring data to make an informed evaluation.

(3) Health issues are surfacing, **whether you expect them or not.** Some such as respiratory problems, immune system deficiencies, reproductive and birth defect issues in animals, etc., remain "anecdotal" because our guardian agencies refuse to acknowledge them. Others are well documented—for example, the continually significantly higher incidence of birth defect rates; increased respiratory symptoms in Midlothian documented by Dr. Legator, et al.

(4) Did you mean to say, "**Additive** effect of **some** mixtures of compounds also were evaluated in this consultation"? As you acknowledge **only mixtures with available HAC values** were evaluated—and as if only an additive effect were possible. There appears to be **an apparent false presumption that synergistic effects are not an issue.** Synergistic effects were not evaluated here. Can we assume dioxin (in addition to many other chemicals) was not considered in the mix? **When so many factors are missing from the equation, how can you logically compute data to make such a strong declaration,** "Long-term aggregate exposures to air contaminants in Midlothian are not expected to result in adverse non-cancer or cancer health effects"? Perhaps this statement should read: **If** we knew monitoring data accurately reflects industrial emissions and community exposure, and **if** we assume there are no synergistic effects of aggregate exposure, and **if** we can say no empirical data exists that may indicate otherwise, **we could assume** long-term aggregate exposures to air contaminants in Midlothian are not expected to result in adverse non-cancer or cancer health effects.

A.5., A.7., & C.1. In this health consultation, DSHS has analyzed each and every individual air sampling result collected from all TCEQ sampling locations in the Midlothian area and has not relied on any TCEQ-summarized data. Also, DSHS has not relied on any of the TCEQ's effects screening levels (ESLs) for determining potential health risks associated with exposures to airborne contaminants in Midlothian.

Response: Thank you for not using the ESLs. It is obvious that you reviewed a large amount of data. However, it is the adequacy of the data that is of issue—not the quantity.

A.6. & D.4. (1) (2) The community was concerned that the potential for adverse health effects may be underestimated due to averaging of contaminant data over time. The initial screening of the air data involved comparing the maximum concentration for each contaminant to its most conservative health-based screening value. Contaminants whose maximum concentrations exceeded the most conservative health-based screening value were evaluated for acute, intermediate, and long-term exposures. None of the compounds examined (with the exception of benzene) had a single 24-hour measurement that exceeded its acute exposure guideline. (3) The acute inhalation MRL for benzene was exceeded three isolated times in 13 years. Consequently, after reviewing all of the available data (which includes 94,932 individual 24-hour measurements), we find no evidence to suggest that adverse health effects would be anticipated as a result of any of the short-term or peak exposures to VOCs or Metals. (4) The potential for adverse health effects due to exposure to EPA's NAAQS compounds will be evaluated in a future health consultation.

Response:

(1) Although not listed here, A.6 Reflects our concern that TCEQ monitors may not be representative of actual exposures because collection sites may not be optimally positioned to accurately characterize air emissions in Midlothian. **This remains our major concern and the Achilles hill of this report.** See our prior discussion regarding placement of air monitors.

(2) **Averaging still remains a concern because in your analyses this is actually what was done—except for even longer periods of time—years.** The toxicity of a given element depends upon when and to whom it is delivered. A minute dose delivered at a specific time in development (for example to the fetus) can yield physical and mental abnormalities quite evident at birth, or may not be detected until later in life. Exposure during fixed time frames when programming of the endocrine system is occurring may result in deleterious life altering effects. There are too many questions and red flags raised by scientific research related to the short "windows of vulnerability" when chemical exposure can have a negative impact on the developing fetus, a pregnant mother or the immune suppressed. Time frames for these "windows of vulnerability" are generally measured in days and weeks—not years. **This extended averaging concept removes life's reality from the formula.**

(3) "The acute inhalation MRL for benzene was exceeded three isolated times in 13 years . . ."—**that you know of!** This is a misstatement. It should read, "Based on the limited available data, the acute inhalation MRL for benzene was exceeded at least three times in a 13-year period . . ." The data that you have represents snapshots by the monitors of selected short periods in time and in "select" locations. There is a high probability benzene exceeded the acute inhalation MRL also when the monitors were not running. There is a higher probability that if air monitors were methodically situated to gather data based on prevailing winds, fallout patterns and community exposure, results would be very different. At all three sites (0007, 0015, 0016) the CREG was exceeded 94 percent, 98 percent, 99 percent (respectively) of the time with spikes up to 118, 512, 319 (respectively) times higher than the CREG. Exposure to benzene is Midlothian is consistent 24 hours per day and long-term. Low-level long-term exposure (over two years) has been shown to lead to anemia and affect the immune system. A safe level for the fetus has not been established. Benzene passes the placental barrier and cause breaks in chromosomes and change in chromosome number. Animal studies suggest benzene can cause low-birth weight, bone marrow damage, and delayed bone formation in the fetus.

(4) Whether the analyses of the NAAQS data is an exercise in futility or whether it produces a reliable indicator of the impact on public health depends on several factors: (a) direction and speed of prevailing wind **for each sam-**

ple; (b) whether current science—not regulatory levels—are used to determine impact on public health (c) whether readings of upwind samples are averaged with readings from downwind samples to dilute the impact (d) whether air monitors collecting NAAQS data are capable of completely capturing total lead emissions.

A.8., B.4., C.4., & D.1. The community was concerned about asthma, allergies, immune system deficiencies, and other health problems in adults as well as children. Data for these health problems are not routinely collected in Texas. Therefore, we were not able to systematically assess whether the levels of these conditions in Midlothian are different than in other areas of the state.

Response: Would it make any difference (other than to disregard it) if you did have an assessment of this condition? There appears to be a propensity in this report towards trivializing empirical data. There is no indication that anyone is asking, "Is there something we are missing?" Note the wording below.

B.1., B.2., & D.2. Over the years, the Texas Cancer Registry and Texas Birth Defects Registry have conducted incidence, mortality, and prevalence investigations to determine if cancer and birth defect rates were higher or lower in the Midlothian area compared to the rest of the state (Appendix D). No statistically significant elevations of specific or total cancers were found. (1) The prevalence for a few birth defects were higher than expected and for a few other birth defects were lower than expected based on state rates. These higher prevalence rates were not unique to Midlothian/Ellis County but were also observed throughout Health Service Region 3 (which includes 18 other counties primarily north and west of Ellis County). (2) Because of the numerous factors involved, it is not possible to determine if these increases are due to environmental exposures or differences in reporting practices in this region compared with the rest of the state. (3) Furthermore, it should be noted that only three of the 99 compounds with health based comparison values (i.e., ethylbenzene, 2-butanone, and methyl isobutyl ketone) listed "developmental effects" as the critical effect (i.e., the first observable physiological or adverse health effect occurring at the lowest exposure dose known to produce any effect at all). Hazard quotients for those three compounds were 0.000352, 0.0000653, and 0.00000793 respectively, levels that are far below levels that might be expected to result in an increased risk for birth defects.

Response:

(1) Prevalences for only a "few" birth defects were higher? How "few" is few enough? The attempted play on words here is insulting and appears to be an intent to downplay and obscure the significantly higher impact of birth defects in the community and downwind neighbors. This wording is reminiscent of the wording in the infamous "Cafeteria Talk" (see discussion below under section *Past DSHS & ATSDR Involvement and Data Review*). The fact is that the prevalence of **total birth defects for our entire region is significantly higher** than the State—that is the point we have been making. Ellis County's total birth defect rate is higher than the region and has been **significantly higher** than the State for all years 1999–2003. And there were **no "few"** significantly lower—there was **only one** in Public Health Region 3. In 2002 the unadjusted prevalence for birth defect rates in **Ellis County (689.1) was 186 percent that of Texas (370).** In 2002 Ellis County had the highest birth defect rate in Public Health Region 3.

(2) It is understandable if you contend that because of the numerous factors involved you cannot say environmental exposure **is (as well as you cannot say it is not)** involved—but the most perplexing excuse of all is "because it is not possible to determine if these increases are due to environmental exposures or differences in reporting practices in this region compared with the rest of the state."

According to Texas DSHS own website: *http://www.dshs.state.tx.us/birthdefects/BD_—data.shtm*

> "The Birth Defects Epidemiology and Surveillance Branch (BDES) uses **active surveillance.** This means it does not require reporting by hospitals or medical professionals. Instead, trained program staff members regularly visit medical facilities where they have the authority to review log books, hospital discharge lists, and other records. From this review, a list of potential cases is created. Program staff then review medical charts for each potential case identified. If the infant or fetus has a birth defect covered by the registry, detailed demographic and diagnostic information is abstracted. That information is entered into the computer and submitted for processing into the registry. **Quality con-**

trol procedures for finding cases, abstracting information, and coding defects help ensure completeness and accuracy."

Unlike the Cancer Registry, Texas BDES Registry **does not depend** on the good will of medical facilities **nor** their **"better reporting practices."** Their data collection efforts and **active surveillance** have been statewide since 1999. Because of the method of collection, this database presents the **best empirical evidence** available to TDSHS to determine **whether and where** health issues are surfacing.

(3) Furthermore, a multitude of teratogenic and mutagenic toxins being emitted into the local air are known to cause birth defects and are known endocrine disruptors. Current science continues to produce evidence that raises questions regarding the adequacy of current levels that are deemed safe. There are many unanswered questions regarding the synergy of these toxins and their impact on the fetus during certain stages of development. There is significant scientific evidence surfacing that makes it impossible to state with the slightest degree of certainty that these toxins that are known to be endocrine disruptors and known to cause birth defects do not contribute to the significantly higher birth defects in Ellis and the surrounding downwind counties in Region 3. **This statement is especially true when you factor in the fact that you do not have a complete picture of the emissions.**

B.3. It has been suggested that the Down syndrome cluster reported in Ellis, Hood, and Somervell Counties in 1991–1994 may have been related to a cesium-137 source melt that occurred at Chaparral Steel on September 16, 1993. This might seem plausible in that one of the risk factors for Down syndrome is exposure of the mother or the father to excessive radiation prior to conception of the child. However, the time line is not right for this to have been a possibility, because the non-disjunction of chromosome 21 that results in the manifestations of Down syndrome would have had to have occurred prior to the date of the cesium-137 source melt for 15 out of 18 of the reported Down syndrome cases (based on the estimated date of conception for each of the children with Down syndrome). Also, analysis of the wind rose patterns for Midlothian during a similar time period to the cluster (i.e., 1992–94), revealed that the wind would have been blowing in the direction of one of the Down syndrome cases for less than two percent of the time during the three-year period. Although the precise wind direction on the exact day of the source melt in not known, the prevailing winds are out of the SSE during September, which would have been blowing toward none of the three Down syndrome cases whose estimated date of conception was after the cesium-137 source melt (two of these cases were from Granbury, which is approximately 44 miles west of Midlothian, and the other was from Palmer which is 21 miles ESE of Midlothian). And finally, although the exact quantity of radiation released is unknown, modeling of this release as though the entire source (approximately 89 millicuries of cesium-137) was vaporized and released into the air (and not caught in baghouse dust as most of it was), indicates that the additional radiation would not have been detectable above background radiation levels.

1. **No one** in this community raised the issue regarding the two other Down Syndrome clusters in **Somervell or Hood County.** The only issue raised was the cluster along FM 664 in northern **Ellis County.** Furthermore, the lone "September 1993" incineration of cesium-137 correlation to this cluster surfaced solely in-house at TDSHS.

2. According to the study, the conception dates for the mothers in Ellis County occurred in March 1991, February and March 1992, February and March 1993 and February 1994. Ten of the 12 dates of delivery occurred in 1993 and the first half of 1994. **Documented in the study,** cesium-137 was reported to have been in scrap material that went into the steel mill at Chaparral Steel in Midlothian **on at least two known occasions in 1991–1994.** *(Note reference above to timeline of exposure.)* The cluster along the Ovilla Road corridor is east and north of Chaparral Steel. It is accurate that this area is not in a prevailing wind pattern; however, what percentage of the time must the wind blow in this direction for there to be a potential problem? *[Incidentally, the same concept regarding probabilities and wind patterns should be applied when evaluating the adequacy of the air monitoring data.]*

3. The study concluded that the median distance (12 miles) between Chaparral Steel and the cluster was too far to be impacted by the cesium-137 release—and this is also implied in your analyses above regarding cases in Palmer and Granbury. It appears that cesium-137's ability to stay aloft and travel long distances was disregarded.

4. The point to this issue has been missed. This issue was raised to point out the gaps in our public health efforts, the inability or reluctance to associate health issues with the environment and the too often inaccurate characterizations related to the transport of constituents via air. In this Down Syndrome study, traditional factors were ruled out—the only factor that was not ruled out was the environment. In this study, cesium-137 was disregarded because of the distance between the Ellis County cases and the source. Cesium-137 was raised as an example of a constituent associated with aneuploidy that stays aloft and travels a long distance before it reaches the ground. Below is an excerpt from our petition letter to Dr. Sanchez dated July 11, 2005.

> *The TDSHS also conducted one Down Syndrome study in Ellis County. A concerned parent living in northern Ellis county reported that he was aware of eight children with Down Syndrome that had been born in the immediate area during 1992 to 1994; an additional four cases were identified via the Texas Department of Health Bureau of Vital Statistics. Eleven were live births and one was a fetal death. The observed 12 cases were 2.78 times the expected number of 4.32 cases. This finding was considered "statistically significant." Unlike the cancer clusters identified in Ellis County, this cluster was deemed to be "statistically significant" and thus progressed to a higher level of epidemiological investigation. Other traditional factors that have been known to be linked to Down syndrome were reviewed but ruled out. Unfortunately the study was not designed to review the potential association of environmental factors to Down Syndrome; even though these are probably the only major variables left to consider. The primary investigator made the point that this cluster occurred several miles away from the Midlothian industries and thus it was not likely that there would have been an association. This assertion could be correct but again, keep in mind that the study was not designed to review the impact of environmental factors. There could also have been some unlikely occurrences related to wind direction and velocity that could have occurred during the Spring of 1993 when most of the children were conceived. Just because the "prevailing" winds are from south to north doesn't mean that the winds blow in this direction 100 percent of the time. Also, some constituents are more "persistent" than others. For example, cesium-137 was known to have been incinerated by Chaparral Steel during this time period and this element has a known association to Down Syndrome and leukemia. The ATSDR Public Health Statement on cesium-137 also states that this element has the ability to travel a long distance in the air before being brought back to the Earth by rainfall and gravitational settlings. Cesium has a half-life of 30 years.* **I am not saying that cesium-137 caused the cluster of Down Syndrome, but this, again, emphasizes not only the gaps in our air monitoring but the inaccurate perceptions related to the transport of constituents via air. We do not monitor for all elements and we do not take into account the ability of certain elements to travel at time, rate and speed beyond the ability of the monitors to capture their full impact.**

Also note: Author of this section (B.3) still seems to have an inaccurate understanding of cesium-137's persistency to stay aloft for long periods of time and to travel a considerable distance before being brought back to earth. It is also known that shielded cesium-137 (example a gauge encased in lead) was difficult to detect prior to incineration. Since a certain percentage of cesium-137 continued to show up in the EAF dust one would question whether encased cecium-137 continued to be incinerated. Again, this is not to say that cesium-137 is the cause of these Down Syndrome babies—**but to stress the gaps in the system.** *[Again, the concern about wind rose patterns expressed here is to be complimented. The same attitude should prevail when assessing the adequacy of the monitoring data.]*

C.2. This concern turned out to be unfounded, in that all three CAMS monitoring locations have collected air sampling data on 97–99 of the 119 different VOCs, amounting to 60,396 individual contaminant measurements. The CAMS–94 location collected air sampling data on 52 metals or other inorganics present in **$PM_{2.5}$** particulate matter amounting to 8,164 individual contaminant measurements, and the CAMS–302 location collected air sampling data on 24 metals or other inorganics present in PM_{10} particulate matter, amounting to 4,344 individual contaminant measurements. Only the CAMS–52 location collected no air samples for metals or other inorganics present in particulate matter. The confusion may have arisen because the CAM sites only collect data for the NAAQS compounds on a continuous basis (i.e., 24 one-hour-average levels per day). The other contaminants (VOCs and metals) are collected noncontinuously as one 24-hour-average level collected once every six days.

The concern that we were given conflicting data by TCEQ was not unfounded. *Refer to documentation (e-mails from TCEQ) in the petition file.* The **source** of confusion was not the petitioner but **TCEQ.** However, you have pointed out one of the inadequacies of the data for **8,164** contaminant measurements for 52 metals and other inorganics collected at CAMS–94 and **4,344** individual measurements for metals or other inorganics collected at CAMS–302. **$PM_{2.5}$ and PM_{10}** are not adequate for determining the amount of metals released into the ambient air because the larger particulate matter to which these metals bind are screened out. This is particularly true in assessing local impact since these larger particles have a tendency to settle closer to the source. This data may satisfy regulatory obligations, but is not reflective of true public exposure. Again, it is quality not quantity that should be of essence here.

C.4. & D.5. (1) Health problems reported in domesticated animals and livestock were shared with veterinarians at Texas A&M University. (2) While DSHS does not have animal-species-specific health-based comparison values to evaluate the risks for health effects in animals, many of the health-based comparison values used in our evaluation of human exposures are derived from animal studies and consequently, we would expect these human HAC values to be equally conservative in protecting animal health for most common domestic and farm animals.

(1) So you talked to veterinarians at Texas A&M . . . and? You were presented with strong empirical evidence that should prompt the following questions. **"Are these animals sentinels to what may be happening to people? Are there deficiencies in the data we are reviewing? Are we missing something?"** The casual dismissal of this issue is extremely disconcerting especially when some local veterinarians are pointing to the environment as the potential source of the problems. We would have expected that the inherent scientific curiosity (and ethical obligation) of the author (s) of this report would have automatically "kicked in" and that this issue would have been aggressively pursued.

(2) This response avoids the issue as to why concerns of health effects in animals have been surfacing throughout the years. The community was concerned that the effects they were seeing in the animals paralleled health problems in the community. The question was, **"Are these animals canaries in the coal mine?"** Animals are exhibiting immune symptoms, reproduction problems, inability to carry offspring to term, low birth weights, birth defects, etc. An example *http://midlothiannow.com/MY_DOGS___MYSELF.html.* This was some of the documentation provided with the petition. Levels of toxins in the blood samples and hair analysis from these animals and manifestation of disease do not match the findings and "assumptions" of this report. Again, "Are we missing something?"

Past DSHS Health Data Reviews

(1) Maternal age- and race/ethnicity-adjusted prevalence rates for total birth defects and for hypospadias/epispadias in Midlothian were significantly elevated with respect to Texas. Similarly adjusted prevalence rates for total birth defects and for craniosynostosis were significantly elevated in Ellis County with respect to Texas. Similarly adjusted prevalence rates for total birth defects, craniosynostosis, microcephaly, hypospadias/epispadias, and obstructive genitourinary defects were significantly elevated in Health Service Region 3 with respect to Texas. (2) Similarly adjusted prevalence rates for pyloric stenosis were significantly lower in Health Service Region 3 than in Texas as a whole.

(1) We appreciate the fact that you acknowledge significantly elevated birth defect rates in Midlothian, Ellis County and Public Health Region 3.

(2) It is fascinating the number of times you have mentioned this one insignificant fact in this report as if though it should trivialize and negate the preponderance of evidence that establishes the significantly higher birth defect rates.

General Findings

1. One hundred thirteen contaminants (47 VOCs and 66 metals or other inorganic compounds) had no levels exceeding the most conservative HAC value (or had no reported levels above the detection limit). No known health effects are associated with exposure to these contaminants at the concentrations measured in Midlothian; therefore, exposure to these contaminants would not be expected to result in adverse health effects.

Response: . . . therefore, exposure to these contaminants would not be expected to result in adverse health effects. Any respectable scientist would question and challenge whether data reviewed represents true and complete emissions and community exposure. Unless you can assure that the data reviewed accurately captures emissions and reflects community exposure, a statement like ". . . therefore, exposure to these contaminants would not be expected to result in adverse health effects" is without a solid scientific basis.

2. Health based screening values were not available for 87 contaminants (59 VOCs and 28 metals or other inorganic compounds). Additional information is needed to determine the public health significance of these contaminants.

Response: We appreciate that you acknowledge screening values were not available for a large number of regulated contaminants.

3. Thirteen VOCs had one or more measured level above the most protective health-based screening value. Three of the VOCs (1,1,2-trimethylbenzene; 1,3,5-trimethylbenzene; and m- and p-xylene) had one or more level above the most conservative contaminant-specific *non-cancer* screening value. Ten of the VOCs (benzene; 1,3-butadiene; carbon tetrachloride; chloroform; 1,2,-dibromoethane; 1,2-dichloroethane; methylene chloride; 1,1,2,2-tetrachloroethane; 1,1,2-trichloroethane; and vinyl chloride) had one or more level above the most conservative contaminant-specific *cancer* screening value.

Response: Statements like ". . . had one or more level above the most conservative contaminant-specific *cancer* screening value . . ." although technically true, sound so trivializing, especially when the data shows that benzene levels exceeded this "most conservative screening value" over 97 percent of the time.

Again, the only issue is not just what you found. We remain concerned about what may not have been identified due to the inadequacy of data due to the placement of the monitors. Comment in #1. above applies here.

4. Fourteen metals or other inorganic compounds had one or more measured level above the most protective health-based screening value. Four of the metals or other inorganic compounds [chlorine ($PM_{2.5}$), lead (TSP), manganese (TSP), and manganese (PM_{10})] had one or more level above the most conservative contaminant-specific non-cancer screening value. Ten metals [arsenic (PM_{10}), arsenic $PM_{2.5}$), arsenic (TSP), beryllium (PM_{10}), cadmium (PM10), cadmium ($PM_{2.5}$), cadmium (TSP), chromium (PM_{10}), chromium ($PM_{2.5}$), and chromium (TSP)] had one or more level above the most conservative contaminant-specific cancer screening value.

Response: The response to item #1 above also applies here. Metal speciation based on $PM_{2.5}$ and PM_{10} does not adequately capture true levels of metals in the ambient air. The last year metal speciation was based on TSP was 1998.

Individual Contaminants—Non-Cancer Health Effects Evaluation

Using reasonable maximum exposure scenarios, only manganese (both as PM_{10} and as TSP) exceeded ATSDR's chronic inhalation MRL by a small margin. After an in-depth review of the toxicological information and the uncertainty factors used in deriving the chronic inhalation MRL, we concluded that it is highly unlikely that the manganese levels seen in Midlothian would result in any observable adverse health effects, even after long-term exposure.

Response: The response to item #3 above also applies here.

Individual Contaminants—Cancer Health Effects Evaluation

Exposures Prior to 1982:

Based on ambient air samples collected prior to calendar year 1982, the estimated excess lifetime cancer risks associated with reasonable maximal exposure to arsenic (TSP), cadmium (TSP), and chromium (TSP) ranged from 5.38×10^{-5} (a total of 1 excess cancer in 18,597 people exposed for 70 years) to 9.30×10^{-5} (a total of one excess cancer in 10,748 people exposed for 70 years). If these exposures were to continue for 70 years, they would pose a low increased lifetime risk for cancer and would not be expected to result in measurable harmful health effects. Past exposures to these compounds (prior to 1982) therefore posed "no apparent public health hazard."

Response: "Based on exposures prior to 1982 . . ." Are you referring to the 1981 monitoring at site 0001 (City Hall roof)? If yes, then this should be stated as thus. Also, do you believe, based on prevailing wind patterns, this monitor was adequately situated to capture true emissions from Ash Grove, TXI and Chaparral Steel? It should be pointed out: 1) that ambient air data prior to 1982 was limited to 1981

and was scarce (practically non-existent) since monitoring for **most** heavy metals and VOCS was not done and 2) there is insufficient data to make an informed statement regarding public health impact. And why would we say, ". . . and if these exposures continue . . ." **when we know they did not!**—We know that population, industry, production, mobile sources, etc. increased.

Exposures 1982 through 1992:

This time span should not have been omitted. It should be noted that for a critical six-year period ambient air data for heavy metals and VOC's is missing. This period is of particular concern to the community because Ashgrove unsafely burned hazardous waste derived fuel (HWDF) from 1986 to 1992. It was not until after Ashgrove's "trial burn" in 1992 that it was determined that this facility **could not safely burn** HWDF. Holcim went online in 1987. Also, during this period EPA issued citations to TXI for violations involving hazardous waste burning.

Exposures 1993 through 2005:

In the entire history of air monitoring in Midlothian, site 007 (Tayman Drive) was the **only site** in a prevailing wind pattern that had the potential to facilitate capturing data from all industries. There is no data from this site for metals. Data was collected only for 1993–1997. A large number of samples were collected upwind of all the industries at CAMS–94. Averaging in readings from CAMS–94 when the wind is blowing out of the south only serves to dilute the true impact.

Ongoing Exposures:

It would be prudent to ask what monitoring is currently taking place. Are the sites in position to collect data that accurately reflects true public impact from all sources? The response may give insight to TCEQ's intent and attitude regarding public health.

Overall Conclusions

We found that the majority of the risks associated with exposure to the chemicals analyzed in this health consultation were low. However, we are classifying this site as an *Indeterminate Public Health Hazard* because further information is needed to fully characterize the extent of the public health hazard posed by air contaminants in Midlothian. This classification is based on the following facts:

Overall Response to this section:

Response: **We truly appreciate the fact that it was recognized that insufficient data exists to make a solid conclusion whether a public health hazard does or does not exist.** It is quite evident (through no fault of ATSDR or TDSHS) that the collection of data to assess public health or to capture a complete picture of emissions and true public impact was not a factor in the placement of air monitoring stations. Consequently, the data is insufficient and inadequate for this purpose. Adequate data does not exist that would permit TDSHS to make a sound analysis that would warrant a call in either a safe or unsafe direction. Thus, it is quite disconcerting that an effort was made to assess public health impact to **any degree.** This serves only to discredit ATSDR's and TDSHS' purported mission to protect public health.

Again, it is not our intent to insist a public health problem be identified if one does not exist. However, it was our hope that **all conclusions or statements derived regarding the community's public health would be based on the recent and developing science and on solid data appropriate to identifying real public exposure.**

1. Sixteen out of 59 VOCs and two out of 28 metals or other inorganic compounds for which health-based screening values were not available had average levels above average background (levels obtained from other areas in Texas and/or the U.S.). Additional information is needed to determine the public health significance of these contaminants.

2. While individual contaminants produced, at most, a low increased lifetime risk for cancer and no apparent public health hazard, under the aggregate exposure scenario, total excess lifetime cancer risk for all cancers combined could be interpreted as posing a public health hazard. However, this conclusion is based on the assumption that all the chromium detected in the air is of the most toxic form [i.e., chromium (VI)], an assumption that is inconsistent with information obtained from other areas of the state. The relative proportions of chromium (III) and chromium

(VI) will need to be determined in order to accurately define the risk estimate for total cancer (all sites combined).

3. While this health consultation reviewed the majority of the contaminants measured in Midlothian air (119 VOCs and 108 metals and other inorganics), EPA's NAAQS compounds still need to be evaluated in a future consultation.

4. There are data gaps both in sampling locations and parameters of interest. No air data for the analysis of VOCs were collected prior to 1993. Air data for the analysis of metals and other inorganic compounds were collected at only one location from 1981 through 1984. No air data for these contaminants were collected prior to 1981 and none were collected between 1985 and 1992. For the time periods when air data does exist, data were collected from a limited number of monitoring stations and may not reflect conditions throughout the community. (2) However, since the major monitoring locations were relatively close to one or more of the primary emission sources, we do not anticipate that air pollutant levels for much of the city would be too much higher than those observed.

Response:

(1) You are right to assert ". . . data was collected from a limited number of monitoring stations and may not reflect conditions throughout the community," **because it definitely does not.** The only monitoring site capable of collecting emissions from all sources was 0007 on Tayman Drive and its data limitations are quite obvious.

(2) **"Relatively close" does not suffice.** Monitor placement in relationship to both the source(s) and wind rose patterns should be the criteria. Other than Tayman Drive (site 007), no monitors were "close to" or in a prevailing wind pattern to adequately capture emissions from Ashgrove and Holcim. Most of the metals were monitored at CAMS–94 (site 0015) which is **upwind** from **all sources.** Based on the wind rose patterns this is the one spot that is **least likely** to capture data representative of local emissions. The second site (based on the wind rose patterns) least likely to capture emissions is CAMS–302 which is west of TXI/Chaparral Steel and south of the other industries. The majority of the VOC's were collected at site 0015 and 0016. Site 0016 is south of Holcim and Ashgrove and again (based on prevailing winds) not in an ideal location to capture emissions from Ashgrove or Holcim. TSP monitoring for metal speciation was limited before 1998 and non-existent after 1998.

Recommendations

We have made the following recommendations in response to these findings:

1. As resources allow, research the toxicology literature for contaminants measured in Midlothian air for which health-based screening values were not available, and determine the potential public health impact of exposures to these substances.
2. Collect additional ambient air samples from previously sampled locations to determine the specific distribution of chromium species and to refine the risk estimates for this contaminant.

   Response: Since previously sampled locations were obviously not optimally situated to capture true emissions, is there some logic to limiting collection to the previously sampled site?

3. Evaluate the levels of EPA's NAAQS compounds in the continuous air monitoring data.

   Response: Although we appreciate your efforts, if data was collected at CAMS–94, which is obviously not in an ideal position to capture true emissions from the industries, of what value would it be when assessing public health impact? It would just be another exercise in futility. Also, it is not possible to determine a community's true lead impact from ambient air based on anything other than TSP readings.

4. Where possible identify and fill data gaps with additional data from TCEQ to identify any additional air contaminants that might need evaluation and/or sampling.

   Response: This report has surfaced deficiencies in the system that should already have been identified by TCEQ. Before we proceed to identify additional air contaminants that need evaluation we need to get a firm handle on the ones that have already been identified. Current TCEQ monitoring does not give an accu-

rate picture of total emissions and public impact. **If public health is a concern, and if there is a serious intent to assess community impact, a methodology based on wind rose patterns, terrain, emission sources, populace, etc., needs to be scientifically devised and implemented.**

Actions Completed

Historically, the TCEQ has collected a vast amount of environmental data in Midlothian, Texas, including air monitoring samples, soil samples, vegetation samples, and others dating back to the early 1980's.

Response:

(1) Historically TCEQ has shown that this agency's ties and loyalty lies with industry and that public health cannot be allowed to trump economic welfare. The lack of monitoring sites placed in and around Midlothian as a result of a methodology scientifically based on prevailing winds, major emissions sources, populace, etc., testifies to this. This brings us to problems faced in this consultation—data that does not measure true impact of emissions—data deficient for assessing public health. One can only presume this was part of the design.

(2) *The Evaluation of the Screening Risk Analysis for the Texas Industries Facility in Midlothian,* by Dr. Stuart Batterman, et al., points out that the monitoring system was deficient considering the scale of industry and waste combustion. Furthermore this evaluation documents inconsistencies and deficiencies/omissions in many of the emissions and soil sampling/analyses. TCEQ was criticized for its tendency to go far beyond what is scientifically supportable by the existing data in making sweeping generalizations regarding the present and future safety of waste combustion in Midlothian. This document was submitted with the petition and should have been a factor in the analysis of data quality/adequacy of the TCEQ data.

2. Earlier data were analyzed by the TCEQ using EPA methodology and TCEQ's screening levels [4, 10].

Response: Again, refer to *The Evaluation of the Screening Risk Analysis for the Texas Industries Facility in Midlothian,* by Stuart Batterman, et al. This was part of the petition package and part of the evidence submitted. It should not have been ignored. It critically reviews the documents referred to here [4, 10]. This evaluation points out TCEQ's failures at times to use EPA methodology. It sheds a light on serious omissions, inconsistencies, selective use of critical data; sampling times, techniques and locations inappropriate to characterize impact; meteorological and other data not presented to interpret monitoring data; advance notice given to industry prior to ambient air monitoring, etc.

3. DSHS staff reviewed summarized monitoring data (1993 through 1995), attended numerous meetings with TCEQ staff and area residents, and distributed questionnaires to see if there were consistent reports of odors, or signs or symptoms of illnesses that might be related to environmental pollution.

Response: See our response below under Past Environmental Sampling and Data Review regarding actions and results of TDSHS involvement during this period.

4. The Texas Cancer Registry analyzed cancer morbidity and mortality data for Midlothian and Ellis County, looking for any significant increases in cancer rates in this area over the period 1993 through 2002.

5. The Texas Birth Defects Registry analyzed birth defect data for Midlothian, Ellis County, and Health Service Region 3, looking for any significant birth defect elevations during the period 1999 through 2003.

6. ***

7. DSHS staff obtained detailed (not summarized) TCEQ air monitoring data from 1981 through 1984 and from January 1993 through March 2005 in an electronic format and created a database of monitoring results. With the completion of this health consultation, DSHS has analyzed this data for VOCs and metals or other inorganic compounds and compared these data to health-based screening levels published by ATSDR and EPA. A conservative exposure scenario was generated, and carcinogenic and non-carcinogenic risk estimates were calculated, assuming 70-year lifetime and/or chronic exposures at the *reasonable maximal exposure levels seen in the Midlothian area.

Response: Sufficient data was not available to adequately determine "reasonable maximal exposure levels seen in the Midlothian area."

Actions Under Way

***

Actions Planned

1. DSHS and ATSDR will make this health consultation available to the public, local industries, the local government, and State and federal health/environmental agencies.

2. DSHS and ATSDR will continue to address the community's health concerns relating to air quality.

Response: **"Continue . . ."?** The only way to credibly address a community's health concerns relating to air quality is to have an adequate air monitoring system truly representative of air emissions to which the community is exposed. A scientifically devised system based on a methodology that incorporates prevailing winds as they relate to emission sources, terrain, populace, etc. has never been in place in Midlothian. More of the same is of little value.

3. ***

4. DSHS will discuss with TCEQ the potential for determining the specific distribution of chromium species in Midlothian air. Hopefully we will get a complete picture of the true emissions first.

5. DSHS will discuss with TCEQ the potential for identifying and filling data gaps and identifying any additional air contaminants that might need evaluation and/or sampling.

This community needs an adequate air monitoring system that is based on a scientific methodology designed to capture the total emissions as they impact the community. Then, and only then will our health agencies be able to make a viable evaluation as it relates to public health.

6. DSHS will complete the analysis of the hourly NAAQS data. If this data was collected at upwind monitoring stations situated where the majority of emissions will be missed, this will be an exercise in futility. Also, unless data was collected at a site(s) where (based on prevailing wind) true emissions from all sources are captured it will be of little value in assessing impact on public health.

Appendix D—Birth Defects and Cancer Registries Report Summaries

Birth Defects Registry Report Summaries

A Down syndrome cluster investigation released in 1996 reported that the number of Down syndrome cases in Ellis, Hood, and Somervell Counties among deliveries in 1992 through 1994 was 3.4 times higher than expected based on statewide rates [74]. Those results, which included adjustment for maternal age, were statistically significant at the 95 percent level. While that study did not provide evidence that environmental factors were associated with the excess occurrence of Down syndrome cases, its ability to do so was limited.

Response: **We take this as a statement that the environment could not be ruled out.** We agree with this fact. Also, are we talking about three separate clusters here that occurred in Public Health Region 3 during the same period?

In response to a citizen request, the DSHS Texas Birth Defects registry completed an additional review of birth defects registry data in June 2005 [75]. They examined the occurrence of 48 specific types of birth defects as well as "any monitored birth defect" among deliveries to residents of Midlothian, Venus, and Cedar Hill over the period from 1997 through 2001 and compared those rates to the state as a whole (1999 through 2001). Adjusting for maternal age, the prevalence rate for the occurrence of one type of birth defect related to urinary tract development (hypospadias or epispadias) was approximately **3.7** times higher than the prevalence rate observed for Texas (1999 through 2001). Adjusting for maternal race/ethnicity, the prevalence rate for hypospadias or epispadias was approximately **4.2 times higher** than the prevalence rate observed for Texas (1999 through 2001). These results were statistically significant at the 95 percent level. Similarly, the prevalence of any monitored birth defect among Midlothian residents (1997 through 2001), adjusted for maternal age, was **1.5 times** the prevalence rate for Texas (1999 through 2001), and the result was statistically significant at the 95 percent level. However, adjust-

ing for maternal race/ethnicity, caused the prevalence ratio to drop to 1.2, and the result was no longer statistically significant. It is not clear what effect if any the different time periods for data inclusion in Midlothian vs. Texas may have had on the birth defect prevalence rates.

In response to additional inquiries in August and October 2006, DSHS Texas Birth Defects registry completed an additional review of birth defects registry data in November 2006. They examined the prevalence of total birth defects as well as 48 specific types of birth defects in the 11 Health Service Regions of Texas over the period from 1999 through 2003.

The standardized prevalence ratio (SPR) for any monitored birth defect, adjusted for maternal age and race/ethnicity, in **Health Service Region 3** (which includes Ellis County and 18 other counties in the Dallas-Fort Worth area) was found to be 18 percent higher than the state as a whole, and those results were statistically significant at the 95 percent level. Specific defects found to be significantly elevated at the 95 percent level included **hypospadias/epispadias (SPR=1.14),** obstructive genitourinary defects (SPR=1.11), **microcephaly (SPR=1.31),** and **craniosynostosis (SPR=1.33).** [Pyloric stenosis was significantly lower in Health Service Region 3 than Texas as a whole (SPR=0.84). What is **not** mentioned here is that of **all the eleven Health Service Regions** in Texas, **Public Health Region 3 continues to reflect the highest birth defect rate.**

The maternal age and race/ethnicity adjusted prevalence rate (per 10,000 live births) for total birth defects in **Ellis County was 483.66** compared with 360.70 in Texas as a whole (SPR=1.34); these results also were statistically significant at the 95 percent level. Out of 48 specific birth defects (after adjustment for maternal age and race/ethnicity), only **craniosynostosis (SPR=3.61)** was significantly elevated in Ellis County with respect to Texas as a whole.

We assume you are referring to the **cumulative average rates** for periods 1999 through 2003. An interesting point that should be made here is that in 2002 the unadjusted prevalence for **birth defect rates in Ellis County (689.1) was 186 percent** that of Texas (370). In 2002 Ellis County also had the highest birth defect rate in Public Health Region 3.

Cancer Registry Report Summaries

The Texas Department of State Health Services completed cancer incidence and/or mortality investigations . . .. The incidence and mortality of the other cancer types were not significantly different than what would be expected when compared to the rest of the state.

Response: This report made a comment that the higher birth defect rates in Health Service Region 3 and Ellis County may be due to the difference in reporting practices. Should not the same logic be applied here to the cancer rates. Since, the cancer surveillance depends on the good will of the health providers, is it not possible that there is a difference in reporting practice in the rural areas such as Ellis County and your picture of cancer case may not be complete?

Past Environmental Sampling and Data Reviews

Air monitoring data were collected every six days for a variety of metals and other inorganic constituents of particulates in the Midlothian area sporadically from 1981 to 1984 in accordance with the national schedule. Samples were collected from the roof of the City Hall on North 8th Street and were analyzed for approximately 30 different parameters including total suspended particulates (TSP) adjusted for standard temperature and pressure (STP). No air data were available for the time period from January 1985 through December 1992.

In 1991, the TNRCC initiated an environmental monitoring program in and around Midlothian to evaluate soil, vegetation, slag, and stack emissions for 18 different metals and/or polychlorinated dibenzo-p-dioxins (PCDDs) and dibenzofurans (PCDFs). Of the 175 soil samples collected between 1991 and 1995, one sample exceeded the TNRCC's soil screening level for lead (400 ppm), and six out of 140 soil samples exceeded the TNRCC's soil screening level for arsenic (20 ppm). Measurements for all other soil metals were below their respective soil screening levels.

Response: So based on tests taken 17 years ago, excessive lead and arsenic were identified in the soil? What were the PCDD levels? This paragraph is silent regarding findings in stack emissions. Refer to Batterman, et al., Sections 5.2–5.3.1 analysis of these soil sampling. See Section 4.3.9 Dioxin/furans. These sections all point out questionable quality assurance/quality control and raises questions regarding discrepancies between various soil sampling techniques and discrepancies in airflow and temperatures during stack testing for dioxins/furans, etc.

Additional samples were collected in the vicinity of Chaparral Steel. Results from these samples show that two out of 22 soil samples collected just outside of the Chaparral property line exceeded the TNRCC's soil screening level for lead (400 ppm), and one out of 22 soil samples exceeded the soil screening level for cadmium (40 ppm) [4, 10]. All other soil metals were below the TNRCC's respective soil screening levels.

Response: So excessive levels of lead and cadmium were identified in the soil.

Among 60 soil samples tested, the Toxicity Equivalency Quotient (TEQ) for PCDDs and PCDFs ranged from 0.3–17.9 parts per trillion (ppt); all were below the ATSDR's health-based soil guidance level of 50 ppt.

Response: It appears that dioxin was identified in all 60 soil samples. Dioxin is the deadliest of all man-made chemicals. There is no known safe level for dioxins—what is ATSDR's basis for deeming a "safe" level? How is PCDD's synergistic effects and the endocrine disrupting factor calculated into this "safe level"?

Slag (a by-product of steel production) samples were collected and analyzed for 13 different metals; none exceeded their respective soil screening levels.

As part of the Chaparral Steel special study, hay, wheat, and other vegetation samples were collected from the fields surrounding the steel mill. With the exception of aluminum, cadmium, and iron in samples collected in the field immediately south of Chaparral, all measured metal concentrations were below their respective maximum tolerable levels for **cattle**.[3]

Response: So an issue with aluminum and cadmium and iron surfaced? What about lead?

A letter regarding this study from Dr. Lund dated September 22, 1994 states: "Soil samples collected from the hay field contained elevated **levels of cadmium, manganese, and lead.** Cadmium, manganese, and **lead levels** exceeded the human soil ingestion comparison values by up to 2.1, 1.1, and **6.2 times respectively.** Human ingestion of soil from the hay field with the measured metal concentrations may result in adverse health effects. In addition to exposure through hay and vegetation consumption, animal ingestion of soil during grazing may increase the total metal exposure in the animal.

This letter also indicates eight additional hay-bale samples (four 0–3 inch depth samples and four 3–6 inch depth samples were collected from the rows of hay-bales stored at site #8. The results show that iron, manganese, cadmium, lead and titanium levels in surface samples (0–3 inch depth) **were significantly greater** than samples collected from three to six inches within the hay bales. **These results suggest aerial deposition of the metals.**

Stack samples were collected from all three cement manufacturing facilities while they were burning different combinations of coal, HWDF, and/or tire-derived fuel. The total 2,3,7,8-Tetrachlorodibenzodioxin (TCDD) Toxicity Equivalency Quotient (TEQ) concentrations estimated for each of the test conditions were all below the TNRCC's screening levels.

Response: Again, TCDD is the deadliest of all **man-made** chemicals. There is no known safe level for dioxins—what level does TCEQ (TNRCC) **ESLs** deem acceptable.

Starting in 1993, the TNRCC began collecting air samples for VOCs, particulates, metals, and other inorganic compounds from various locations or Continuous Air Monitoring Stations (CAMS) around the city as follows (see Appendix E, Tables 1a & 1b and Appendix C, Figure 2):

Tayman Drive (Site 0007): **PM_{10}** Total Particulates (0 to 10 μm), 1993 through 1996 (231 results) **Metals & Inorganic Compounds, None** VOCs (78 species), 1993 through 1997 (11,135 results)

CAMS–94 (Site 0015): **PM_{10}** Total Particulates (0 to 10 μm), 1994 through 2004 (690 results) **$PM_{2.5}$ Fine Particulates (0 to 2.5 μm),** 2002 through 2004 (157 results) **Metals & Inorganics in $PM_{2.5}$ (52 species), 2002 through 2004** (8,164 results) VOCs (98 species), 1999 through 2005 (22,955 results)

CAMS–52 (Site 0016): PM_{10} Total Particulates (0 to 10 μm), 1994 through 2004 (685 results) **Metals & Inorganic Compounds, None** VOCs (99 species), 1997 through 2004 (34,842 results)

CAMS–302 (Site 0017): PM_{10} Total Particulates (0 to 10 μm), 1999 through 2004 (262 results) Metals Inorganics in PM_{10} (24 species), 2001 through 2004 & (4,344 results) VOCs (97 species), 2004 through 2005 (2,599 results)

Note: Tayman Drive (007) is the only location (based on prevailing wind patterns) capable of capturing ambient air data representative of public exposure. All others are upwind of Holcim and Ashgrove. CAMS–94 is upwind of all industries and metal speciation is based on $PM_{2.5}$ only. There does not appear to be any **TSP** monitoring for metal speciation at any of these sites.

In 1996, the United States Environmental Protection Agency (EPA) conducted a cumulative risk assessment using air modeling data based upon estimated emissions for the industries in the area during **1985 and 1987 through 1990.** In their report, no increased risk for developing cancer or potential for developing non-cancer health effects were identified above the EPA's regulatory standards for acceptable risk [11].

Response: The EPA assessment was a theoretical mathematical model conducted for regulatory purposes and should not be relied upon to determine public health implications. This assessment was based on estimated data that was already 6–11 years old when the report was issued. How were permit violations factored in? Was Ashgrove's permit violation and failed efforts at burning of hazardous waste in its wet kilns factored in? Much has changed since 1990. Production has increased. Types of fuels have changed. Incineration of hazardous waste and tire-derived fuel has increased. Mobile emissions sources have increased. Population has increased. Emissions have increased. **Findings are obsolete.** Empirical data should trump any theoretical estimate.

Past DSHS and ATSDR Involvement and Data Reviews

(2) Between 1992 and 1995 TDH and ATSDR periodically evaluated the air monitoring data collected in the Midlothian area and attended community meetings. The majority of samples were below the (1) **screening levels considered to be health protective at that time** [12]. (3) Although no consistent pattern of symptoms or illnesses were noted among area residents, there were common complaints among the residents about sulfur odors and excessive dust. At the request of various citizens groups, DSHS Birth Defects and Cancer Registries have analyzed data from Midlothian, Venus, Cedar Hill, Ellis County, and Health Service Region 3 to determine prevalence rates for various types of birth defects and the standardized incidence and mortality rates for various types of cancers in the aforementioned areas. Reports were written by the respective registries and summaries of those reports are presented in Appendix D.

(1) What do you know about screening levels now that you didn't know then? It is noted that data available for review at that time was very limited. However VOC collection on Tayman Drive indicated that 94 percent of the benzene emissions exceeded the CREG values and benzene emissions spiked to an acute chronic inhalation RfC of 20.57 ppb in May 1995. Ashgrove burned hazardous waste derived fuel (HWDF) from 1986 to 1992. It was not until after the "trial burn" in 1992 that it was determined that this facility could not safely burn HWDF. Holcim went online in 1987. Also, it was during this period that EPA issued citations to TXI for violations involving hazardous waste burning. **Refer to "Cafeteria Talk" below and how this was trivialized.**

(2) The results of these visits that culminated in the infamous "Cafeteria Talk" presented November 2, 1995 at the Midlothian Middle School Cafetorium was a source of extreme frustration and disappointment for the community. It was not just in the dismissive and condescending manner in which it was presented with **sweeping generalizations and statements not apparently supported by science.** (Statements like: **"Contrary to some of the claims you may have heard . . . dioxin exposure is not a significant health risk in Midlothian." "ESLs are generally 100 fold or more lower than the LOAEL." "If it has been determined that environmental pollutants in an area are not consistently elevated into a range expected to cause adverse health-effects, then it is a foregone conclusion that differences in disease prevalences cannot be validly attributed to environmental pollution." "After 120 years of study, there are no reports in the medical/scientific literature linking Down Syndrome to any sort of chemical exposure or industrial pollution.")**

What was even more frustrating was that the community's concerns regarding lack of adequate monitoring and health problems surfacing in both the people and the livestock were trivialized. Results of a poorly designed and analyzed questionnaire was embraced to rule out the alleged asthma and breathing problems while

the only peer-reviewed study, *The Health Effects of Living Near Cement Kilns: A Symptom Survey in Midlothian* showing a higher incidence of respiratory problems in Midlothian was totally ignored. A poorly executed and failed Animal Health Survey (which incidentally did surface breeding problems) was abandoned as a failure. The eagerness to place emphasis on the negative and the dismissiveness of potential links was very worrisome.

Troubling are statements made during this "Cafeteria Talk" (like: "The TNRCC's environmental sampling program in Midlothian has been unprecedented!" "Never before in history has the Agency, or its predecessor, the Texas Air Control Board collected so many environmental samples, from so many different media, from so many sampling locations, analyzing for so many different compounds and finding so few of even the mildest of health concerns.") This is troubling, not only from the perspective that the review of the environmental data (especially the air monitoring data) reveals significant gaps and deficiencies that should have been obvious then. But, **what is most troubling and of great concern is whether the author of this "Cafeteria Talk" could develop and maintain sufficient objectivity to adequately evaluate the currently available data and arrive at objective scientific conclusions without bias in this current public health consultation.**

(3) It was acknowledged that levels of sulfur compounds were "on occasion" above the odor threshold levels. The complaints regarding excessive odors (not given credence then) were substantiated.

Methods Used in This Consultation

Because of the diversity of the health and environmental concerns and the volume of data available for the Midlothian area, several health consultations will be needed to address these concerns. In this consultation we reviewed available air monitoring data with respect to volatile organic compounds (VOCs), metals, and other inorganic compounds. Subsequent consultations are planned to address EPA's National Ambient Air Quality Standards (NAAQS) compounds and (*) consideration of wind patterns and other weather data. Additional consultations may be added based on the results of these analyses.

Response: ***This holds promise.** This same consideration/logic should be applied to the data analyzed for this report.

Environmental Data

We reviewed air monitoring data collected by the TCEQ in the Midlothian area from 1981 through 1984 and from January 1993 through March 2005. Air data were not available prior to 1981 or between January 1985 through December 1992. These data, collected every six days in accordance with the national schedule, include 119 VOCs collected from four different monitoring locations and 108 particulate and metal parameters collected from 13 different sampling locations (most data were collected from six locations) in and around Midlothian. Current sampling locations and historical sampling sites are shown in Appendix C, *Figures 1 and 2. Monitoring site locations and the number of measurements made for VOCs and for metals/inorganic compounds at each site are shown in Appendix E, Tables 1a and 1b, respectively.

Response: See our prior remarks regarding adequacy of monitoring sites to capture complete emissions. *Reference figure 2. The "artist" that overlayed this aerial photo with king-size pictures of canisters should be complimented with his ability to create an illusion. At first glance, one is inspired by what really looks like heavy monitoring in most of the critical spots is taking place. Unfortunately a review of the actual air monitoring data and what each of these "canisters" represents, burst the bubble.

Quality Assurance/Quality Control

We obtained detailed (not summarized) ambient air quality data that TCEQ collected in the Midlothian area from May 1981 through March 2005. In preparing this report, DSHS/ATSDR relied on the data provided to us by the TCEQ and (1) assumed adequate quality assurance/quality control (QA/QC) procedures were followed with regard to data collection, chain of custody, laboratory procedures, and data reporting. (2) For the purpose of analysis, concentrations reported as "ND" (or not detected) were assigned numerical values equal to one half the detection limit for the compound.

(1) Assuming QA/QC is a leap of faith especially when it comes to public health issues versus industrial welfare.

(2) When direction of wind and fallout patterns would not support a reading other than a possible non-detect, the non-detect readings should have been discarded. Including them only serves to dilute true concentrations and distort findings. This is true even with uncustomarily low concentrations reflected on days when (based on wind direction) a true measurement cannot be expected.

Health-Based Assessment Comparison (HAC) Values

Media-specific health-based assessment comparison (HAC) values for non-cancer health effects are generally based on ATSDR's minimal risk levels (MRLs), EPA's reference doses (RfDs), or for air, EPA's reference concentrations (RfCs). MRLs, RfDs, and RfCs (1) all are based on the assumption that there is an identifiable exposure dose for individuals including sensitive sub-populations, such as pregnant women, infants, children, the elderly, or the immuno-suppressed, that is likely to be without appreciable risk for non-cancer health effects even if exposure occurs for a lifetime [13].

When a substance is listed as a carcinogen, the lowest available HAC value usually proves to be the cancer risk evaluation guide or CREG. CREGs are based on EPA's chemical specific cancer slope factor (CSF) and represent the concentration [for airborne contaminants, usually expressed as micrograms per cubic meter ($\mu g/m^3$)] that would result in a daily exposure dose [expressed as milligrams per kilogram per day (mg/kg/day)] and theoretical lifetime cancer risk level of one additional cancer case in one million people exposed (a risk of $1x10^{-6}$), assuming a 70 kg person breathes an average of 20 cubic meters (m3) of air per day over a 70 year lifetime [13].

Response: This does not appear to be true of all constituents. Take lead for example. An exposure dose that is likely to be without appreciable risk for health effects (even for short periods of time—such as the "window of vulnerability for the fetus" or for a child in his first few years of life) **has not been identified.** A provisional RfC) 0.375 $\mu g/m^3$ was created for evaluating lead based on a long-ago outdated level (quarterly average) 1.5 µg/m to protect a long-ago outdated once acceptable blood lead level of 30 µg/dl. In addition a blood lead level of 10 µg/dl was used as a comparative value of safety when all reputable science and even CDC say it is not an acceptable level of lead poisoning.

According to the Office of Air Quality Planning and Standards (OAQPS) final staff paper, evidence of a differing sensitivity of the immune system to Pb across and within different periods of life stages indicates a potential importance of exposures as short as weeks to months duration. For example, the animal evidence suggests that the gestation period is the most sensitive life stage followed by early neonatal stage, and within these life stages, critical windows of vulnerability are likely to exist.

OAQPS final staff paper indicates (based on peer-reviewed scientific studies) that for neurological effects on the developing nervous system), no threshold levels can be discerned from the evidence. OAQPS concludes, "*Thus, to the extent one places weight on risk estimates for the lower standard levels, we believe these risk results may suggest consideration of a range of levels that extend down to the lowest levels assessed in the risk assessment, 0.02 to 0.05* $\mu g/m^3$."

OAQPS states: "*In conclusion, staff judges that a level for the standard set in the upper part of our recommended range (0.1–0.2* $\mu g/m^3$*), particularly with a monthly averaging time) is well supported by the evidence and also supported by estimates of risk associated with policy-relevant Pb that overlap with the range of IQ loss that may reasonably be judged to be highly significant from a public health perspective, and is judged to be so by CASAC. A standard set in the lower part of the range would be more precautionary in nature in that it would place weight on the more highly uncertain range of estimates from the risk assessment.*"

In general, comparison values are derived for substances for which adequate toxicity data exist for the exposure route of interest. All substances were evaluated as if inhalation was the only exposure route. Breathing is not the only exposure route for toxins in ambient air to enter the body. Toxins in the air are also absorbed by dermal exposure and ingestion. This is especially relevant to toxins that are persistent in the environment and are continually re-suspended.

Comparison values may be available for up to three different exposure durations: acute (14 days or less), intermediate (15 to 365 days), and chronic (more that 365 days). Usually, HAC values based on long-term exposure guidelines are lower (more conservative) than HAC values based on short-term exposure guidelines. Thus, the

initial screen usually involves comparing each discrete (i.e., short-term) contaminant level with a HAC value based on a long-term exposure guideline. What is the acute, intermediate or chronic long-term exposure for a fetus and its critical "windows of vulnerability"?

Health-Based Screening

Estimation of Long-Term Exposure Levels

Nearly all air samples collected for the measurement of VOCs, metals, and other inorganic substances have come from four primary sampling locations (1) (sites 0007, 0015, 0016, and 0017). *Site 0007 is approximately 1.2 miles northeast of Ash Grove and 1.6 miles northwest of Holcim.* Sites 0015, 0016, and 0017 are approximately 1.6 miles *south,* 1.5 miles north, and 1.2 miles northwest of the TXI/Chaparral facilities respectively (see Appendix C, Figure 2 and Appendix E, Tables 1a & 1b). (2) Some Midlothian neighborhoods are located within 1–1.5 miles of one of the major industrial facilities but *most* are farther away. (3) Since emission levels tend to drop off with distance from the emission source, we expect the levels measured at the 4 primary sampling locations to be fairly representative of the upper range of levels to which the majority of the residents of Midlothian would be exposed. Of course individual exposure concentrations will vary from day-to-day due to changes in emission levels, wind speed and direction, and the movement of people around the city. (4) Consequently, we have averaged the sample results from all monitoring sites together to give the best approximation of the average concentration to which Midlothian residents may have been exposed over extended periods of time.

Response: It appears these sites were established in response to needs other than monitoring public health impact.

Tayman Drive (Site 07) was the only monitor logically placed to capture emissions from all industries and is the only monitoring site that was in a prevailing wind pattern capable of capturing most emissions from Holcim and Ashgrove. Unfortunately this data is 10 to 15 years old and is not reflective of current exposure. Industrial activity has increased significantly since this data was collected and tire derived fuel and other hazardous materials have been added to the mix. **Metals and inorganic compounds were not sampled here.** The majority of the data for metals was taken upwind from all the industries (site 0015, CAMS–94). Site 302 (almost directly west of TXI) also is not in line with prevailing wind rose patterns. TSP monitoring (sites 0001 and 0012) for metals was very limited (six out of the last 27 years) and none in the vicinity of Ashgrove and Holcim. TSP monitoring ended in 1998.

Site 015 is upwind of the town, schools, and the majority of the population. Furthermore, it is **upwind from all industrial activity.** The site was selected as a background monitor for DFW because of its upwind location and is not in a position to capture the majority of the local emissions; however, it could be useful in determining what blows in from the Houston area. **Metals and inorganics were measured here for only three years and these measurements were based on $PM_{2.5}$.** The major contribution that data from this site gives to this study is a dilution of all constituents evaluated and a distortion of true public health impact.

Site 016 is in a position to capture some emissions from TXI and Chaparral Steel, but rarely Holcim and Ashgrove. **Unfortunately, metals and inorganic compounds were not sampled here.**

CAMS–302 (Site 0017). Placed almost directly west and just slightly north. This site is not in a prevailing wind pattern for **any** of the industries. Metals speciation was from PM_{10}—no TSP monitor.

The argument ". . . we expect the levels measured at the four primary sampling locations to be fairly representative of the upper range of levels to which the majority of the residents of Midlothian would be exposed" could hold weight: 1) if data was more representative of emissions from all industries (specifically Holcim and Ashgrove) and at monitoring sites established based on prevailing wind; 2) if all data was simultaneously collected to represent the same level of industrial activity for a given period; and 3) if there were not so many inconsistencies in the data (example: metal sampling). Furthermore, readings captured at CAMS–94 (and possibly CAMS–302) should be disregarded when the wind is blowing out of the south. These readings do not capture community exposure and generally serve only to dilute true impact.

". . . Since emission levels tend to drop off with distance from the emission . . .." This is not true of all emissions. Some constituents can stay aloft and travel for great distances and when and where they come down depends on many variables.

For many constituents, it depends on what size PM to which they attach. Take lead (or any heavy metal) for example. Lead attached to the larger particulate matter (greater than PM_{10}) has a tendency to settle in closer proximity (depending on wind speed) to the source while lead attached to $PM_{2.5}$ becomes aerosol and can stay aloft indefinitely and travel long distances. If you were analyzing data collected on a TSP monitor, this statement could to some degree hold more weight. **Unfortunately no TSP monitoring took place at the sites listed above.**

". . . Of course individual exposure concentrations will vary from day-to-day due to changes in emission levels, wind speed and direction, and the movement of people around the city." While this is true, some locations are more heavily exposed to total emissions for longer periods of time than others. Locations located closer to Holcim and Ashgrove realize a higher impact of total emissions. Unfortunately, monitoring adequate to capture these exposures is severely limited and missing for many constituents (example heavy metals). There could be some logic in evaluating impact on communities within 1.5 miles of the individual monitoring sites—but only for those constituents that were adequately monitored and tend to settle close to the emission site. There are too many variances (created by time lapses, increases in production and TDF increases, lack of metal analysis, limited data capturing emissions from industries on north side of Midlothian, etc.) in monitoring sites to average across the board.

". . . Consequently, we have averaged the sample results from all monitoring sites together . . .." Since when do people get exposed to "averages"? People are exposed to whatever is in the air at the time. What is the average "window of vulnerability" for a fetus?

Evaluating Exposure to Chemical Mixtures

While risk assessments often focus on identifying risks from single contaminant exposures, real-life situations such as the one in Midlothian involve the simultaneous exposure to multiple contaminants. Consequently, in addition to assessing the risks associated with exposure to individual contaminants, we also evaluated aggregate exposures from multiple contaminants for the Midlothian area, both for non-carcinogenic and for carcinogenic effects.

Simultaneous exposures to multiple chemicals may have additive effects (where the combined effect is equal to the sum of the effects of each agent alone), synergistic effects (where the combined effect is greater than the sum of the effects of each agent alone), or antagonistic effects (in which one substance interferes with the effects of another producing a less toxic effect), when compared to a single chemical exposure alone. In general, aggregate exposures to multiple chemicals at levels below their thresholds for minimal effects would, at most, be expected to produce a simple additive effect. Consequently, aggregate exposures to multiple chemicals were evaluated assuming an additive effect. It was also assumed that all compounds contributing to the exposure were elevated in unison and that people were exposed to all the chemicals at the same time.

Response: "Consequently, aggregate exposures were evaluated assuming an additive effect"? How does this tie in to your explanation of synergistic effects? Does "Consequently . . ." mean consequently synergistic effects are not real? The bottom line is that total aggregate effects were not really evaluated unless you have "assumed" synergistic effects and endocrine disruption activity are not possible.

Chemical Mixtures and Non-Carcinogenic Effects

To estimate the potential public health significance of simultaneous exposures to multiple chemicals, we tabulated all of the critical effects for each contaminant listed by the EPA on the Integrated Risk Information System (IRIS) database which were the basis for deriving the RfD or the RfC. We also tabulated all of the critical effects listed by the ATSDR in their Toxicological Profile series which were the basis for deriving their inhalation MRLs. The 95 percent UCL of the estimated average daily exposure dose was divided by the appropriate health-based value to calculate the 95 percent UCL on the Hazard Quotient (HQ) for a particular critical effect (e.g., CNS effects, developmental effects, liver toxicity, etc.). HQs from multiple contaminants known to produce critical effects of a similar nature or on the same organ system were summed to arrive at the Hazard Index (HI) for each critical effect as a result of exposure to the chemical mixture. Aggregate exposures with an HI less than 1.0 were considered to be without appreciable risk for adverse health effects. Aggregate exposures with an HI greater than 1.0 were subjected to further analysis to determine the potential public health significance.

Response: How are synergistic effects and endocrine disrupting activity factored into this formula?

Chemical Mixtures and Carcinogenic Effects

To estimate theoretical excess lifetime cancer risks associated with simultaneous exposures to multiple carcinogens, we tabulated all of the cancer critical effects for each contaminant listed by the EPA on the IRIS database which were the basis for deriving the IUR or the oral slope factor (if applicable). For each contaminant, the 95 percent UCL on the estimated average daily exposure was multiplied by the IUR to calculate the theoretical lifetime risk of developing certain types of cancer (e.g., lung, liver, kidney, etc.), assuming a continuous, 70-year exposure. Risks from exposures to multiple contaminants known to produce the same type of cancer were summed to obtain an estimate of the total excess risk of developing that cancer as a result of exposure to the chemical mixture. Finally, all of the individual cancer risks were summed to obtain a cumulative cancer risk estimate. Aggregate exposures with a cumulative cancer risk estimate less than $1x10^{-4}$ were considered to be without appreciable risk for adverse health effects. Aggregate exposures with a cumulative cancer risk estimate greater than $1x10^{-4}$ were subjected to further analysis to determine the potential public health significance.

Response: How are synergistic effects and endocrine disrupting activity factored into this formula? If you have not factored in these two facets, do you believe you have scientifically evaluated aggregate exposures?

Child Health Considerations

In communities faced with air, water, or food contamination, the many physical differences between children and adults demand special emphasis. Children could be at greater risk than are adults from certain kinds of exposure to hazardous substances. Children play outdoors and sometimes engage in hand-to-mouth behaviors that increase their exposure potential. Children are shorter than are adults; this means they breathe dust, soil, and vapors close to the ground. A child's lower body weight and higher intake rate results in a greater dose of hazardous substance per unit of body weight. If toxic exposure levels are high enough during critical growth stages, the developing body systems of children can sustain permanent damage. Finally, children are dependent on adults for access to housing, for access to medical care, and for risk identification. Thus adults need as much information as possible to make informed decisions regarding their children's health.

Health-based assessment comparison values such as the MRLs, RfDs, and RfCs used in this health consultation are all based on the (1) assumption that there is an identifiable exposure dose for individuals including sensitive sub-populations (such as pregnant women, infants, children, the elderly, or the immuno-suppressed) that is likely to be without appreciable risk for non-cancer health effects, even if exposure occurs for a lifetime. Each of these HAC values employs an uncertainty factor designed to account for human variability or sensitive sub-populations, including children. (2) With regard to CREG values and potentially increased carcinogenic risks for children, only one of the carcinogens observed in Midlothian air (vinyl chloride) is listed by the EPA as having a mutagenic mode of action. Using the recommended additional age-dependent adjustment factors of 10 for exposures occurring between birth and 2.0 years, and three for exposures occurring between the ages of 2.0 and 6.0 years, we would anticipate a 31.3 percent higher lifetime risk than that calculated by conventional methods.

(1) This should read: "*Though there is* **evidence to the contrary** *that an identifiable exposure dose of many toxins exists for individuals including sensitive sub-populations* (such as pregnant women, infants, children, the elderly, or the immuno-suppressed) *that is likely to be without appreciable risk for non-cancer health effects,* even if exposure occurs for a lifetime, *we proceed in our assumptions as if there were.*" Note: prior discussions regarding lead. ATSDR has consistently flown in the face of science by condoning a blood-lead level of 10 µgL as an acceptable level of lead poisoning though science has established (and CDC concurs) that it is not.

(2) The point to this statement is obscure and the information is confusing. Are you saying that cancer is the only issue of concern for children? A large number of the toxins in Midlothian air are known fetotoxins, neurotoxins, endocrine disrupters, teratogens. Mercury, lead, arsenic, benzene, cadmium, chromium have all been associated with mutagenic effects. Safe levels for the fetus for most of these chemicals has not been determined.

Other

On page 29 under Results

Carbon tetrachloride was detected at quantifiable levels in 711 (7.46 percent) of the 952 ambient . . .. Did you mean 74.60 percent—appears to be a typo in both places within this paragraph.

ADDENDUM To Prior Comments Submitted February 3, 2008

MIDLOTHIAN AREA AIR QUALITY PART I:
VOLATILE ORGAN COMPOUNDS & METALS

DECEMBER 11, 2007

Prepared by Sal and Grace Mier, Midlothian, Texas
As addendum to February 03, 2008 Comments
Date: March 09, 2008

Suggestions:

For reasons outlined in our prior comments, air monitoring data collected in Midlothian by TCEQ cannot be scientifically justified as adequate to determine public health implications. Therefore, it is suggested that Under Section **Results and Discussions** (starting on page 22 up through 67) all "Public Health Implications" based on this air monitoring data be removed.

Response to Petitioner and Community Health Concerns (starting on page 5): All responses reflecting an analysis based on TCEQ air monitoring data collected in Midlothian should be revised to reflect adequate data was not available to arrive at a scientific conclusion.

General Findings (page 8) should reflect that TCEQ air monitoring data collected in Midlothian was inadequate to arrive at a scientific conclusion of public health impact of toxic emissions in the air. All conclusions using TCEQ air monitoring data as a basis should be deleted.

Individual Contaminants—Non-Cancer Health Effects Evaluation (page 9): This section should reflect that TCEQ air monitoring data provided insufficient data to evaluate non-cancer health effects. All analyses based on TCEQ data should be deleted.

Individual Contaminants—Cancer Health Effects Evaluation (page 9): This section should reflect TCEQ air monitoring data collected in Midlothian was inadequate to arrive at a scientific conclusion of public health impact of toxins in the ambient air. All analysis based on TCEQ air monitoring data should be deleted.

Aggregate Exposures—Non-Cancer Health Effects (page 9): This section should reflect that due to absence of critical data such as dioxin/furans, VOCs, heavy metals (especially mercury and lead), questions regarding critical windows of vulnerability, questions regarding endocrine disruptive activity and the overall inadequacy of the air monitoring data, aggregate exposures and the impact on public health could not be scientifically evaluated.

Aggregate Exposures—Cancer Health Effects (page 10): This section should reflect that due to absence of critical data such as dioxin/furans, heavy metals (especially mercury and lead), questions regarding critical windows of vulnerability, questions regarding endocrine disruptive activity and the overall inadequacy of the air monitoring data, aggregate exposures and the impact on public health could not be scientifically evaluated. (Note: Estimate on cancer risks considering only chromium (VI) is understated.

Overall Conclusions (page 10): Basis for classification of an "Indeterminate Public Health Hazard" should be revised to reflect all deficiencies that preclude a scientific public health evaluation. Inadequacy of TCEQ air monitoring data for assessing public health precludes such statements as, "We found majority of risks associated with exposure to chemicals analyzed in this health consultation as low." All conclusions and inferences relating to public health based on the TCEQ air monitoring data should be removed.

1. Paragraph 1. It should be reflected that the number of VOCs and metals exceeding background levels could be significantly higher if adequate air monitoring data were available.
2. Paragraph 2. ". . . Under the aggregate exposure scenario, total excess lifetime cancer risk for all cancers combined could be interpreted as posing a public health hazard . . ." **This scenario is understated by inferring that this interpretation is based on the assumption that all chromium detected in the air is chromium (VI). A major omission is the impact of the deadliest of all man-made toxins—dioxins/furans. The statement regarding a possible public health hazard should reflect this omission. This statement should also reflect an assumption was made that all data reviewed adequately reflected a complete picture of toxic exposure (which it does not) and there are no synergistic effects of these aggregate exposures. (Have other pathways for exposure such as dermal or ingestion been factored in?)**
3. Paragraph 3. The adequacy of the EPA NAAQS to capture true public exposure and adequacy for evaluating public health should be scientifically evaluated before proceeding.
4. Paragraph 4. ATSDR should request assistance of a reliable independent scientist for help in evaluating the TCEQ Midlothian air monitoring for adequacy of capturing public impact and for adequacy in evaluating the public health of the community. An assessment for the need for additional and appropriate monitoring could also be recommended.

Recommendations (Page 11):

Please recommend that TCEQ establish a monitoring system that captures a complete picture of toxic emissions from all sources and data adequate for monitoring public health.

Actions Under Way (page 12):

Action to effectuate an adequate monitoring system in Midlothian should be undertaken. DSHS should discuss with TCEQ a methodology for establishing a monitoring system that captures emissions from all major sources and produces data adequate for monitoring public health.

Conclusions (Starting on page 72):

All findings should reflect the inadequacy of TCEQ air monitoring data to capture total emissions and the inadequacy for evaluating public health. All findings based on this inadequate data should be withdrawn.

Aggregate Exposures—Non-Cancer Health Effects (page 73)

The CNS/neurological effects are grossly understated. How were dioxins factored in? How were synergistic effects factored in? Up-wind readings for mercury give you for all intent and purpose zero data on mercury. By the sheer nature of the cement industries and incineration of hazardous waste and tire-derived fuel, you know that the emissions of these toxins are significant. It is not becoming of an agency charged with public health to make such a deficient statement. This statement should be revised to reflect the deficiencies in the data reviewed.

****

Below are corrections to statements made in our original comments submitted on February 3, 2008. It is requested that you substitute statements as amended below. The change is highlighted in bold.

On page 5 in paragraph (3) the reference to the time benzene exceeded the CREG, the sentence should read as follows:

At all three sites (0007, 0015, 0016) the CREG was exceeded **94 percent,** *98 percent, 99 percent (respectively) of the time with spikes up to 118, 512, 319 (respectively) times higher than the CREG.*

On page 11 under response to item 3, the first sentence should read:

Statements like ". . . had one or more level above the most conservative contaminant-specific cancer screening value . . ." although technically true, sound so

trivializing, especially when the data shows that benzene levels exceeded this "most conservative screening value" over **97 percent** of the time.

On page 19 under paragraph in first paragraph (1) response, sentence should read:

However VOC collection on Tayman Drive indicated that **94 percent** *of the benzene emissions exceeded the CREG values and benzene emissions spiked to an acute chronic inhalation RfC of 20.57 ppb in May 1995.*

****

During these last couple of years, there has been much speculation in the community regarding the delay of this report. The initial anticipated completion period of three months was stretched to six months, and then went on indefinitely for over two years on an apparent merry-go-round between TDSHS and ATDSR.

Speculation for the delay ranged from "possible political interference" to "a delay is a form of non-response—a method to keep the community at bay for as long as possible." TDSHS' reason for delay was, "The data was so comprehensive that it would take a very long time to complete the analyses."

It was obvious to the community from the onset that based on the positions of the air monitors, data collected by TCEQ would not be adequate for assessing public health. It was our naïve hope that adequate data based on sound science was being collected. As it turned out, this was not the case. This consultation was based on readily available data that could be pulled into Access and/or Excel databases along with the comparison data and easily manipulated to generate the results provided in this report. Readily available references were used. Prior TDSHS documents should have been easily accessible. Community visits were completed in the first three months. Can you provide some logic to the delay? Or was this delay just an effort to keep the community pacified and at bay?

Final Comment:

We truly appreciate the fact that ATSDR/TDSHS acknowledged that a finding less than an "Indeterminate Public Health Hazard" is not appropriate. However, the basis for this finding omits the most glaring and pertinent deficiencies—the lack of valid data to make an appropriate health assessment of any kind. Premature assessments (based on deficient air monitoring data) of a finding of "no apparent health hazard" for many of the constituents evaluated in this consultation are very disconcerting.

I refuse to be so cynical to imply that ATSDR/TDSHS are not concerned about public health, because there are many professionals working for these agencies who have demonstrated their commitment. However there appears to be a pervasive institutionalized philosophy and culture that does not allow public health issues to surface if they will trump economic and industrial goals. Your agencies, professionals and the communities to which you have a public health obligation deserve better than this.

Addendum #10

NOT "JUST STEAM"
A Review of "Emissions Data from Midlothian Industry"

FOR THE TEXAS SENATE NATURAL RESOURCES COMMITTEE,

SEPTEMBER 9TH, 2008

In the summer of 2008 Amanda Caldwell and Susan Waskey, two University of North Texas Geography graduate students, did something no one had previously done. They added up all the emission reports submitted to State and Federal Government by the three cement plants and adjacent steel mill in Midlothian. Their report, "Midlothian Industrial Plant Emission Data" was the first to try to document the cumulative impact from what is the largest concentration of smokestack industries in North Texas.

Although there has been an operating cement plant in Midlothian since 1960, emission data was only available from the state beginning in 1990, and from the EPA beginning in 1988. The last available data from both sources is currently 2006. Besides providing an idea of the total pollution burden imposed by these facilities for the first time, Caldwell and Waskey also spotlight the differences in reported volumes of air pollution when industry submits emissions reports to the State versus the Federal governments. The two databases reveal some interesting contrasts in tracking 16 years of air pollution emissions that call for closer examination.

Caldwell and Waskey's work definitively puts to rest the oft-repeated unofficial explanation by the companies and their boosters that that plant's emissions are "just steam." In fact, pollution from the smokestacks of these facilities is the largest industrial threat to public health in North Texas, and has been for decades.

1. The Facilities

Texas Industries, Inc. (TXI) cement plant
One dry kiln
Four wet kilns
Fuel: coal, hazardous waste, permitted for tires

Holcim US Inc. cement plant
Two dry kilns
Fuel: coal, tires, oil filter fluff, petroleum coke, used oils

Ash Grove Texas L.P. cement plant
Three wet kilns
Fuel: coal and tires

Gerdau Ameristeel, (formally Chaparral Steel)
Electric Arc Furnace Steel Mill

2. The Emissions Reports

A) USEPA's Toxic Release Inventory (TRI)

Toxic Release Inventory reports are generated by industries as required by the *Emergency Planning and Community Right-to-Know Act* (EPCRA), enacted in 1986. According to the EPA,

> "EPCRA's primary purpose is to inform communities and citizens of chemical hazards in their areas. EPCRA Section 313 requires EPA and the states to annually collect data on releases and transfers of certain toxic chemicals from industrial facilities, and make the data available to the public in the Toxic Release Inventory (TRI) . . . EPA compiles the TRI data each year and makes it available through several data access tools, including the TRI Explorer." (USEPA 2008)

The release data used in this project are self-reported by each facility, and neither the quality of the data, nor the quantities reported should be assumed to be precisely accurate.

Caution should be taken in interpreting trends from the TRl reports as the list of "reportable" chemicals has changed over the years. Since its inception in 1987, the list of toxic chemicals that must be reported has doubled to more than 650, with most of the additions occurring in 1995. Also, numerous changes have been made

to the list, including de-listing some chemicals and modifying reporting thresholds of others.

B) Texas Commission on Environmental Quality's Annual Contaminant Summary Reports

The second half of the data collection effort was focused on the State of Texas' *Contaminant Summary Report*. Again, like the federal data, 2006 is the latest reporting year for which data are available. Reported data earlier than 1990 do not exist from the state, according to a conversation with the Emissions Assessment Section Manager at TCEQ. Data was also not collected in 1991 at the State level, for reasons not readily known to the TCEQ manager.

The *Contaminant Summary Report* contains data detailed in three sections: Criteria Emissions Total, Contaminant Summary Report, and Hazardous Air Pollutants (RAPS) Summary Report. The Criteria Emissions Total section lists data for seven "Pollutant Classes," namely:

$PM_{2.5}$—suspended particulate matter of a size 2.5 microns or less (requirement added in 2000),

PM_{10}—suspended particulate matter of a size 10 microns or less,

VOC—volatile organic compounds,

CO—carbon monoxide,

NO_X—nitrous oxides,

SO_2—sulfur dioxide, and

PB—lead.

These requirements originate from the National Ambient Air Quality Standards (NAAQS), established by the USEPA under the direction of the *Clean Air Act*, and annual reporting is further required under the Texas Clean Air Act.

The Hazardous Air Pollutants (HAPS) Summary reports chemicals for which both the federal and State *Clean Air Act* requires annual reporting. Data from both the Criteria Emissions Total and HAPS Summary Report were included in this report. The third section titled "Contaminant Summary Report" is a catch-all listing of chemicals required by a mix of requirement, sources, including Criteria Emissions, HAPS, permit, and other requirements, according to the TCEQ manager Kevin Cauble. Chemicals unique to this listing are **not** included in this project's analysis.

3. The Volume of Pollution

Between 1990 and 2006, the three cement plants and steel mill reported to State and/or Federal Government that their facilities released approximately one billion pounds—986,509,069—of harmful air pollution into the North Texas skies, including:

10,000 pounds of Mercury

91,000 pounds of lead

Over seven million pounds of " EPA-classified toxic" air pollution

Approximately 35 million pounds of respirable Particulate Matter

Over 134 million pounds of global waning gases

Over 300 million pounds of smog-forming Nitrogen Oxide

Approximately 400 million pounds of acid rain causing Sulfur Dioxide

That's an average of over 61 million pounds of air pollution released every year, 7000 pounds an hour, 117 pounds per minute, two pounds per second over 16 years. And yet, the position of the Texas Committee on Environmental Quality is that Midlothian has some of the cleanest air in the state.

Because it's heavier than the gaseous pollution released by the Midlothian plants, Particulate Matter contaminated with metals and other combustion residues will usually fall out within 10 miles of the source, with the heaviest concentrations in the areas most consistently downwind of the cement plants, or in very close proximity of the plants themselves.

A 10-mile radius around the Midlothian cement plants would include portions of Arlington, Cedar Hill, DeSoto, Grand Prairie, Mansfield, Midlothian, Red Oak, and Venus, and incorporate 314 square miles.

34,903,092 pounds of PM_{10}, or soot, from all four facilities is enough to deposit 111,156 pounds on each square mile in that 10-mile radius over the last 16 years.

Almost all of the Lead and Mercury released by the cement plants is emitted as Particulate Matter pollution. 91,000 pounds of lead is enough to deposit 289 pounds of the poison on each square mile. 10,103 pounds of Mercury is enough for 32 pounds to be deposited on each square mile in that same area.

334,816,276 pounds of Nitrogen Oxide is the equivalent smog-forming pollution from the annual emissions of nine million automobiles.

402,516,432 pounds of Sulfur Dioxide is the equivalent to the SO_X released by 20 coal plants in a year.

4. Toxicity of Selected Pollutants

A) Particulate Matter, or soot, is toxic in its own right, more so when other toxins are hitching a ride on its surface—almost all of the Lead and Mercury released by the cement plants is emitted as Particulate Matter pollution. Soot from engines, or industrial processes like cement manufacturing is much smaller than the sand dust or fire soot which evolution equipped human beings to expel. Because it's smaller it remains deep in the lungs, doing damage.

In the last few years, PM pollution has been linked by scientists to lung damage, asthma, heart attacks, strokes, blood clots, brain cancer, genetic damage, and Parkinson's Disease. Toxicologists specializing in PM pollution believe to be no "safe" level of exposure to PM pollution.

B) Mercury does not decompose or exit the environment once it's been released into the atmosphere. It is deposited back onto the ground, where it persists in soil and water, and bio-accumulates in fish and wildlife.

According to leading scientists, as little as 1/24th of an ounce of Mercury can contaminate a 20-acre lake and all the fish in it. Using this measuring stick, 10,000 pounds of Mercury is enough to contaminate over 133,000,000 20-acre lakes. Joe Pool Lake is within five miles of all the Midlothian cement plants and steel mill, and the closest plant is within two miles of the Lake.

C) Lead and lead compounds can be highly toxic when eaten or inhaled. Although lead is absorbed very slowly into the body, its rate of excretion is even slower. With constant exposure, lead accumulates gradually in the body. It is absorbed by the red blood cells and circulated through the body where it becomes concentrated in soft tissues, especially the liver and kidneys. Lead can cause lesions in the central nervous system and apparently can damage the cells making up the blood-brain barrier that protects the brain from many harmful chemicals. Most of the leading scientists specializing in lead poisoning believe there is no safe level of exposure to lead—that is no level that is not capable of causing some neurological or physiological effect.

D) According to the Agency of Toxic Substances and Disease Registry, long-term exposure to Sulfur Dioxide

> "can affect your health. Lung function changes were seen in some workers exposed to low levels of sulfur dioxide for 20 years or more. However, these workers were also exposed to other chemicals, so their health effects may not have been from sulfur dioxide alone. Asthmatics have also been shown to be sensitive to the respiratory effects of low concentrations of sulfur dioxide.
>
> Animal studies also show respiratory effects from breathing sulfur dioxide. Animals exposed to high concentrations of sulfur dioxide showed decreased respiration, inflammation of the airways, and destruction of areas of the lung.

5. Specific Plants and Pollutants

"Criteria Air Pollutants" as reported to the state of Texas 1990-2006 In Pounds

	TXI	Holcim	Ash Grove	Ameristeel
PM 2.5	2,134,389	5,046,097	3,323,425	2,305,006
PM 10	9,390,498	8,622,812	12,416,103	4,473,678
VOCs	2,054,302	10,871,857	2,054,302	7,712,107
CO	25,794,554	94,523,052	13,891,342	57,371,754
NOx	143,073,757	79,430,708	96,899,096	15,412,715
SOx	154,531,598	109,471,684	135,685,591	2,827,559

Individual Criteria Air Pollutant Totals 1990-2006 In Pounds

PM 10	34,903,091	(PM 2.5 included)
VOCs	22,692,568	
CO	191,580,702	
NOx	334,816,276	
SOx	402,516,432	

TOTAL Criteria Air Pollutants Released 1990-2006 In Pounds
986,509,069

A) TXI

TOTAL AIR POLLUTION 1990–2006: 336,979,556 pounds

TXI is the largest cement plant, and largest industrial facility among the four examined in this analysis, so it's not surprising it would lead in total pollution.

In general, the amount of TRI chemicals released to the environment through the air by TXI spiked in the year 2000, to over 1.2 million pounds.

This coincided with TXFs bringing the fifth cement kiln into operation at their Midlothian plant. Subsequently, TRI releases stabilized at a level lower than one million pounds after 2000, but at a significantly higher rate than in the past (more than 480,000 lb/yr).

In 1999, reporter Steve Brown wrote in *The Dallas Morning News* that TXI had promised that this $200 million expansion to add the 5th kiln to their operation "would not increase pollution," and it would "have advanced pollution controls that would keep the project from harming air quality" (Brown 1999). The data from both the EPA Toxic Release Inventory and the State Hazardous Air Pollutants reports show a different outcome. Air releases from both reports are higher than prior to 2000.

B) Holcim

TOTAL AIR POLLUTION 1990–2006: 307,966,836 pounds

Holcim's TRI releases and state emissions inventory consist mostly of Toluene (404,288 lbs.), Benzene (232,109 lbs.), Sulfuric Acid (172,145 lbs.) and unspeciated/mixed Xylenes (145,982 lbs.). Holcim has also had lesser amounts of on-site landfill releases over the years.

Holcim's State air emissions (HAPS emissions consist mostly of Toluene (508,429 lbs.), Benzene (329,279 lbs.), Xylenes (248,103 lbs.), and Hydrochloric Acid (196,566 lbs.).

C) Ash Grove

TOTAL AIR POLLUTION 1990–2006: 263,141,444 pounds

Ash Grove's toxic air emissions consist mostly of sulfuric acid (872,185 lbs) and hydrochloric acid (171,473 lbs). On-site landfill releases are also of note , consisting

mostly of Magnesium and Magnesium Compounds (1,903,018 lbs.), and smaller amounts of Chromium (34,464 lbs.) and Lead (8224 lbs.).

The State Air Emissions Inventory (HAPS) shows that most prevalent toxic chemical released over the 17-year reporting period was Hydrogen Chloride (334,655 lbs.) Ash Grove's state Criteria Emissions Releases show that Sulfur Dioxide (SO_X) and Nitrous Oxides (NO_X) were the most prevalent components of these emissions. Furthermore, there is a discouraging upward trend in released amounts of Sulfur Dioxide during the recent past.

What remarkable about Ash Grove's numbers are that they're so large for the smallest cement plant. It has more SO_X, NO_X and PM_{10} than Holcim, which is twice its size.

D) Ameristeel

TOTAL AIR POLLUTION 1990–2006: 89,655,098 pounds

Most air releases were Zinc (352,076 lbs), Lead (47,238 lbs) or Manganese (46,904 lbs). Chaparral's releases are primarily "off-site," with zinc releases over the 17-year period approaching 50 million pounds.

The State air emissions inventory (HAPS) consist mostly of Manganese Dioxide (58,609 lbs.) or PM_{10}–Manganese Dioxide (72,583 lbs.), and Lead Oxide (50,337 lbs.) or PM_{10}–Lead Oxide (38,237 lbs.). The Nitrous Oxide (NO_X) component of those emissions seems to beholding steady at one million pounds per year.

6. These are Underestimates

The fact that there is absolutely no emissions data from either EPA or the state for the first 30 years of industrial operations in Midlothian—including the first four years of hazardous waste-burning at two cement plants—means that the large numbers reported here for the first time are inherently vast underestimates of the total pollution burden produced by heavy industry in the town since 1960. This is anything but a comprehensive review.

Even when records begin in 1990, there are large discrepancies in the data reported to both the State and Federal governments. TRI and State emissions data for several of the companies were not reported for many of the years during the project time period:

Chaparral did not report TRI data in 1990.

Holcim did not report TRI data for the years 1990–1999.

Ash Grove did not report TRI data for the years 1990 and 1993–1995.

Holcim did not report Hazardous Air Pollutants data to the state for the years 1990–1999.

It is unlikely that these facilities were not releasing anything worthy of reporting to either the USEPA or State databases during these years. Omissions such as these ensure that, even during the period when records do exist, this analysis only gives a glimpse into the actual pollution burden caused by the four facilities.

7. Contradictions in Data

A cursory examination of EPA air release data in Figure 56 (Total Air Releases per Firm 1990–2006) and TCEQ air release data in Figure 60 (Total Hazardous Air Pollutants per Firm 1990–2006), show strikingly different results. For this reporting period, the EPA data shows TXI to be the firm with the largest amount of toxic chemicals released to the air (5,287,384 lbs.), while the state's data show Holcim to be the largest emitter of hazardous air pollutants (1,507,663 lbs).

According to the plants' TRI reports, there were almost 48,000 pounds of lead air pollution released by all four facilities over the entire 16 years, versus the over 90,000 pounds of lead the same plants reported sending up their stacks to the TCEQ and its predecessors during the same period.

According to the plant's TRI reports, there were approximately 5000 pounds of Mercury air pollution released by all four facilities from 1990 to 2006 versus the approximately 10,000 pounds of Mercury air pollution reported to the state over the same time.

Even within the same reporting system, the method used to calculate or estimate reported quantities for various chemicals may have differed from firm to firm and year to year, making comparisons or trend analysis difficult. Take the case of Volatile Organic Compounds at the cement plants that are literally across the street from each other. When Holcim finally began reporting volumes for TRI in 2000, it immediately cited large numbers for VOCs such as Toluene, Xylene, and Benzene. It has been Holcim's position that these VOCs come from the limestone itself and

testing done over the last three years generally supports this conclusion. On the other hand, neither TXI nor Ash Grove have ever reported the large numbers of these VOCs that Holcim has, despite mining and using the same Midlothian limestone. The result is that even though Holcim did not report ANY emissions for nine of the 16 years covered in this analysis, it is the largest historical VOC polluter in the study, with VOC totals that are at least five times that of the next cement plant. Is Holcim's limestone that much different than the other two plants, or are TXI and Ash Grove under-reporting their emissions?

Some of these calculation differences could be investigated further, as could the apparent reporting gaps (missing data) from some of the firms. Also, the company-to-company differences in what chemical substance get reported in which section of the annual report to the state could be evaluated. Those chemicals from the state's *Contaminant Summary Report* block that are not included in the HAPS or Criteria Emissions blocks of data could also be scrutinized for inclusion in this dataset.

Addendum #11

BIRTH DEFECT INVESTIGATION REPORT
Birth Defects Among Deliveries to Residents of Midlothian, Venus, & Cedar Hill, Texas, 1997–2001

PREPARED JUNE 29, 2005 BY MARY ETHEN, EPIDEMIOLOGIST
BIRTH DEFECTS EPIDEMIOLOGY AND SURVEILLANCE BRANCH
TEXAS DEPARTMENT OF STATE HEALTH SERVICES

BACKGROUND

A community member expressed concern over birth defects in Midlothian (Ellis County), Venus (Johnson County), and Cedar Hill (Ellis and Dallas Counties), Texas. The community member also expressed concern about pollution from cement kilns in or near these three communities and a steel mill in or near Venus, Texas.

METHODS

Case Definition

The areas of interest are south of Dallas and Fort Worth. The Texas Birth Defects Registry began collecting information in this part of the state with deliveries in January 1997, and the most recent delivery year for which the registry has completed data collection is 2001.

Based on this information, a case was defined as an infant or fetus . . .

- with any of 48 specific birth defects, or with any birth defect monitored by the registry;
- born between January 1997 and December 2001;
- born to a mother who resided in Midlothian, Venus, or Cedar Hill at the time of delivery.

Each community was examined separately from the other two communities.

Case Finding

The Texas Birth Defects Registry was searched to find cases meeting the case definition. The mother's place of residence at the time of delivery was based on information reported on the child's birth or fetal death certificate, when available. If a birth or fetal death certificate could not be found, the mother's place of residence at the time of delivery was based on information in the Texas Birth Defects Registry that had been abstracted from hospital medical records.

Occurrence Evaluation

Unadjusted Prevalence: Cases in the registry were used to calculate prevalence rates per 10,000 live births for 48 specific birth defects and for infants and fetuses with any birth defect monitored by the registry. Calculations were done for the three communities separately. The 95 percent confidence interval for each prevalence was calculated based on the Poisson distribution. In order to determine if there was a statistically significant elevation in the occurrence of birth defects, the prevalence rates for the areas and time period of interest were compared to the prevalence rates for all of Texas during January 1999 through December 2001. Prevalence rates were considered statistically significantly different if their 95 percent confidence intervals did not overlap.

Adjusted Prevalence: The occurrence of many types of birth defects is known to vary between mothers of different age groups, mothers of different racial/ethnic groups, and between male and female infants. For each type of birth defect that was statistically significantly elevated based on the unadjusted prevalence, we calculated prevalence rates adjusted separately for age, race/ethnicity, and sex. Adjustment accounts for any differences in the age, racial/ethnic, or sex composition of populations being compared, in this case, differences between the communities of interest during 1997–2001 and all of Texas during 1999–2001.

Using the direct method of standardization, maternal age-specific rates for the area of interest were standardized (adjusted) to the maternal age distribution of all Texas resident live births during 1999–2001. The resulting adjusted rate is the hypothetical rate that would have been observed in the area of interest if that area

had the same maternal age distribution as Texas overall in 1999–2001. Similarly, maternal racial/ethnic-specific rates for the area of interest were standardized to the maternal race/ethnic distribution of Texas resident live births during 1999–2001, yielding the hypothetical rate that would have been observed if the area of interest had the same maternal race/ethnic distribution as Texas. Finally, adjustment for infant sex was accomplished in the same manner.

The DIRST module of Computer Programs for Epidemiologists,[1] version 4.0, was used to calculate directly standardized rates and their associated 95 percent confidence intervals.

Age-, Race-, and Sex-specific Prevalence: For the types of birth defects that were statistically significantly elevated based on the unadjusted prevalence and that remained statistically significant after adjustment, we have shown prevalence by maternal age group, maternal racial/ethnic group, and infant sex, plus 95 percent confidence intervals based on the Poisson distribution.

Estimated Date of Conception: The estimated date of conception was calculated and graphed for cases having the types of birth defects that remained statistically significantly elevated after adjustment. If the last menstrual period (LMP) date was available, the estimated date of conception was calculated as the LMP date plus 14 days. If LMP date was not available, the estimated date of conception was calculated as the expected date of delivery minus 266 days.

Spot Map: For the types of birth defects that remained statistically significant after adjustment, a spot map was made using the mother's residence address at the time of delivery, as reported on the child's birth or fetal death certificate. The map is not included in this report to protect the privacy of the families.

RESULTS

Unadjusted Prevalence: We examined the occurrence of 48 types of birth defects and any birth defect monitored by the registry among deliveries during January 1997 through December 2001 to residents of Midlothian, Venus, and Cedar Hill separately.

For Venus and for Cedar Hill during 1997–2001, none of the birth defects examined was statistically significantly higher than the statewide prevalence in 1999–2001. The prevalence of any monitored birth defect also was not statistically significantly elevated in Venus or Cedar Hill, compared to the entire state.

For Midlothian during 1997–2001, two categories of birth defects were statistically significantly higher than the statewide prevalence in 1999–2001.

The unadjusted prevalence of hypospadias or epispadias among Midlothian resident deliveries during 1997–2001 was 102.39 cases per 10,000 live births (95 percent confidence interval 52.91–178.85) (Table 1), which was 3.5 times the prevalence for Texas in 1999–2001 (28.87 cases per 10,000 live births, 95 percent CI 27.86–29.88) and statistically significant.

The unadjusted prevalence of any monitored birth defect among Midlothian resident deliveries during 1997–2001 was 511.95 cases per 10,000 live births (95 percent CI 390.61–658.96) (Table 2). This was 1.5 times the prevalence for Texas in 1999–2001 (350.12 cases per 10,000 live births, 95 percent CI 346.59–353.65) and statistically significant.

Adjusted Prevalence: Adjusted prevalences were calculated for hypospadias or epispadias and for any monitored birth defect among Midlothian resident deliveries during 1997–2001.

For hypospadias or epispadias (Table 1), adjusting for infant sex had no impact on the prevalence, yielding a sex-adjusted prevalence of 102.75 cases per 10,000 live births, which was essentially unchanged from the unadjusted prevalence of 102.39 cases per 10,000 live births. Adjusting for maternal age group caused the prevalence of hypospadias or epispadias to increase very slightly, from 102.39 unadjusted to 106.02 after adjustment. Adjusting for maternal race/ethnicity caused the prevalence of hypospadias/epispadias to increase from 102.39 unadjusted to 119.86 after adjustment.

This means that the elevation observed in Midlothian during 1997–2001 for hypospadias or epispadias cannot be attributed to differences between Midlothian and Texas overall in the proportion of boys and girls being born, or in the race/ethnic or age distribution of women having children. The prevalence of hypospadias or

[1] Abramson JH, Gahlinger PM. *Computer Programs for Epidemiologists: PEPI, version 4.0. !Salt Lake City, Utah: Sagebrush Press, 2001.*

epispadias remained statistically significantly elevated in Midlothian after adjustment for sex, maternal age, and maternal race/ethnicity.

Table 1. Unadjusted and adjusted prevalence of hypospadias or epispadias among Midlothian resident deliveries, 1997-2001, compared to Texas, 1999-2001.

Mother's residence at delivery	Time Period	Adjusted* for	Prevalence per 10,000 live births	95% Confidence Interval for Prevalence
Midlothian	1997-2001	Unadjusted	102.39	52.90 - 178.84
		Infant sex	102.75	45.20 - 160.29
		Maternal age group	106.02	45.38 - 166.66
		Maternal race/ethnicity	119.86	27.86 - 211.86
Texas	1999-2001	Unadjusted	28.87	27.86 - 29.88

* Adjusted to the distribution of Texas resident live births during 1999-2001.

For any monitored birth defect (Table 2), adjusting for sex had no impact on the prevalence. The sex-adjusted prevalence, 512.58 cases per 10,000 live births, was nearly the same as the unadjusted prevalence, 511.95. Likewise, adjusting for maternal age group had no impact on the prevalence of any monitored defect (511.95 unadjusted compared to 513.71 after adjustment).

Adjusting for maternal race/ethnicity caused the prevalence of any monitored birth defect to decrease from 511.95 per 10,000 unadjusted to 402.69 adjusted (95 percent CI 256.37–549.01) (Table 2). Further, the adjusted prevalence was no longer statistically significantly elevated compared to Texas in 1999–2001 (350.12; 95 percent CI 346.59–353.65).

This means that the elevation observed in Midlothian during 1997–2001 for any monitored birth defect can be explained by differences between Midlothian and Texas overall in the race/ethnic distribution of women having children. In Midlothian, 83.2 percent of mothers who gave birth in 1997–2001 were non-Hispanic White women, while in Texas during 1999-2001, only 39.2 percent of births were to non-Hispanic White mothers. Further, in Texas overall during 1999–2001, the prevalence of any monitored birth defect was statistically significantly higher among non-Hispanic White mothers (374.16 per 10,000 live births; 95 percent CI 368.33–380.00) than among African American mothers (339.69; 95 percent CI 329.34–350.04) or Hispanic mothers (340.34; 95 percent CI 335.21–345.48). Because most Midlothian mothers are non-Hispanic White women, and because the prevalence of any monitored birth defect is higher among mothers of this race/ethnic group, the unadjusted prevalence of any monitored birth defect in Midlothian was higher than the Texas prevalence, and it decreased after adjustment for race/ethnicity.

Table 2. Unadjusted and adjusted prevalence of any monitored birth defect among Midlothian resident deliveries, 1997-2001, compared to Texas, 1999-2001.

Mother's residence at delivery	Time Period	Adjusted* for	Prevalence per 10,000 live births	95% Confidence Interval for Prevalence
Midlothian	1997-2001	Unadjusted	511.95	390.61 - 658.96
		Infant sex	512.58	386.66 - 638.50
		Maternal age group	513.71	385.32 - 642.11
		Maternal race/ethnicity	402.69	256.37 - 549.01
Texas	1999-2001	Unadjusted	350.12	346.59 - 353.65

* Adjusted to the distribution of Texas resident live births during 1999-2001.

Age-, Race-, and Sex-specific Prevalence: Since hypospadias or epispadias was the only type of birth defect that was statistically significantly elevated after adjustment, we took a closer look at it. Table 3 shows the prevalence of hypospadias or epispadias by maternal age group, maternal race/ethnicity, and infant sex among Midlothian resident deliveries during 1997–2001. Data for Texas in 1999–2001 are also presented for comparison.

The mothers of Midlothian children with hypospadias or epispadias ranged in age from 17 to 37. The prevalence of hypospadias or epispadias among mothers less than 20 years old was statistically significantly higher in Midlothian than in Texas. For all other maternal age groups, the Midlothian prevalences did not attain statistical significance.

Midlothian mothers of 'Other' race/ethnicity were significantly more likely to have a child with hypospadias or epispadias than mothers of 'Other' race/ethnicity statewide. This was the only racial/ethnic group that was statistically significantly higher than the state.

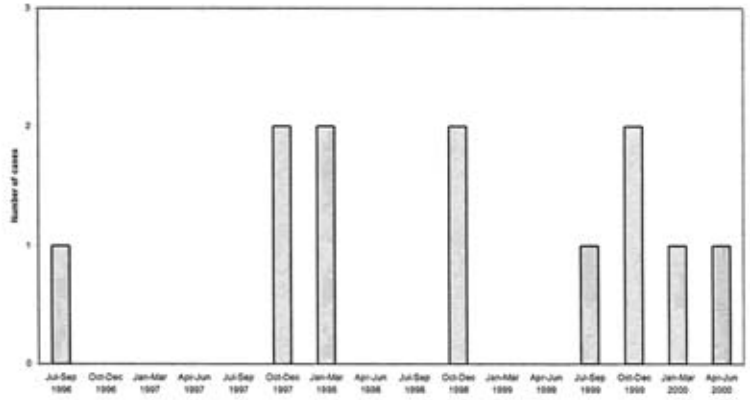
The prevalence of hypospadias or epispadias among male infants was also statistically significantly higher in Midlothian than Texas.

Table 3. Prevalence of hypospadias or epispadias by maternal age group, maternal race/ethnicity, and infant sex, Midlothian 1997-2001 and Texas 1999-2001.

Area and Time Period	Characteristic		Cases	Live Births	Prevalence per 10,000 live births	95% Confidence Interval for Prevalence
Midlothian, 1997-2001	Total		12	1172	102.39	52.90 - 178.84
	Maternal age group	<20	3	141	212.77	43.97 - 621.99
		20-24	3	278	107.91	22.30 - 315.47
		25-29	4	393	101.78	27.74 - 260.56
		30-34	0	234	0.00	0.00 - 157.69
		35-39	2	109	183.49	22.02 - 662.39
		40+	0	17	0.00	0.00 - 2170.59
	Maternal race/ ethnicity	non-Hispanic White	9	975	92.31	42.26 - 175.18
		African American	0	11	0.00	0.00 - 3354.55
		Hispanic	1	174	57.47	1.72 - 320.11
		Other	2	12	1666.67	200.00 - 6016.67
	Infant sex	Male	12	597	201.01	103.85 - 351.09
		Female	0	575	0.00	0.00 - 64.17
Texas, 1999-2001	Total		3111	1077574	28.87	27.86 - 29.88
	Maternal age group	<20	435	164724	26.41	23.93 - 28.89
		20-24	771	304357	25.33	23.54 - 27.12
		25-29	825	288532	28.59	26.64 - 30.54
		30-34	679	208993	32.49	30.05 - 34.93
		35-39	334	92476	36.12	32.24 - 39.99
		40+	67	18368	36.48	28.27 - 46.32
	Maternal race/ ethnicity	non-Hispanic White	1730	422278	40.97	39.04 - 42.90
		African American	422	121787	34.65	31.34 - 37.96
		Hispanic	883	495559	17.82	16.64 - 18.99
		Other	69	36946	18.68	14.53 - 23.64
	Infant sex	Male	3098	550818	56.24	54.26 - 58.22
		Female	1	526756	0.02	0.00 - 0.11

Estimated Dates of Conception: The 12 Midlothian children born during 1997–2001 with hypospadias or epispadias were estimated to have been conceived from September 1996 through April 2000. No more than one case was conceived in any given month during this time period, nor was there any other evidence of clustering in time (Figure 1).

Figure 1. Estimated dates of conception for Midlothian children born during 1997-2001 with hypospadias or epispadias.



Spot map: The spot map of maternal residence address at time of delivery for the 12 Midlothian children born during 1997–2001 with hypospadias or epispadias did not show any strong evidence of geographic clustering within Midlothian. Seven of the residences were distributed within the current Midlothian city limits and five were outside the city limits. The map is not included in this report to protect the privacy of the families.

DISCUSSION

Using data in the Texas Birth Defects Registry, we examined the occurrence of 48 specific birth defects and any defect monitored by the registry among deliveries during 1997–2001 to residents of Midlothian, Venus, and Cedar Hill, Texas. None of the birth defects examined were statistically significantly elevated in Venus or Cedar Hill. Any monitored birth defect and hypospadias or epispadias were elevated in Midlothian during 1997–2001.

The prevalence of any monitored defect in Midlothian decreased and was no longer statistically significantly elevated after adjusting for maternal race/ethnicity. This indicates that the elevation observed in Midlothian for any monitored birth defect can be attributed to differences between Midlothian and Texas in the race/ethnic distribution of women having children. If Midlothian had the same maternal race/ethnic distribution as Texas, the prevalence of any monitored birth defect in Midlothian would have been within the range of what is expected.

Hypospadias or epispadias remained statistically significantly elevated in Midlothian after adjustment for sex, race/ethnicity, and age, meaning that this elevation cannot be explained by differences between Midlothian and the state in the proportion of boys and girls being born, or in the race/ethnic or age distribution of women having children.

Hypospadias is a congenital defect in which the urinary meatus (urinary outlet) is on the underside of the penis or on the perineum (the area between the genitals and the anus). In epispadias, the urinary meatus opens above (dorsal to) the normal position. The corresponding defects in females are very rare.

All of the 12 Midlothian children had hypospadias, rather than epispadias.

A spot map did not indicate geographic clustering within Midlothian of the residences of the mothers of children with hypospadias, and a graph of estimated conception dates did not indicate clustering in time of conception.

We made 147 comparisons of community level birth defects data to statewide data (48 birth defects plus any monitored defect, times three communities). At the 95 percent level of significance, we would expect five percent of the 147 comparisons, or seven comparisons, to have been statistically significant due to chance. We found two that were statistically significant, and one that remained significant after adjustment for sex, maternal race/ethnicity, and maternal age.

Although hypospadias/epispadias was elevated in Midlothian, it does not meet criteria to continue this investigation and thus further study at this time is unlikely to yield useful results. To continue, our protocol requires at least three cases with a documented biologically plausible exposure that the cases have in common, or at least five cases with an observed rate of more than 10 times the expected rate. However, because of the elevation, the Texas Birth Defects Registry will continue to monitor hypospadias. As more years of data become available in the future, we will re-examine the prevalence of hypospadias in the area.

CONCLUSIONS

Hypospadias or epispadias was elevated among Midlothian resident deliveries during 1997–2001. We will re-examine the occurrence of hypospadias or epispadias after subsequent delivery years are completed in the Texas Birth Defects Registry.

For more information, contact Mary Ethen at the Birth Defects Epidemiology and Surveillance Branch at 512–458–7111, ext. 2052, or e-mail *mary.ethen@dshs.state.tx.us, or visit our web site at http://www.dshs.state.tx.us/birthdefects/*

Addendum #12

Summary of Investigation into the Occurrence of Cancer Zip Codes 76065, 75104, and 76084, Midlothian, Cedar Hill, and Venus Ellis, Dallas, and Johnson County, Texas 1993–2002

MAY 19, 2005

Background:

Concern about a possible excess of cancer prompted the Texas Cancer Registry (TCR) Branch of the Texas Department of State Health Services (DSHS) to examine the occurrence of cancer in zip codes 76065, 75104, 76084, Midlothian, Cedar Hill, and Venus, Texas. Local residents were concerned that benzene, 1, 3 butadiene, and radiation from the nearby cement plants may be causing cancer among residents. Laryngeal cancer has been associated with workers exposed to cement dust. Benzene has shown an association with acute myeloid leukemia and non-Hodgkin's lymphoma in the scientific literature, while radiation has been weakly linked with several leukemia subtypes, non-Hodgkin's lymphoma, and brain cancer. Exposure to 1, 3 butadiene has been associated with leukemia. The TCR evaluated 1995–2002 incidence data and 1993–2002 mortality data for cancers of the female breast, prostate, lung and bronchus, colon and rectum, male bladder, corpus and uterus, non-Hodgkin's lymphoma, brain/CNS, larynx, selected leukemia subtypes, and total childhood cancers. Incidence data are the best indicator of the occurrence of cancer in an area because they show how many cancers were diagnosed each year. Cancer mortality data are used as a supplemental measure and are complete for the entire state through 2002. The rest of this report examines the investigative methods the TCR used, the results of the investigation, recommendations, and general information on cancer risk factors.

Methodology:

According to the National Cancer Institute, a cancer cluster is a greater than expected number of cancers among people who live or work in the same area and who develop or die from the same cancer within a short time of each other. The cancer cluster investigation is the primary tool used by the TCR to investigate the possibility of excess cancer in a community. The cancer cluster investigation cannot determine that cancer was associated with or caused by environmental or other risk factors. Instead, the cancer cluster investigation is specifically intended to address the question "Is there an excess of cancer in the area or population of concern?"

The TCR follows guidelines recommended by the Centers for Disease Control and Prevention for investigating cancer clusters[1] and often works with the DSHS Environmental and Injury Epidemiology and Toxicology Branch, as well as other state and federal agencies. In order to determine if an excess of cancer is occurring and if further study is recommended, biologic and epidemiologic evidence are considered. Such evidence may include documented exposures; the toxicity of the exposures; plausible routes by which exposures can reach people (ingesting, touching, breathing); the actual amount of exposure to the people which can lead to absorption in the body; the time from exposure to development of cancer; the statistical significance of the findings; the magnitude of the effect observed; risk factors; and the consistency of the findings over time. The occurrence of rare cancers or unlikely cancers in certain age groups may also indicate a cluster needing further study. Because excesses of cancer may occur by chance alone, the role of chance is considered in the statistical analysis.

If further study is indicated, the TCR will determine the feasibility of conducting further epidemiologic study. If the epidemiologic study is feasible, the final step is to recommend and/or perform an etiologic investigation to see if the cancer(s) can be related to an exposure. Very few cancer cluster investigations in the United States proceed to this stage.

To determine whether a statistically significant excess of cancer existed in the geographic areas of concern, the number of observed cases and deaths was compared

[1] *Guidelines for Investigating Clusters of Health Events,* Centers for Disease Control and Prevention, MMWR 1990; 39 (RR–11): 1–16.

to what would be "expected" based on the state cancer rates. Calculating the expected number(s) of cancer cases takes into consideration the race, sex, and ages of people who are diagnosed or die from cancer. This is important because peoples' race, sex, and age all impact cancer rates. If we are trying to determine if there is more or less cancer in a community compared to the rest of the state, we must make sure that the difference in cancer rates is not simply due to one of these factors.

The attached Tables 1–6 present the number of observed cases and deaths for males and females, the number of "expected" cases and deaths, the standardized incidence ratio (SIR) or standardized mortality ratio (SMR), and the corresponding 99 percent confidence interval. The standardized incidence or mortality ratio (SIR, SMR) is simply the number of observed cases or deaths compared to the number of "expected" cases or deaths. When the SIR or SMR of a selected cancer is equal to 1.00, then the number of observed cases or deaths is equal to the expected number of cases or deaths, based on the incidence or mortality in the rest of the state. When the SIR or SMR is less than 1.00, fewer people developed or died of cancer than we would have expected. Conversely, an SIR or SMR greater than 1.00 indicates that more people developed or died of cancer than we would have expected. To determine if an SIR or SMR greater than 1.00 or less than 1.00 is statistically significant or outside the variation likely to be due to chance, confidence intervals are also calculated.

A 99 percent confidence interval is used for statistical significance and takes the likelihood that the result occurred by chance into account. It also indicates the range in which we would expect the SIR or SMR to fall 99 percent of the time. If the confidence interval contains a range that includes 1.00, no statistically significant excess of cancer is indicated. The confidence intervals are particularly important when trying to interpret small numbers of cases. If only one or two cases are expected for a particular cancer, then the report of three or four observed cases will result in a very large SIR or SMR. As long as the 99 percent confidence interval contains 1.00, this indicates that the SIR or SMR is still within the range one might expect and, therefore, not statistically significant.

Results:

The analysis of incidence data for zip codes 76065, 75104, and 76084, Midlothian, Cedar Hill, and Venus, Texas, from January 1, 1995–December 31, 2002, and mortality data from January 1, 1993–December 31, 2002, found cancers of the breast, lung and bronchus, corpus and uterus, brain/CNS, bladder, colorectal, non-Hodgkin's lymphoma, selected leukemia subtypes, and total childhood cancers (0–19) to be within normal ranges in both males and females. Prostate cancer mortality was statistically significantly lower than expected in zip code 76065 males while prostate cancer incidence was statistically significantly lower than expected in zip code 76084 males. Analysis summaries are presented in Tables 1–6.

Discussion:

Like other studies, this cancer cluster investigation had limitations. The number of years of incidence data examined was limited to eight years and did not include data for the most recent years. Ten years of mortality data were examined as a supplemental measure. Also, cancer incidence data are based on residence at the time of diagnosis and mortality data the residence at the time of death. It is possible that some residents who may have been exposed and developed cancer no longer lived in the area at the time of diagnosis or death, so were not included in the analyses. However, it is also possible that people may have moved into the area and then developed or died from cancer because of an exposure from a prior residential location or other factors. These cases and deaths are included in the investigation.

Recommendations:

Based on the findings and the information discussed above, it is not recommended at this time to further examine the cancers in zip codes 76065, 75104, 76084, Midlothian, Cedar Hill, and Venus, Texas. As new data or additional information become available, consideration will be given to updating or re-evaluating this investigation.

Information on Cancer and Cancer Risk Factors:

Overall, the occurrence of cancer is common, with approximately two out of every five persons alive today predicted to develop some type of cancer in their lifetime.[2] In Texas, as in the United States, cancer is the second leading cause of death, exceeded only by heart disease. Also, cancer is not one disease, but many different diseases. Different types of cancer are generally thought to have different causes. If a person develops cancer, it is probably not due to one factor but to a combination of factors such as heredity; diet, tobacco use, and other lifestyle factors; infectious agents; chemical exposures; and radiation exposures. Although cancer may impact individuals of all ages, it primarily is a disease of older persons with over one-half of cancer cases and two-thirds of cancer deaths occurring in persons 65 and older. Finally, it takes time for cancer to develop, more than 10 years can go by between the exposure to a carcinogen and a diagnosis of cancer.[3]

The chances of a person developing cancer as a result of exposure to an environmental contaminant are slight. Most experts agree that exposure to pollution, occupational, and industrial hazards account for fewer than 10 percent of cancer cases.[4] According to Richard Doll and Richard Peto, renowned epidemiologists at the University of Oxford, pollution and occupational exposures are estimated to collectively cause four to six percent of all cancer deaths.[5] The Harvard Center for Cancer Prevention estimates five percent of cancer deaths are due to occupational factors, two percent to environmental pollution and two percent to ionizing/ultraviolet radiation.[6] Additionally much of the evidence that pollutants and pesticide residues increase cancer risk is presently considered quite weak and inconsistent. In contrast, the National Cancer Institute estimates that lifestyle factors such as tobacco use and diet cause 50 to 75 percent of cancer deaths.[7] Eating a healthy diet and refraining from tobacco are the best ways to prevent many kinds of cancer. One-third of all cancer deaths in this country could be prevented by eliminating the use of tobacco products. Additionally, about 25 to 30 percent of the cases of several major cancers are associated with obesity and physical inactivity.[8]

Known Risk Factors for Cancers Examined in This Investigation:

The following is a brief discussion summarized from the American Cancer Society and the National Cancer Institute about cancer risk factors for the specific cancers studied in this investigation.[9,10]

The occurrence of cancer may vary by race/ethnicity, gender, type of cancer, geographic location, population group, and a variety of other factors. Scientific studies have identified a number of factors for various cancers that may increase an individual's risk of developing a specific type of cancer. These factors are known as risk factors. Some risk factors we can do nothing about, but many are a matter of choice.

Prostate Cancer

Prostate cancer is the most common type of malignant cancer (other than skin) diagnosed in men, affecting an estimated one in five American men. Risk factors for prostate cancer include aging, a high fat diet, physical inactivity, and a family history of prostate cancer. African American men are at higher risk of acquiring prostate cancer and dying from it. Prostate cancer is most common in North America and northwestern Europe. It is less common in Asia, Africa, Central America, and South America.

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[2] American Cancer Society website: *http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_Who_gets_cancer.asp?sitearea=*. Accessed 04/15/05.

[3] National Cancer Institute website: *http://cis.nci.nih.gov/fact/3—58.htm*. Accessed 04/15/05.

[4] Cancer: What Causes It, What Doesn't. American Cancer Society website: *http://www.cancer.org/docroot/PUB/content/PUB_1_1_Cancer_What_Causes_It_What_Doesnt.asp*

[5] Doll R, Peto R. *The Causes of Cancer*. Oxford: Oxford University Press, 1990.

[6] Harvard Reports on Cancer Prevention. Harvard Center for Cancer Prevention. Volume 1: Human Causes of Cancer. Harvard School of Public Health website: *http://www.hsph.harvard.edu/cancer/publications/reports/vo11_summary.html*

[7] 2001 Cancer Progress Report. National Cancer Institute website: *http://progressreport.cancer.gov/doc*

[8] Cancer and the Environment. National Cancer Institute website: *http://www.cancer.gov/images/Documents/5d17e03e-b39f-4b40-a214-e9e9099c4220/Cancer%20and%20the%20Environment.pdf*

[9] American Cancer Society website. *http://www.cancer.org*. Accessed 03/31/2005.

[10] National Cancer Institute website: *http://www.nci.nih.gov/*. Accessed 03/31/2005.

Breast Cancer

Simply being a woman is the main risk factor for developing breast cancer. Breast cancer can affect men, but this disease is about 100 times more common among women than men. White women are slightly more likely to develop breast cancer than are African-American women, but African Americans are more likely to die of this cancer because they are often diagnosed at an advanced stage when breast cancer is harder to treat and cure. Other risk factors for breast cancer include aging, presence of genetic markers such as the BRCA1 and BRCA2 genes, personal and family history of breast cancer, previous breast biopsies, previous breast irradiation, diethylstilbestrol therapy, oral contraceptive use, not having children, hormone replacement therapy, alcohol, and obesity. Currently, research does not show a link between breast cancer risk and environmental pollutants such as the pesticide DDE (chemically related to DDT) and PCBs (polychlorinated biphenyls).

Lung and Bronchus Cancer

The greatest single risk factor for lung cancer is smoking. The American Caner Society estimates that 87 percent of lung cancer is due to smoking. Several studies have shown that the lung cells of women have a genetic predisposition to develop cancer when they are exposed to tobacco smoke. Other risk factors include secondhand smoke, asbestos exposure, radon exposure, carcinogenic agents in the workplace such as arsenic or vinyl chloride, marijuana smoking, recurring inflammation of the lungs, exposure to industrial grade talc, people with silicosis and berylliosis, personal and family history of lung cancer, diet, and air pollution.

Brain/CNS Cancer

The large majority of brain cancers are not associated with any risk factors. Most brain cancers simply happen for no apparent reason. A few risk factors associated with brain cancer are known and include radiation treatment, occupational exposure to vinyl chloride, immune system disorders, and family history of brain and spinal cord cancers. Possible risk factors include exposure to aspartame (a sugar substitute) and exposure to electromagnetic fields from cellular telephones or high-tension wires.

Bladder Cancer

The greatest risk factor for bladder cancer is smoking. Smokers are more than twice as likely to get bladder cancer as nonsmokers. Whites are two times more likely to develop bladder cancer than are African Americans. Other risk factors for bladder cancer include occupational exposure to aromatic amines such as benzidine and beta-napthylamine, aging, chronic bladder inflammation, personal history of urothelial carcinomas, birth defects involving the bladder and umbilicus, high doses of certain chemotherapy drugs, and use of the herb Aristocholia Fangchi.

Colon and Rectum Cancer

Colorectal cancer is the second leading cause of cancer death in both men and women. Researchers have identified several risk factors that increase a person's chance of developing colorectal cancer: family and personal history of colorectal cancer, hereditary conditions such as familial adenomatous polyposis, personal history of intestinal polyps and chronic inflammatory bowel disease, aging, a diet mostly from animal sources, physical inactivity, obesity, smoking, and heavy use of alcohol. People with diabetes have a 30 percent–40 percent increased chance of developing colon cancer. Recent research has found a genetic mutation leading to colorectal cancer in Jews of Eastern European descent (Ashkenazi Jews).

Laryngeal Cancer

Risk factors for laryngeal and hypopharynx cancer include tobacco use, alcohol abuse, poor nutrition, infection with human papillomavirus, a weakened immune system, and occupational exposure. Men who are aging and African Americans are more likely to be diagnosed with this cancer.

Acute Lymphocytic Leukemia

Possible risk factors for ALL include the following: being male, being white, being older than 70 years of age, past treatment with chemotherapy or radiation therapy, exposure to atomic bomb radiation, or having a certain genetic disorder such as Down syndrome.

Chronic Lymphocytic Leukemia

Possible risk factors for CLL include the following: being middle-aged or older, male, or white; a family history of CLL or cancer of the lymph system; having relatives who are Russian Jews or Eastern European Jews; or having exposure to herbicides or insecticides including Agent Orange, an herbicide used during the Vietnam War.

Acute Myeloid Leukemia

Possible risk factors for AML include the following: being male; smoking, especially after age 60; having had treatment with chemotherapy or radiation therapy in the past; having treatment for childhood ALL in the past; being exposed to atomic bomb radiation or the chemical benzene; or having a history of a blood disorder such as myelodysplastic syndrome.

Chronic Myeloid Leukemia

Most people with CML have a gene mutation (change) called the Philadelphia chromosome. The Philadelphia chromosome is not passed from parent to child.

Non-Hodgkin's Lymphoma

Risk factors for non-Hodgkin's lymphoma include infection with Helicobacter pylori, human immunodeficiency virus (HIV), human T-cell leukemia/lymphoma virus (HTVL–1), or the Epstein-Barr virus and malaria. Other possible risk factors include certain genetic diseases, radiation exposure, immuno-suppressant drugs after organ transplantation, benzene exposure, the drug Dilantin, exposure to certain pesticides, a diet high in meats or fat, or certain chemotherapy drugs.

For additional information about cancer, visit the "Resources" link on our web site at *http://www.dshs.state.tx.us/tcr/*.

Questions or comments regarding this investigation may be directed to Ms. Brenda Mokry, Texas Cancer Registry, at 1–800–252–8059 or *brenda.mokry@dshs.state.tx.us*

Table 1

Number of Observed and Expected Cancer Cases and Race Adjusted Standardized Incidence Ratios, Selected Cancers, Zip Code 76065, Midlothian, TX, 1995–2002

Males				
Site	**Observed**	**Expected**	**SIR**	**99% CI**
Prostate	53	62.22	0.85	0.58– 1.20
Larynx	6	4.00	1.50	0.38 – 3.92
Lung and Bronchus	52	41.18	1.26	0.86 – 1.79
Colorectal	24	24.58	0.98	0.54 – 1.62
Bladder	11	12.71	0.87	0.34 – 1.79
Non-Hodgkin's Lymphoma	14	10.19	1.37	0.61 – 2.63
Brain/CNS	5	4.61	1.09	0.23 – 3.07
Acute Lymphocytic Leukemia	0	1.20	0.00	0.00 – 4.41
Chronic Lymphocytic Leukemia	0	2.01	0.00	0.00 – 2.63
Acute Myeloid Leukemia	4	1.97	2.03	0.34 – 6.39
Chronic Myeloid Leukemia	2	0.95	2.09	0.11 – 9.71
Aleukemic, Subleukemic, & NOS	0	0.38	0.00	0.00 – 13.99
Total Childhood Cancers (0-19)	3	4.44	0.68	0.08 – 2.47
Females				
Site	**Observed**	**Expected**	**SIR**	**99% CI**
Breast	57	71.58	0.80	0.55 – 1.11
Lung and Bronchus	25	27.20	0.92	0.51 – 1.51
Colorectal	18	20.33	0.89	0.44 – 1.58
Larynx	0	0.91	0.00	0.00 – 5.83
Non-Hodgkin's Lymphoma	10	7.82	1.28	0.48 – 2.74
Brain/CNS	1	3.59	0.28	0.00 – 2.07
Corpus and Uterus	5	10.62	0.47	0.10 – 1.33
Acute Lymphocytic Leukemia	0	0.82	0.00	0.00 – 6.49
Chronic Lymphocytic Leukemia	0	1.26	0.00	0.00 – 4.21
Acute Myeloid Leukemia	1	1.50	0.67	0.00 – 4.96
Chronic Myeloid Leukemia	1	0.63	1.59	0.01 – 11.82
Aleukemic, Subleukemic, & NOS	0	0.32	0.00	0.00 – 16.59
Total Childhood Cancers (0-19)	3	3.57	0.84	0.09 – 3.08

Note: The SIR (standardized incidence ratio) is defined as the number of observed cases divided by the number of expected cases. The latter is based on race-, sex-, and age-specific cancer incidence rates for Texas during the period 1995–2002. The SIR has been rounded to the second decimal place.

*Significantly higher than expected at the $p < 0.01$ level.
**Significantly lower than expected at the $p < 0.01$ level.

Investigation #05026

Table 2

Number of Observed and Expected Cancer Deaths and Race Adjusted Standardized Mortality Ratios, Selected Cancers, Zip Code 76065, Midlothian, TX, 1993–2002

Males				
Site	**Observed**	**Expected**	**SMR**	**99% CI**
Prostate	2	9.86	0.20**	0.01 – 0.94
Larynx	1	1.33	0.75	0.00 – 5.57
Lung and Bronchus	50	41.95	1.19	0.80 – 1.70
Colorectal	9	11.15	0.81	0.28 – 1.79
Bladder	2	2.62	0.76	0.04 – 3.53
Non-Hodgkin's Lymphoma	11	5.11	2.15	0.84– 4.45
Brain/CNS	7	4.14	1.69	0.49 – 4.14
Acute Lymphocytic Leukemia	0	0.47	0.00	0.00 – 11.24
Chronic Lymphocytic Leukemia	0	1.01	0.00	0.00 – 5.23
Acute Myeloid Leukemia	2	1.65	1.21	0.06 – 5.60
Chronic Myeloid Leukemia	0	0.52	0.00	0.00 – 10.13
Aleukemic, Subleukemic, & NOS	0	0.71	0.00	0.00 – 7.51
Total Childhood Cancers (0-19)	1	0.98	1.02	0.01 – 7.55
Females				
Site	**Observed**	**Expected**	**SMR**	**99% CI**
Breast	16	17.25	0.93	0.44 – 1.71
Lung and Bronchus	25	25.66	0.97	0.55 – 1.60
Colorectal	11	9.43	1.17	0.46 – 2.41
Larynx	0	0.29	0.00	0.00 – 18.06
Corpus and Uterus	2	2.06	0.97	0.05 – 4.51
Non-Hodgkin's Lymphoma	5	3.96	1.26	0.27 – 3.58
Brain/CNS	2	3.05	0.66	0.03 – 3.04
Acute Lymphocytic Leukemia	0	0.31	0.00	0.00 – 16.98
Chronic Lymphocytic Leukemia	0	0.58	0.00	0.00 – 9.21
Acute Myeloid Leukemia	2	1.25	1.60	0.08 – 7.41
Chronic Myeloid Leukemia	0	0.33	0.00	0.00 – 16.21
Aleukemic, Subleukemic, & NOS	0	0.47	0.00	0.00 – 11.24
Total Childhood Cancers (0-19)	1	0.74	1.34	0.01 – 9.98

Note: The SMR (standardized mortality ratio) is defined as the number of observed deaths divided by the number of expected deaths. The latter is based on race-, sex-, and age-specific cancer mortality rates for Texas during the period 1993–2002. The SMR has been rounded to the second decimal place.

*Significantly higher than expected at the $p < 0.01$ level.
**Significantly lower than expected at the $p < 0.01$ level.

Investigation #05026

Table 3

Number of Observed and Expected Cancer Cases and Race Adjusted Standardized Incidence Ratios, Selected Cancers, Zip Code 75104, Cedar Hill, TX, 1995–2002

Males				
Site	Observed	Expected	SIR	99% CI
Prostate	62	81.75	0.76	0.53– 1.04
Larynx	4	6.16	0.65	0.11 – 2.04
Lung and Bronchus	45	57.16	0.79	0.52 – 1.14
Colorectal	29	34.88	0.83	0.49 – 1.32
Bladder	13	15.42	0.84	0.36 – 1.65
Non-Hodgkin's Lymphoma	11	15.11	0.73	0.29 – 1.51
Brain/CNS	5	6.67	0.75	0.16 – 2.12
Acute Lymphocytic Leukemia	1	1.98	0.51	0.00 – 3.76
Chronic Lymphocytic Leukemia	3	2.59	1.16	0.13 – 4.23
Acute Myeloid Leukemia	2	2.81	0.71	0.04 – 3.31
Chronic Myeloid Leukemia	3	1.46	2.05	0.23 – 7.50
Aleukemic, Subleukemic, & NOS	0	0.54	0.00	0.00 – 9.88
Total Childhood Cancers (0-19)	4	7.72	0.52	0.09 – 1.63
Females				
Site	Observed	Expected	SIR	99% CI
Breast	121	119.28	1.01	0.79 – 1.28
Lung and Bronchus	31	40.45	0.77	0.46 – 1.20
Colorectal	23	34.47	0.67	0.36 – 1.12
Larynx	1	1.55	0.64	0.00 – 4.79
Non-Hodgkin's Lymphoma	16	12.66	1.26	0.60 – 2.33
Brain/CNS	5	5.71	0.88	0.19 – 2.48
Corpus and Uterus	7	16.26	0.43	0.13 – 1.05
Acute Lymphocytic Leukemia	0	1.47	0.00	0.00 – 3.61
Chronic Lymphocytic Leukemia	3	1.87	1.60	0.18 – 5.86
Acute Myeloid Leukemia	5	2.56	1.96	0.42 – 5.54
Chronic Myeloid Leukemia	0	1.16	0.00	0.00 – 4.56
Aleukemic, Subleukemic, & NOS	0	0.55	0.00	0.00 – 9.55
Total Childhood Cancers (0-19)	5	6.71	0.74	0.16 – 2.11

Note: The SIR (standardized incidence ratio) is defined as the number of observed cases divided by the number of expected cases. The latter is based on race-, sex-, and age-specific cancer incidence rates for Texas during the period 1995–2002. The SIR has been rounded to the second decimal place.

*Significantly higher than expected at the p< 0.01 level.
**Significantly lower than expected at the p< 0.01 level.

Investigation #05026

Table 4

Number of Observed and Expected Cancer Deaths and Race Adjusted Standardized Mortality Ratios, Selected Cancers, Zip Code 75104, Cedar Hill, TX, 1993–2002

Males				
Site	**Observed**	**Expected**	**SMR**	**99% CI**
Prostate	10	12.97	0.77	0.29 – 1.65
Larynx	1	2.22	0.45	0.00 – 3.34
Lung and Bronchus	54	58.45	0.92	0.63 – 1.30
Colorectal	11	16.20	0.68	0.27 – 1.41
Bladder	2	3.26	0.61	0.03 – 2.84
Non-Hodgkin's Lymphoma	6	7.28	0.82	0.21– 2.15
Brain/CNS	8	5.66	1.41	0.45 – 3.28
Acute Lymphocytic Leukemia	1	0.77	1.30	0.01 – 9.64
Chronic Lymphocytic Leukemia	0	1.29	0.00	0.00 – 4.12
Acute Myeloid Leukemia	1	2.28	0.44	0.00 – 3.25
Chronic Myeloid Leukemia	0	0.87	0.00	0.00 – 6.08
Aleukemic, Subleukemic, & NOS	0	0.96	0.00	0.00 – 5.52
Total Childhood Cancers (0-19)	2	1.98	1.01	0.05 – 4.09
Females				
Site	**Observed**	**Expected**	**SMR**	**99% CI**
Breast	34	32.03	1.06	0.65 – 1.63
Lung and Bronchus	29	38.29	0.76	0.44 – 1.20
Colorectal	14	16.48	0.85	0.38 – 1.63
Larynx	0	0.54	0.00	0.00 – 9.83
Corpus and Uterus	2	3.51	0.57	0.03 – 2.64
Non-Hodgkin's Lymphoma	6	6.32	0.95	0.24 – 2.48
Brain/CNS	6	4.61	1.30	0.33 – 3.40
Acute Lymphocytic Leukemia	0	0.62	0.00	0.00 – 8.50
Chronic Lymphocytic Leukemia	2	0.96	2.08	0.11 – 9.64
Acute Myeloid Leukemia	3	2.14	1.40	0.16 – 5.13
Chronic Myeloid Leukemia	0	0.63	0.00	0.00 – 8.48
Aleukemic, Subleukemic, & NOS	0	0.86	0.00	0.00 – 6.13
Total Childhood Cancers (0-19)	2	1.70	1.17	0.06 – 5.44

Note: The SMR (standardized mortality ratio) is defined as the number of observed deaths divided by the number of expected deaths. The latter is based on race-, sex-, and age-specific cancer mortality rates for Texas during the period 1993–2002. The SMR has been rounded to the second decimal place.

*Significantly higher than expected at the $p < 0.01$ level.
**Significantly lower than expected at the $p < 0.01$ level.

Investigation #05026

Table 5

Number of Observed and Expected Cancer Cases and Race Adjusted Standardized Incidence Ratios, Selected Cancers, Zip Code 76084, Venus, TX, 1995–2002

Males				
Site	Observed	Expected	SIR	99% CI
Prostate	6	24.76	0.24**	0.06– 0.63
Larynx	3	1.74	1.72	0.19 – 6.30
Lung and Bronchus	15	16.70	0.90	0.41 – 1.69
Colorectal	6	10.47	0.57	0.15 – 1.49
Bladder	1	4.87	0.21	0.00 – 1.52
Non-Hodgkin's Lymphoma	2	4.58	0.44	0.02 – 2.02
Brain/CNS	1	2.01	0.50	0.00 – 3.69
Acute Lymphocytic Leukemia	0	0.54	0.00	0.00 – 9.84
Chronic Lymphocytic Leukemia	1	0.79	1.27	0.01 – 9.42
Acute Myeloid Leukemia	0	0.85	0.00	0.00 – 6.21
Chronic Myeloid Leukemia	0	0.45	0.00	0.00 – 11.73
Aleukemic, Subleukemic, & NOS	0	0.16	0.00	0.00 – 33.24
Total Childhood Cancers (0-19)	1	1.71	0.58	0.00 – 4.33
Females				
Site	Observed	Expected	SIR	99% CI
Breast	14	23.70	0.59	0.26 – 1.13
Lung and Bronchus	9	8.67	1.04	0.36 – 2.31
Colorectal	7	6.28	1.12	0.32 – 2.73
Larynx	0	0.30	0.00	0.00 – 17.74
Non-Hodgkin's Lymphoma	1	2.54	0.39	0.00 – 2.93
Brain/CNS	0	1.23	0.00	0.00 – 4.31
Corpus and Uterus	2	3.48	0.57	0.03 – 2.66
Acute Lymphocytic Leukemia	1	0.32	3.10	0.02 – 23.03
Chronic Lymphocytic Leukemia	0	0.38	0.00	0.00 – 14.01
Acute Myeloid Leukemia	1	0.50	2.00	0.01 – 14.86
Chronic Myeloid Leukemia	0	0.21	0.00	0.00 – 25.58
Aleukemic, Subleukemic, & NOS	0	0.09	0.00	0.00 – 59.80
Total Childhood Cancers (0-19)	1	1.35	0.74	0.00 – 5.49

Note: The SIR (standardized incidence ratio) is defined as the number of observed cases divided by the number of expected cases. The latter is based on race-, sex-, and age-specific cancer incidence rates for Texas during the period 1995–2002. The SIR has been rounded to the second decimal place.

*Significantly higher than expected at the p< 0.01 level.
**Significantly lower than expected at the p< 0.01 level.

Investigation #05026

Table 6

Number of Observed and Expected Cancer Deaths and Race Adjusted Standardized Mortality Ratios, Selected Cancers, Zip Code 76084, Venus, TX, 1993–2002

Males				
Site	**Observed**	**Expected**	**SMR**	**99% CI**
Prostate	2	3.75	0.53	0.03 – 2.48
Larynx	0	0.60	0.00	0.00 – 8.89
Lung and Bronchus	16	16.94	0.94	0.45 – 1.74
Colorectal	1	4.74	0.21	0.00 – 1.57
Bladder	0	1.00	0.00	0.00 – 5.27
Non-Hodgkin's Lymphoma	1	2.21	0.45	0.00– 3.36
Brain/CNS	0	1.73	0.00	0.00 – 3.07
Acute Lymphocytic Leukemia	0	0.23	0.00	0.00 – 23.14
Chronic Lymphocytic Leukemia	1	0.39	2.58	0.01 – 19.16
Acute Myeloid Leukemia	0	0.70	0.00	0.00 – 7.59
Chronic Myeloid Leukemia	0	0.26	0.00	0.00 – 20.57
Aleukemic, Subleukemic, & NOS	0	0.29	0.00	0.00 – 18.35
Total Childhood Cancers (0-19)	0	0.38	0.00	0.00 – 13.95
Females				
Site	**Observed**	**Expected**	**SMR**	**99% CI**
Breast	3	5.50	0.55	0.06 – 2.00
Lung and Bronchus	6	8.07	0.74	0.19 – 1.94
Colorectal	2	2.74	0.73	0.04 – 3.38
Larynx	0	0.09	0.00	0.00 – 56.98
Corpus and Uterus	0	0.62	0.00	0.00 – 8.55
Non-Hodgkin's Lymphoma	0	1.20	0.00	0.00 – 4.43
Brain/CNS	0	1.00	0.00	0.00 – 5.29
Acute Lymphocytic Leukemia	0	0.12	0.00	0.00 – 46.07
Chronic Lymphocytic Leukemia	0	0.15	0.00	0.00 – 34.47
Acute Myeloid Leukemia	2	0.40	4.97	0.26 – 23.05
Chronic Myeloid Leukemia	0	0.10	0.00	0.00 – 52.51
Aleukemic, Subleukemic, & NOS	0	0.14	0.00	0.00 – 38.86
Total Childhood Cancers (0-19)	0	0.28	0.00	0.00 – 18.91

Note: The SMR (standardized mortality ratio) is defined as the number of observed deaths divided by the number of expected deaths. The latter is based on race-, sex-, and age-specific cancer mortality rates for Texas during the period 1993–2002. The SMR has been rounded to the second decimal place.

*Significantly higher than expected at the $p < 0.01$ level.
**Significantly lower than expected at the $p < 0.01$ level.

Investigation #05026

BIOGRAPHY FOR SALVADOR MIER

Sal Mier lives in Midlothian, Texas with his wife Grace.

Sal's 37-year career in public health started with the Centers for Disease Control (CDC) in New Orleans, shortly after he graduated from the University of New Mexico. This career took him to Puerto Rico, Arkansas and New Mexico where he had a temporary assignment to the Navajo Nation.

Sal worked for an interim period with the U.S. Public Health Service, Health Resources and Services Administration, for a short period. He returned to work with CDC where he ended his federal career as Director, Division of Prevention Region VI, in Dallas, Texas.

After retiring from CDC, Sal was a private public health consultant with a focus on U.S./Mexico Public Health issues, HIV and STDs.

Sal and his wife Grace have worked tirelessly these last five years trying to get answers from what he refers to as "our guardian agencies" about health issues that are surfacing in the community. "Our only motivation is the health of our children, our grandchildren and those yet to be born," he explains.

Chair MILLER. Thank you, Mr. Mier.

Professor Parrish.

STATEMENT OF DR. RANDALL R. PARRISH, HEAD, NATURAL ENVIRONMENTAL RESEARCH COUNCIL (NERC) ISOTOPE GEOSCIENCES LABORATORY, BRITISH GEOLOGICAL SURVEY

Dr. PARRISH. It is a privilege to be here and I thank you for the opportunity. It is an interesting contrast to my day job as research professor at University of Leicester and I run a large environmental isotope analysis facility in the U.K. My role here today is really just to provide you with my perspective on the Colonie, New York, that is a suburb of Albany, New York, health consultation as a result of my conducting research there on depleted uranium pollution at the site as part of a broader investigation of depleted uranium and health issues.

What I want to do is really just emphasize some of the most relevant and compelling facts and issues about the health consultation. As illustrated on the side panels, depleted uranium munitions and other uranium manufactured items were made at the National Lead Industries plant in Colonie, New York, from 1958 to 1984 when the plant was closed due to the company's environmental negligence from release of excessive radioactive uranium oxide aerosols on the surrounding community, and the community can be seen to surround the remediated plant. In about the mid-1980s the Federal Government accepted responsibility for this site and up to 2006 has spent approximately $200 million remediating the site. In response to the community concerns expressed to the Army Corps of Engineers, the ATSDR concluded a health consultation in 2004 and its fundamental conclusion was that in the active years of emissions, these emissions endangered the local population and workers' health by the risk of inhalation exposure to uranium oxide. On this conclusion, there is general broad agreement.

With regards to the health consultation that ATSDR did at the site, let me just mention a few specific outcomes. You will recognize some themes here that are common to other health consultations. The Agency decided not to conduct any new research as part of its health consultation and did not pursue any further environmental investigations or health surveillance activities. It misunderstood or was unaware of the analytical tools available at the time to identify the presence of depleted uranium in urine bioassays via isotope

analysis. It concluded that the 20-year length of time from the 1984 closure would make identification of any DU exposure, DU meaning depleted uranium, impossible. It also concluded that it simply wasn't feasible or possible to identify the cohort of workers and residents with the highest exposure. It gave also incomplete and in part unbalanced descriptions of the relative health importance of the two exposure pathways, one being the relatively benign ingestion pathway, that is, coming into contact with contaminated soil, and the other being the more insidious inhalation pathway which has higher health risks associated with it. In short, the Agency appeared to dismiss the viability of conducting any further health studies on the exposed population.

Now, the difference in the Colonie situation with respect to some other sites where health consultations have taken place and probably the reason I am here is that our research group has, so to speak, sort of picked up the pieces of the situation following the health consultation and we have conducted some of the work that ATSDR could and should have done. For example, we determined the chemical form for some of the particulates and showed that it was the least soluble of all forms of uranium oxide. We also used a high-sensitivity method for uranium isotope urine testing that we had previously developed in the U.K., and we showed that depleted uranium could be identified in the urine of exposed individuals and it can be quantified, even more than 20 years after these people were exposed. We extended substantially the existing 1980s vintage environmental surveys and we worked in a collaborative fashion with the community to identify a portion of the historically exposed cohort. In short, we in part accomplished what ATSDR said was not possible and we did this with very modest resources and actually at no expense to the U.S. taxpayer. This brings this whole issue into even sharper focus about the shortcomings of the health consultation.

Sort of taking a step back, there is a larger perspective about depleted uranium and health issues that relates to broader issues such as Gulf War illness that affects veterans and the continued use of depleted uranium munitions by the U.S. military. ATSDR did not appear to recognize an opportunity at Colonie to shed further light on these broader issues, the opportunity being to study long-term health consequences, if any, of exposure to inhaled depleted uranium oxides. The exposure to DU has been an ongoing issue in the media and government with respect to exposure of soldiers to this toxin and its health consequences, and the issue does not have sufficient study at present. A comprehensive study could have added new knowledge to help resolve this issue and it is therefore part of the government's duty of care to soldiers and veterans who have unselfishly served the Nation.

Considering the acknowledged risks to health at Colonie that arose partly that were obvious in the first place but also confirmed by the health consultation, the lack of any resources devoted to targeted health studies at Colonie when compared to the $200 million spent on remediation is, if one is being generous, grossly imbalanced, and if you are shedding it in the worst light, you could say that this is somewhat immoral and perverse.

Let me just conclude with a few general comments about ATSDR and perhaps the way forward. The ATSDR remit sets quite a high bar to reach, that is, basically effectively protecting the health of the Nation. This is a complicated and potentially very expensive challenge. The pattern of performance in recent years as I have gathered simply from reading documents in the past few weeks and learning more about this committee appears to suggest that this standard is not being achieved. So it seems to me there are two options. One is that we partly admit that some of this high bar, this high standard of performance may be unachievable, in which case, you know, it should be redefined so that ATSDR can actually have realistic goals.

Alternatively, if the remit of ATSDR is a valid, you know, public service imperative, then it seems to me you have to do three things and they have to be coordinated and done effectively together. The first is that the Agency has got to have a strong vision, it has to have strong leadership and especially needs commitment throughout the organization to its mission and it has to basically embrace that ethos. The second point is that the Agency needs to have the resources to pursue its investigations to their logical and defensible conclusions and be able to resist interference. Both of these two recommendations, it seems to me, are essential to restore the credibility of the Agency. The third thing that needs to be done in concert with the rest is that the Agency needs to find and implement a mechanism that effectively and defensibly prioritizes its investigations and resources so that it actually can deliver its remit. This external review prior to release of documents could form a component of that. This third one basically would allow the Agency to maintain credibility once it establishes a renewed sort of presence for the future.

So that is the end of my statement. I will be glad to answer questions later on. Thank you.

[The prepared statement of Dr. Parrish follows:]

PREPARED STATEMENT OF RANDALL R. PARRISH

Summary

National Lead Industries (NLI) contracted with the Department of Energy and processed uranium at Colonie NY in the period 1958–84, but in its latter years was environmentally negligent, badly polluting with depleted uranium aerosols the surrounding site and community. The amount of Depleted Uranium (DU) aerosol emissions were comparable to the total respirable DU released in the entire 1991 Gulf War, highlighting the significant pollution issue. In 2003–04, the ATSDR conducted a relatively superficial examination of the health consequences of the pollution of this site. The report lacked depth and substance, failed to address community concerns with adequate scientific data and explanation, it conducted no new research at the site, and presented a confusing picture of the toxic hazards. It did not draw upon the best science available. The site was remediated (completion 2007) by the Army Corps of Engineers, costing more than $190M. The ATSDR consultation significantly concluded that there was a real and significant health risk to the public from depleted uranium oxide emissions from the plant stack during its active years (1958–1982), but it decided not to pursue any environmental surveying or health surveillance activities for poorly articulated reasons. Planned actions related to uranium were not done subsequent to the report's publication. The liaison with the local community appeared to be relatively poor, delivering little in the way of satisfactory communication, and no perceived benefit. No new insight on the situation was presented that was not already apparent and the nature of uranium toxicology was not well balanced. In several respects it failed to take advantage of the best science available to address the issues at the site. It offered little in the way of comment on how to redress the health concerns of the community. In most respects

other than providing information on toxins, it failed to deliver its remit for the Colonie site.

My UK research group, beginning in 2004, investigated the nature of the uranium aerosols, made isotope measurements that documented the isotope characteristics of the source emissions, studied particle dissolution in the natural environment—a parameter relevant to their solubility, extended the survey of uranium pollution much more widely, and studied the mobility of uranium in soils and plants, all in order to gain a better understanding of the environmental pollution. We also worked closely with the community to identify former workers and residents who lived or worked in or near the plant for many years during its operation, in order to gather oral history of events and practices in the plant and to identify part of the exposed cohort for potential health screening. TSDR evidently decided that this type of approach was not possible or would not be a productive activity. It was instead feasible and useful, and not particularly costly. We had already developed a urine uranium isotope test that was capable of detecting trace depleted uranium in urine. We then tested a small cohort of residents and former workers and clearly showed that our method was capable of identifying a substantial exposure to depleted uranium aerosols more than 20 years after exposure. This clearly offered a way forward to link health outcomes to exposures at Colonie, something ATSDR in 2004 decided was not possible.

There is a breath-taking lack of environmental and community justice in the Colonie situation. While the polluter, National Lead Industries, was absolved two decades ago by the U.S. Government of responsibility and while the Army Corps of Engineers spent nearly λ200M on site cleanup, no Federal Government monies have been spent on even a modest-scope targeted health study to identify what if any health outcomes have occurred for the exposed cohort of people who for years lived near or worked in the site during its active years of uranium pollution. The community has been left with no research, no credible way forward, little or no redress, and a significant environmental pollution legacy with a reasonable probability of some consequences to health of those affected.

Much could have been learned about the environmental health issue of aerosol depleted uranium emissions had ATSDR acted differently; this could have informed U.S. Government policy as it pertains to Veterans' Health related to DU munitions exposure in the battlefield (Gulf Wars I and II) and potentially helped provide vital data to test any potential connection between Gulf War Illness and depleted uranium exposure. It would certainly have improved the medical knowledge database on the inhalation hazard of respirable uranium oxide particles, a relatively rare toxicological pathway which does not currently have benefit of any systematic study of an exposed population, to my knowledge. The need for additional research at the Colonie site is as acute now as it was in 2003–04 when the ATSDR conducted its Health Consultation.

My remit—instructions from Congressional subcommittee

The Subcommittee has asked me to do two things: summarize my investigations into the National Lead Industries (NLI) Colonie NY site and critique the 2004 Colonie ATSDR report and suggest how to improve its environmental health assessments in the future. My contribution herein is largely concerned with the uranium issues at Colonie, not the full menu of pollution-related toxins.

Background and current position; summary of expertise

I am Randall R. Parrish and occupy a joint position of Professor of Isotope Geoscience, University of Leicester (UK) and Head of the UK Natural Environment Research Council Isotope Geosciences Laboratory, a national isotope research and analysis facility serving the UK scientific, mainly the academic scientific community. I have occupied this joint post since 1996. More details on my expertise, skills, publications, research and so forth is contained in the CV and biography provided as part of the requested testimony.

I conduct research in many areas of geo- and environmental science, but have a particular expertise in analysis of uranium and lead isotopes using high sensitivity mass spectrometry and am a recognized authority in this area. I have published extensively using such methods, mainly in geoscience in the field of geochronology—the determination of the age of rocks and minerals using radioactive decay of Uranium. Although most of my research has been and continues to be in Earth science, since 2003 I have applied this expertise to environmental health research on topics that relate to the issue of depleted uranium (DU) pollution and health. Our work has had some impact on how the UK government approaches its duty of care to the UK soldiers that may have been exposed to depleted uranium munitions and its en-

vironmental consequences. I developed a keen interest in this problem because of the lack of thorough relevant studies, its novelty, and the fact that it was and still is an issue in dire need of sound scientific data to combat the huge amount of media and political noise surrounding 'depleted uranium' and its potential relationship to Gulf War Illness.

The wider justification for study of the Colonie site

The overriding reason that I got involved in research at the National Lead Industries Colonie NY site was to try to solve a long-standing problem: how long does inhaled DU oxide reside in the human body and what relationship, if any, does such an exposure have on human health and how might it be quantified? In spite of notions to the contrary, this problem has not been solved because **no cohort of people exposed by inhalation to this particular toxin has been adequately studied.** As it turns out the NLI Colonie NY site is virtually unique in its relevance to this issue, quite apart from the intrinsic need to address the environmental stewardship and potential health issues of this highly polluted site. My role has been to provide the analytical and environmental science to address this problem. I hope my testimony will clarify your understanding of the problem and the perspective I have on the 2004 Colonie ATSDR Health Consultation.

Some observations about the Colonie situation

- The uranium pollution at Colonie originated at the former National Lead Industries site; all agencies appear to accept that there is no other credible source for the uranium pollution there. From my knowledge base, I agree.
- The uranium pollution is primarily composed of depleted uranium oxide aerosol particles, which have a distinctive isotope composition with some limited variability; we have measured this extensively in our studies. My Ph.D. student published an article on this just last week—it is appended in these documents.
- The uranium pollution at Colonie occurred as a result of environmental negligence of National Lead Industries through inadequate filtration and capture of combusted depleted uranium metal waste.
- The period of active pollution was ~1958–1982 and aerosol pollution ceased with plant closure, though re-suspension of polluted soil undoubtedly occurred after plant closure.
- Our recent research has shown that household dust may have unacceptably high levels of DU; this may be a risk to health if disturbed—a potential health issue, and certainly a perceived concern of the community at the present time.
- ATSDR's 2004 principle conclusion of merit was that the level of airborne radioactivity emitted from the plant represented a distinct health risk during plant operation. The ATSDR report's lack of recommendations concerning past risk to health was a puzzling omission from the report and an obvious source of frustration to the community.
- The ATSDR 2004 report has an overemphasis on ingestion exposure to DU by comparison with the acknowledged more hazardous inhalation pathway, because the latter may lead to long-term internal radiation whilst the former is likely to be cleared quickly in the intestinal tract. This is all the more important since our recent research has shown that the uranium aerosol pollution at Colonie is very weakly soluble, and contains a significant proportion of respirable particles. This de-emphasis of the inhalation exposure pathway is a significant weakness of the report.
- In the assessment of health risks and exposures, what is important is getting at an estimate of the cumulative inhalation uranium exposure of workers and residents; this is not simple. It needs to be appreciated that it is entirely *wrong* to conclude that because urinary uranium levels are relatively low *now* that there was/is no health issue. In this 'historic exposure situation' the comparison of current excretion levels in relation to the overall population is a flawed basis for health risk assessment.
- The task of calculating a cumulative historic inhalation uranium oxide dose is complex, but can be modelled using existing, relatively well accepted biokinetic models along with a range of solubilities of DU oxide particles, using experimental data, and estimates of excretion of inhaled DU. The U.S. Army Capstone (~2004) report specifically investigated this issue; the ATSDR report was apparently unaware of it and in any case chose not to pursue this avenue

of investigation. A fairly thorough discussion of this topic was available in the period 2000–2004 and for example is contained in the Royal Society report on DU (2001). I have included an explanation of this later in the written testimony explaining how current excretion levels of DU can be used to calculate the much larger quantities of inhaled uranium during an historic exposure.

- The detection of depleted uranium as a component of the urinary uranium excreted by affected people is a challenging but feasible measurement; it was feasible in 2003–04 (via for example the UK DUOB website) when ATSDR concluded there was no method available, but it had yet to be published in the refereed literature.
- The quantity of inhalable DU oxide deposited in the vicinity of the Colonie Plant is comparable to the total aerosolized inhalable DU oxide produced in the entire 1991 Gulf War conflict; in Colonie, >95 percent of this quantity was deposited within 2km radius of the NLI plant; in the 1991 Gulf conflict, the area of dispersion in Iraq-Kuwait was very much larger and partly in sparsely inhabited areas along the Basra Road. Thus the environmental pollution and health risk is likely to have been much higher for Colonie residents than for Gulf War veterans. This sobering perspective has never been appreciated or recognized and is all the more unbalanced when considering how funds have been spent on research into DU and health.
- No credible well-designed health assessment has been funded or conducted at Colonie; yet, >$190M has been spent on the NLI cleanup within its perimeter fence, not to mention funding allocated to ATSDR for its Health Consultation and that dedicated to other DU-Health research such as the Capstone study of the U.S. Army. This whole funding situation appears perverse, misdirected, and lacking a natural sense of balance (one could say fairness & justice), in my opinion.
- In my opinion the 'zip code' based cancer occurrence 'studies' cited by the ATSDR Health Consultation and conducted by NY State agencies were unlikely to accurately identify any significant rise in illness that might have arisen from long-term significant inhalation exposure to DU from the NLI plant of a cohort of heavily exposed workers or residents. The movement of people with time in and out of the area, the lack of tracking of the most exposed few hundred individuals, and the study of former workers unlikely to have lived nearby meant that this type of study was doomed from the beginning of delivering insight. Why ATSDR opted to not design a more targeted study or to more intelligently discuss the shortcomings of these NY State studies is baffling to me, and no doubt a serious source of frustration to the community.
- The studies that I and my team have conducted at Colonie, both urinary testing (on a small scale) and environmental surveying, have been modest in scale and cost, and were entirely feasible at the time of the 2004 ATSDR Consultation; the ATSDR paper made no recommendations to undertake any such study.
- Unfortunately the 2004 ATSDR Health Consultation undertook no new research and seemed uninterested in such follow-up work; while clearly recognizing the inherent health risk of the plant, the paper concluded without recommending any way of redressing the community concerns about uranium pollution, whether well-founded or not. It is no wonder that the report satisfied few.
- I have solicited feedback about the 2004 report by the Community Concerned about National Lead; their comments are very critical of ATSDR. This is primarily because while the health hazard was clearly admitted, no recommendations for new research or health screening were made, for reasons that were poorly articulated and justified. As a scientist, I too find a puzzling lack of credible justification for the lack of action arising from the report. The report has therefore made little if any contribution to knowledge or public understanding of the scientific and health issues of the Colonie site that were not already available.

Our research at Colonie 2004–2009

With information from several sources, in ~2004 I recognized the unique situation of significant historic uranium aerosol inhalation exposure of a large urban population in Colonie, a mixed industrial-residential part of Albany NY. Its attributes of interest were:

(1) there was a great amount of uranium pollution;
(2) the nature of the pollution was primarily by aerosol deposition of combusted uranium oxide particles;
(3) it took place over a long period of time but ceased more than 25 years ago;
(4) many individuals who had lived through the active period of aerosol deposition were still living in the area; and,
(5) it seemed certain that if individuals living there also had aerosol-contaminated soil, then they would have inhaled the toxin over a long period of time.

It thus appeared to be a well-controlled experiment where one had an opportunity to address the health impacts of those exposed to inhaled DU, and that such study might have a bearing on the larger issue of inhaled DU and Veterans' Health. Though this latter problem falls outside of the remit of ATSDR, I think it is important for Members of the Committee to gain a perspective on how the Colonie example could benefit and contribute to other scientific issues of acute interest to the American Government, namely the health of Gulf War(s) Veterans.

Chronological perspective on DU research and the Colonie site

To provide a better perspective, I will outline the pertinent events leading up to the present that bear on my research at Colonie, DU and Health, and the ATSDR consultation.

In chronological order, they are:

- 1958–1982: Colonie site uranium pollution;
- ~1984; U.S. Government accepts responsibility of site from the polluter, National Lead; DU munitions production shifts to other U.S. plants.
- 1982–2007: Assessment of site and major remediation by Army Corps of Engineers within the former National Lead Industries site costing >$190M.
- 2001: publication of the WHO and Royal Society papers on Depleted Uranium and Health, during a period when DU was a major issue in the American, Canadian, and UK media.
- 2001: UK government established the Depleted Uranium Oversight Board (DUOB) to oversee and undertake a voluntary program of testing of veterans who may have been exposed to DU through service primarily in the 1991 Gulf Conflict. The minutes of this Board were available.
- The DUOB undertook to establish a reliable urinary DU exposure test that could potentially detect a milligram-sized inhaled DU dose after 10 years had passed, in order to satisfy the concerns of potentially exposed veterans. This test was available as of late 2003. This was to be a much more sensitive test than was available any where else in the world. The program of testing took place between 2004 and 2006. To my knowledge this capability currently exists only in the UK and possibly Germany.
- The NIGL laboratory of which I am Director was one facility offering this test and it was engaged in the analysis of many hundreds of urine samples during this period. I played a key role in this development and testing.
- The Final Report of the DUOB testing program (published eventually in 2007) showed that no individual tested in the program was DU-positive.
- Because of the preponderance of DU-negative results, even in 2004 part way through the program, I felt that there were two explanations possible for these results:

  (1) Some of the veterans were significantly exposed to DU but the passage of time had ensured that residual DU contamination was undetectable; thus health harm may have occurred without a DU-positive test.
  (2) The veterans with DU-negative test results were not significantly exposed to DU.

  Unfortunately there was no study available at the time to quantify the residence time of inhaled DU oxide particles, and both alternatives remained viable explanations of the data; the debate in the UK concerning DU exposure and Health therefore could not yet be fully resolved.
- In the period around 2001–2004 unpublished information became available from Iraqi medical officials of an apparently progressive and significant rise in unusual cancers and birth defects throughout the 1990s; this was not clearly verified but Iraqi and some western medical officials attributed this to DU exposure. This added some anecdotal evidence that there might be a DU–

Health connection even though other reports were suggesting that the connection between DU and Gulf War Illness was weak.

- In 2004 I learned of the Colonie site; as noted earlier in this testimony, it appeared to involve a significant aerosol DU oxide pollution footprint in an urban area, with the implication that it was likely that many people had a DU oxide inhalation exposure; thus it to me seemed worth pursuing since it offered a way to resolve the alternatives expressed above about the interpretation of the DUOB DU-negative results.
- With considerable anticipation of new insight, I read the ATSDR 2004 report, and while pleased to read of its conclusion that the uranium emissions during the plant's active period was hazardous, I was quite disappointed with its lack of new data/research and its lack of tangible actions and recommendations for the future. To my knowledge no follow up work was done by ATSDR related to uranium.
- In 2004 I initiated a research project at Colonie, aimed at providing (1) a modern environmental study to document the nature and mobility in the environment of the DU oxide aerosols and (2) urinary tests of potentially significantly exposed individuals (former workers of the plant and residents who had lived nearby for years) to determine whether any urinary DU could be detected. A Ph.D. student (Nicholas Lloyd) was given the environmentally-oriented project, while I undertook the urinary testing. We cooperated in these studies with colleagues at the University at Albany (Dr. David Carpenter and Dr. John Arnason). Funding for this work was provided by the British Geological Survey and the UK Natural Environment Research Council.
- In latest 2004 the analysis of the Colonie urine samples showed that it was possible to detect DU in humans more than 20–25 years following exposure (eventually published in 2008). This allowed one to favor one interpretation of the DUOB-tested Gulf War veterans—that they had not acquired a significant DU inhalation dose. We knew in latest 2004 that our method of testing offered a way forward to identify and potentially quantify the cumulative inhalation dose of DU for the Colonie exposed population; this conclusion had very important implications for any follow-on actions arising from the 2004 ATSDR report.
- Our environmental study data was progressively completed in the period 2005–2008; it had several important conclusions, namely:

  (1) DU in soil profiles has very limited mobility, indicating a lack of rapid dissolution of DU in the natural environment;

  (2) Particles of DU oxide aerosol could be located and studied in contaminated soil, and in household dry dusts, and after study (using a synchrotron X-ray source), it was confirmed that UO_2 was the principle chemical component, a finding that is expected in thoroughly combusted material; UO_2 is the least soluble of any uranium oxide.

  (3) UO_2 particles form a minor component of the man-made metal oxide aerosol particles contained in soil; the bulk of the remainder mainly consists of lead particles.

  (4) Particles of UO_2 within soil were found to have suffered minor (generally <10 percent) dissolution by being subject to natural weathering for more than 25 years; this confirms that the combustion product aerosol emissions from Colonie were relatively insoluble.

  (5) Samples of trees, plants, berries, etc., growing on contaminated soil contain DU; this indicates that some component of DU is soluble and taken up in plants.

  (6) No sample of soil collected to date, including those up to seven km (minus five miles) from the NLI site, is free of DU; the pollution plume is much larger than was originally thought.

  (7) With our data, a calculation of the total mass of DU emitted from the plant was made, the resultant quantity being approximately 10 metric tons (give or take a few). This is comparable to the total aerosolized DU oxide produced by the Allied Forces in the entire 1991 Gulf Conflict, demonstrating the relative magnitude and concentration of DU in the Colonie site.

- 2008: Publication of the Parrish et al. paper on the Colonie site in Science of the Total Environment; this study when combined with the efforts of the Community Concerned about National Lead (CCNL), resulted in a renewed

effort to obtain NY State funding for a credible targeted follow-up health study of affected residents/workers of the NLI site; this activity is ongoing.

Critique of the ATSDR Health Consultation

Prior to making some criticism of the document, it is important to note the strengths of the 2004 ATSDR Colonie Health Consultation, namely:

- It provided a good review and summary of the history of the site and all previous investigations, and brought together information from a variety of sources.
- It used measurements of emissions of radioactivity from the site available from environmental monitoring to conclude that there was a significant health risk to those who lived nearby during the period of active emissions.
- It made an effort to have meetings with the community to present its findings, take note of concerns before preparing its final report.
- It recommended two specific actions related to the NLI plant, namely,

  (1) ATSDR will work with local physicians and provide information on taking patients' environmental exposure histories. ATSDR will also make available resources related to environmental exposure, including contaminant-specific case studies and fact sheets.

  (2) ATSDR is evaluating the feasibility of conducting a study that would compare the mortality rates of former NL workers to the mortality rates of the general public. Former workers likely received the highest exposures to depleted uranium from 1958 to 1984 during operation of the facility. Currently, ATSDR is determining whether relevant past worker records exist.

Unfortunately it also had many shortcomings. I will outline what I feel are the most important problems rather than undertake a detailed critique.

- The study presents a skewed and narrow portrayal of the potential hazards of DU in that it over-emphasized the ingestion-related pathway and underplayed the inhalation hazard. This may have been influenced by the lack of published literature on health impacts to cohorts exposed to inhaled DU—a situation arising because of the rarity of such incidents. The report appears to have used the lack of literature to downplay the importance of this problem instead of undertaking a credible analysis of the inhalation hazard with available data and models. This should have been done, but was not. The analysis of the Royal Society (2001), WHO (2001) and Depleted Uranium Oversight Boards (website 2001 onwards) had fairly thorough treatment of this issue, but these sources of information evidently failed to influence the report.
- The discussion on pages 15–16 concerns the health risks of exposure, pathways of exposure, and health survey design analysis. It has undoubtedly left members of the public confused because it contains inconsistencies, is partly wrong, lacks detailed logic and explanation, and is sort of a shopping list of assertions and conclusions without satisfactory elaboration.

  This section should have explained the inhalation hazard and its consequences in detail, since this was the main exposure pathway for the Colonie area (i.e., by breathing aerosols during the plants operation). In my opinion, addressing the health hazard of DU oxide inhalation exposure is the single most important reason to have conducted this Health Consultation. Therefore it should have noted the relative magnitude of pollution of the site—one of the largest concentrations of DU aerosol pollution in the world, if not the largest. It should have explained that the consequences of inhalation of respirable particles of DU oxide would lead to long residence times in the lungs, on the order of years, with consequent internal organ irradiation by alpha emitters and the likely illness that a major dose of such radiation could have led to. It should have sharply contrasted the differences between the inhalation and ingestion pathways and their implications of short (with ingestion) and long (with inhalation) residence times in lungs. It should have mentioned the consequences to subsequent urinary testing of these two ingestion and inhalation scenarios. It could have and should have summarized biokinetic models that are in theory capable of modelling (i.e., predicting retrospectively) the magnitude of cumulative inhalation dose if the time elapsed since exposure was known and if the daily excretion of DU can be determined. It should also have outlined generally the method of detection (i.e., explained what bioassays methods were available, especially the isotope tests) and their

detection limits, to explain to the public whether or not tests available at the time were capable of detecting such residual DU in urine. It should have acknowledged that a urinary measurement made more than 20 years after exposure would be expected, even with very large initial exposure, to be orders of magnitude lower in concentration than it would have been initially. There is much missing in this section; only ATSDR officials can provide the rationale for such a superficial treatment of some of these issues. The section appears to avoid dealing with the main issue.

- The statement on top of page 16 states that if DU had been found in urinary tests, that such tests would be incapable of indicating 'where the DU came from.' This is largely wrong; isotope analysis is a very powerful technique to establish plausible links (or refute them) between sources and exposures. This is all the more surprising since they discuss the NLI plant as the only source of DU for the uranium pollution of the site (on page 19). There is essentially a dismissal of the role that isotope analysis of uranium could play in testing this link. The report shows a lack of insight and understanding of this whole area of measurement. This is all the more surprising since analytical laboratories within CDC itself are conducting research into such measurements of uranium in urine. Perhaps there is a lack of joined up communication within CDC in this regard. One could be forgiven for concluding that they just were not interested in recommending any kind of urinary uranium testing.
- Pages 16–17 discuss the issue of existing health surveys and the possibility of a new health assessment. I found this an exceptional frustrating aspect of the study and the single most disappointing part of the paper. Having concluded already that there was a significant health risk from uranium aerosols during the plant's emission history, they use these two pages to first explain why the earlier zip code surveys of NY State officials could not have worked in identifying any possible excess of cancers arising from the plant. I would have thought this would have prompted them to explain how a well-designed health survey ought to be designed for this situation, but they failed to do this. Instead, on page 17 the report appears to signal a resignation that no possible survey could be designed that might identify whether or not excess illness might have arisen in the cohort of exposed individuals. This is not a satisfactory outcome of a Health Consultation of this type.

  To provide a satisfactory basis for doing nothing, they needed to explain why it would have been impossible to conduct a survey to locate former workers at the plant and individuals who lived in close proximity to the plant for many years. These people could have been ranked in terms of potential exposure by duration of exposure, and proximity to areas of very high uranium in soil (as a proxy for the aerosol uranium concentration).

  Ironically the Concerned Citizens about National Lead group was able to gather a lot of this sort of information and had some of it at the time of the report's writing. In our work we used their information effectively. In my time dealing with the Colonie site, I have had conversations with residents of a street adjacent the site in the heavily exposed pollution halo who communicated an alarming number of health issues (mainly cancers) and deaths in the past 25 years in houses in that particular area. Precautionary instincts suggest this ought to be investigated as a priority. No questions of this type were asked by the Consultation. This to me seems a major oversight.
- Part of the reason not to pursue further health assessments appears to have been predicated on the perceived inability to detect a low percentage of excess cancers that might be attributed to the pollution in a much larger cohort population (thousands of people). I fully agree that to use the thousands of people in a current zip code as the 'exposed population' is a poor experimental design for a health assessment of the Colonie situation. Such an approach stands no chance of succeeding in being insightful for the Colonie situation where only a relatively small number of individuals (probably less than 1,000) was likely to have suffered a significant inhalation dose. This is in essence the flaw with the former NY State surveys. However, to do nothing and recommend nothing in the face of this is not a satisfactory option or outcome.

  Instead, the report should have recommended conducting a survey on the most exposed group of people; it should have located the several hundred most heavily exposed individuals, wherever they might now live, in addition to collecting death statistics from cancer (for example) from those who formerly lived near the site during its active years. This type of systematic census work is both necessary and feasible. The health issues with this targeted

cohort could have been studied to either (1) discover any alarming illness patterns) relative to the general population, or (2) show that nothing was identifiably anomalous. Had the survey identified excess illnesses, then a campaign of appropriate-sensitivity uranium isotope testing could have been commissioned to see whether DU could be identified as part of the excreted uranium, in order to provide quantitative data on possible past exposure to DU. This is the sort of investigation that would have been a satisfactory outcome to the ATSDR report; it needn't have been hugely expensive or undertake the work.

- The ATSDR authors were aware of inhalation exposure computer models that could be used to make predictions on exposure of an inhaled compound using particle grain size, airborne concentration at the point of emission, density of particles, and meteorological data. They could have made assumptions about particle size and density and used existing meteorological data to do this, but they did not. Give the relative ease with which our own research was able to isolate particles from contaminated soil or household dust, and study their general size, shape and composition, the lack of interest or awareness of this avenue of investigation represents a significant oversight, and may indicate a lack of interest in pursuing a credible, reasonably in-depth investigation into the DU pollution.
- On pages 30–31 in addressing direct concerns of the community the report provides a misleading answer by failing to mention the dangers of internal alpha radiation (in lungs in inhalation exposure) after noting that airborne emissions were the main hazard; the report obfuscates the issue here by appealing to the benign nature of alpha radiation to skin, which mixes up internal and external doses. This confusion was entirely unnecessary.
- On page 35 in addressing the 5th concern of the community, the report explains the challenges in designing a health survey and attributing any outcomes to NLI pollution. A lot of the reason the report recommends that no health survey would work is because the report concluded there was no means of establishing a distinct exposure to DU. The authors would have known that standard existing uranium bioassays and uranium isotope urine tests had defined limits of detection that would limit the ability of these tests to detect DU. They should have realized that significant progress had been made on method improvement and that further improvement in reducing detection limits would be likely. They should have noted this in the report and recommended that should methods become available that could potentially quantify the past exposure via a urine test, that this whole issue should have been revisited. They should have recommended this be done.
- On page 37–38 are the conclusive recommendations and 'planned actions' arising from the Consultation. No recommendations are made with regards to DU exposure at all. In the planned actions are mentioned the following two items:

  1) ATSDR will work with local physicians and provide information on taking patients' environmental exposure histories. ATSDR will also make available resources related to environmental exposure, including contaminant-specific case studies and fact sheets.
  2) ATSDR is evaluating the feasibility of conducting a study that would compare the mortality rates of former NL workers to the mortality rates of the general public. Former workers likely received the highest exposures to depleted uranium from 1958 to 1984 during operation of the facility. Currently, ATSDR is determining whether relevant past worker records exist.

I am not aware that there has been any progress on these two 'planned actions'; I have also checked with CCNL, the main community group and they agree that no action on these was done following the publication of the Consultation. This has increased the sense of frustration by the community and is to say the least, puzzling. ATSDR should comment on this lack of follow-up actions, if in fact this is the case.

Scientific Recommendations to address environmental health issues at NLI Colonie NY site

The ATSDR report has failed to resolve any of the outstanding environmental health issues arising from NLI pollution at Colonie. A sensible course of action for ATSDR for the future would be to embrace the shortcomings of its report and take

a new approach putting in place a number of actions to make some substantial progress. For example,

- Community consultation in light of this hearing and recent research
- Establish funding for limited health assessment study
- Exposure screening of cohort with highest likelihood of significant inhalation exposures—workers and residents, perhaps several hundred individuals
- Design and implement targeted health assessment of cohort, including investigation of death statistics of those likely to have had a relatively heavy exposure
- Evaluate health data using precautionary ethos given the small cohort size
- Investigate further cleanup of indoor and outdoor properties where resuspension of heavily contaminated dust could be a problem.

Comments on the ATSDR mission/remit and its performance

The remit of ATSDR Health Consultations is articulated in the ATSDR website is to "serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and diseases related to toxic substances".

At Colonie, while noting the useful case history of the site and especially its main conclusion that there existing a substantial health risk from uranium emissions during the active years of the NLI plant, the Agency in my opinion has failed to locate, present, and apply the best science to Colonie, and when combined with the lack of any identifiable responsive health actions arising from its investment of resources, it is hard to conclude that in this case, it has come anywhere near fulfilling its mission.

Recommendations to Congress concerning ATSDR

ATSDR's remit forms an important component of public health policy and mitigation in the United States by undertaking prompt assessment and recommending a course of action to mitigate toxic hazard risks and derive new knowledge concerning unusual toxin situations. The work is important and needs to be highly credible and to reflect the best knowledge available anywhere.

The Colonie example shows that ATSDR needs to work considerably harder in order deliver credible assessments and solutions commensurate with its remit.

In cases like Colonie where it appears it had insufficient experience with an unusual hazard (in this case the inhalation hazard of uranium oxides) it needs to ensure that it taps into the best knowledge available, not just the in house expertise. The Colonie consultation could have been miles better if it had acquired an up to date knowledge of concurrent activities taking place on this same hazard in other government agencies (U.S. Army research on DU inhalation; CDC uranium isotope measurement; National Academy of Sciences reports on DU) and in other countries (UK DUOB screening program, Royal Society biokinetic models of inhaled uranium exposure and health risks for example). They appear to have failed to 'leave no reasonable stone unturned' in the Colonie study.

Governments (and certain industries) may fear what they might uncover by doing a thorough study into a politically-charged issue like depleted uranium. My view is that it is best to be transparent, face up to the risks of doing the credible science where it appears justified both fiscally and scientifically, do it well, and communicate clearly the issues, risks and conclusions. I think it is likely that the science will put some issues to bed instead of letting them fester without resolution for years. The public deserve this transparency, and responsible environmental stewardship dictates that we should understand the environmental consequences of industrial processes (and negligence) and assess risks properly in order to decide how best to find credible solutions to these issues.

Other Supporting Documents

Summary of current community concerns

The following is a letter with concerns of the community submitted to ATSDR arising from the Health Consultation. It is my impression that most if not all of these concerns are still current because they were not addressed in the report or in any follow-up actions. I have relied on Anne Rabe of the Community Concerned with National Lead for this input.

Citizens' Environmental Coalition

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November 3, 2003

Re: Colonie, New York NL Industries Site, EPA Facility ID: NY0890137854

Dear Ms. Treffiletti:

The following are the comments of Citizens' Environmental Coalition (CEC) in response to the August 15, 2003 ATSDR Health Consultation regarding the former National Lead (or NL) Industries site, located at 1130 Central Avenue in Colonie, New York. Also attached is a petition letter to ATSDR signed by 89 people—most of whom are residents living near the NL Industries plant—which states, *"We strongly urge ATSDR to conduct a comprehensive health study of the community impacted by NL Industries pollution, with input from a community-appointed Citizen Advisory Committee."* We also note that at the last public hearing over 200 people raised their hand when asked if they wanted ATSDR to conduct a community health study. We hope you will respond to each of the residents who signed the letter petition. Thank you.

CEC agrees with the ATSDR statement on page 1, "that in the past, the uncharacterized emissions from the NL plant were a public health hazard to the community surrounding the Colonie Site."

An article in the *Schenectady Gazette* on February 6, 1980, reported that NL's uranium emissions for January 2-23, 1980, exceeded 417 microcuries. On page 11 of ATSDR's report, in bold print, there is a section heading, "How much DU was released in air emissions from the NL plant?" The answer to that question is extremely important but not provided nor is any estimate made. Can ATSDR provide any quantitative answer as to how much uranium NL might have emitted over the years? Would it be a gram, an ounce, a pound, one hundred pounds? Also, what is the range of the size of the uranium particles NL emitted? What is the shape(s) of these particles? How does the size and shape of the particle inhaled impact health?

Did ATSDR consult with the US Department of Energy, the US Army Corps of Engineers, Albany County Health Department or former NL Industries employees to determine if uranium air emission data for the years 1958-1979 exists? What happened to it? Where is it now located? Did ATSDR contact NL Industries to determine if the company has retained any stack emission records, employment records, or other information that might help quantify the uranium emissions?

On page 12 of the report, ATSDR stated: "Based on the levels of DU found in soil, and the fact that the NL plant scaled down operations during the late 1970s and early 1980s (USDOE 1989b), the earlier (pre-1979) air emissions were probably

higher." It is our understanding based upon news reports from 1979-1982 and interviews with former NL workers, that NL operations were at their peak in late 1979 and early 1980.

Can ATSDR quantify the amount of total stack emissions based on the amounts of uranium found in the soil on-site and in the surrounding community? We request ATSDR expand its exposure evaluation by doing a computer model to estimate air emissions based on the levels of DU found in the soil. This has been done at other sites, such as the Kelly site. It is critical that additional research be done to much more accurately estimate the exposure to the community. ATSDR should contact NL Industries, DOE, the Albany County Health Department, the Army Corps of Engineers and any consultants to legally request all their NL emissions information. It should also conduct an exposure evaluation on the likely air emissions based on the levels of DU found in the soil.

The ATSDR report does not comment on the exposures children might have had because of the inhalation or ingestion of DU particles that landed on the ground and then were resuspended in the air. This is a very important omission that should be corrected. There were scores of children and teenagers who lived in close proximity to the NL facility for much or all of their early years. For example, a child born in 1958 who lived within a block of the NL Industries facility until 1980 would or might have been exposed to 21 or 22 years of air emissions. How many particles of ceramic uranium oxide or other types of uranium might that person have inhaled and retained in his or her lungs? How many particles must be inhaled to cause injury? Could the inhalation of as few as one particle cause cancer or other illnesses?

ATSDR noted on page 12 of its report that the Department of Energy (DOE) regulatory soil cleanup limits "were decided for the purposes of remediation and not based on health risk or dose." DOE obviously did not remove all of the uranium NL emitted. Does the uranium that remains in the soil off-site pose a health risk to humans? This is an important question. There are many people who never walked or played on or near the NL property but who live or used to live a half-mile or a mile or two miles away from the NL site. Some of these people desire to know if there is a health risk to them from either the uranium particles they might have breathed in during the years NL operated or from any uranium that remains in the ground now. Leonard Dietz has demonstrated that uranium particles emitted from the NL factory were transported via air currents to a distance of at least 25 miles from the NL factory.

The ATSDR report stated, "Little scientific information is available regarding how touching DU or DU-contaminated soil can affect health" but then downplayed concerns about this phenomenon. (Page 12.) If little information is available, how can ATSDR be so confident that there is little risk? Children played in the dirt, played football on the NL property, sat on the ground, splashed in puddles, waded in stream, swam in the pond, dug holes in the ground and touched interesting looking and unusual objects. Having spoken to many people who lived in the NL neighborhood for part or all of their childhood and teenage years, we are aware that many children and teenagers played with pieces of radioactive debris that NL buried or discarded in the neighborhood. (We informed ATSDR of this concern in our meeting with agency officials.) If children had open wounds, cuts or scrapes in the skin, or if the DU came in contact with their eyes, nose, ears, or mouth, they could

have absorbed or inhaled DU. We believe both children and adults had substantial exposure to DU through inhalation, ingestion, and skin exposure for many, many years. Many children spent parts of many days playing on or near the NL property. These people had repeated exposures to the soil contamination in addition to the 1958-1984 air emission exposures.

Another key concern is that many children—who are the most sensitive and vulnerable to toxic chemicals—ingest soil while playing in the dirt. ATSDR stated that contacting DU contaminated soil is not expected to cause illness. However, ATSDR grossly underestimated children's exposures to soil contaminated with DU and lead by ignoring important soil ingestion studies by Dr. Edward Calabrese of the University of Massachusetts. His study found that 62% of the children at a day care center ingested 1 gram of soil a day; with 33% of the children ingesting over 10 grams of soil a day. ATSDR bases its assessment on the assumption that children ingest a much smaller amount of soil—500 or 100 milligrams per day. We request a reassessment of the health risk based on 1 and 10 grams of soil ingestion per day assuming 373 milligram per kilogram for lead and 600 picocuries per gram for DU contaminated soil.

We note that the precautionary recommendations for people concerned about not exposing themselves or their children to lead and DU contaminated soil is buried in the report. On pages 18, 19 and 27, ATSDR states that children should be tested for lead exposure and people can prevent exposures by ensuring children wash their hands after playing in dirt and peeling vegetables. Approximately 710 children 6 years and younger live within 1 mile of the NL site. ATSDR should provide clear, understandable recommendations for parents in Fact Sheets and in the beginning of the report.

Depleted uranium is radioactive. It is well known that any increased exposure to radiation causes an increased risk of cancer. Radiation exposure can also cause birth defects and weaken the immune system. ATSDR has not included many medical journal references on the hazards of radiation in its health assessment literature. ATSDR has substantially downplayed the health risks of cancer and birth defects from exposure to DU uranium. We request that ATSDR correct its report to fully include the hazards of DU radiation in its health assessment. Environmentally induced cancers can take 5 to 40 years to show up. The inadequate evaluations by the ATSDR (health consultation) and the Department of Health (cancer cluster investigations) do not do justice to addressing the community's concerns and question—what did NL's pollution do to my health? It is interesting that the priority community concern was not included in the ATSDR summary. Our organization and numerous residents told ATSDR officials that a community health study was the priority action that everyone wanted. This was not mentioned in the community concern summary in the report.

Has ATSDR attempted to speak with the hundreds of people who lived near the NL site from 1958 (when the uranium emissions began) through the 1980s (when the emissions ended and the DOE removed some of the uranium from some of the neighborhood properties?)? These residents and former residents can provide vast amounts of information about their activities, which ATSDR could use to determine uranium exposures. Some of these people also worked at NL Industries. As part of

the health consultation, ATSDR might benefit from conducting a public hearing or a series of hearings where people could provide oral and written testimony about their exposures, their knowledge of NL's operations, and their health concerns.

Did ATSDR make any effort to contact former NL Industries employees to obtain information about the day-to-day practices and manufacturing processes at the NL facility? The ATSDR report provides only skimpy and superficial information about what actually was taking place at the NL facility. Based on what ATSDR knows about NL operations, does the agency think production workers were heavily exposed to uranium? We believe there is substantial evidence that this occurred. We also believe a health study of the surviving workers is warranted. We request that ATSDR contact NIOSH and recommend that NIOSH undertake such a study. NIOSH did investigate the NL Industries plant in the 1980s and was concerned about health risks to workers.

We are concerned about the homes that have contaminated VOC vapors in their basements *above* the federal guidance levels. We request that ATSDR recommend immediate action be taken by the Army Corps to address this health risk.

In summary, we request that ATSDR redo the Health Consultation to expand and improve on the report so it provides an accurate assessment of the community's health risks. The agency needs to fully address the radioactive hazards posed by DU. The agency needs to substantially improve the emissions estimates and exposure scenarios. We also support the comments of Leonard Dietz, William Kelleher, Assemblyman Robert Prentiss and Thomas K. Simpson, and urge ATSDR to incorporate their recommendations in a new report as well. In addition, we request that ATSDR include a recommendation for a Community Health Surveillance investigation to fully evaluate exposures and adverse health outcomes or increases in illnesses, and issue recommendations to adequately address health risks and adverse health outcomes. A community-appointed Citizen Advisory Committee should have full input into the design and implementation of the health surveillance study. Thank you for considering our comments. We look forward to hearing from you.

Sincerely,

Tom Ellis
Board Chairperson
Citizens' Environmental Coalition

43 N. Pine Street
Albany, NY 12203

Anne Rabe
Representative
Citizens' Environmental Coalition

1265 Maple Hill Rd.
Castleton, NY 12033

Enclosures: Letter Petition (5 pages)

Other materials/research relevant to the Colonie site.

- Illustrations of aspects of the Colonie site, urine testing, particles emitted by the NLI plant, etc.
- 2003 DUOB extract—summary and annex on biokinetic models
- 2006 Health Physics paper on the measurement of uranium isotopes in urine
- 2008 Science of the Total Environment on the Colonie site and urine tests there
- 2009 *Journal of Atomic and Analytical Spectroscopy* paper on the Colonie uranium oxide particles and their isotope composition.

Depleted uranium (DU) and environmental health : The former National Lead Industries Colonie NY site

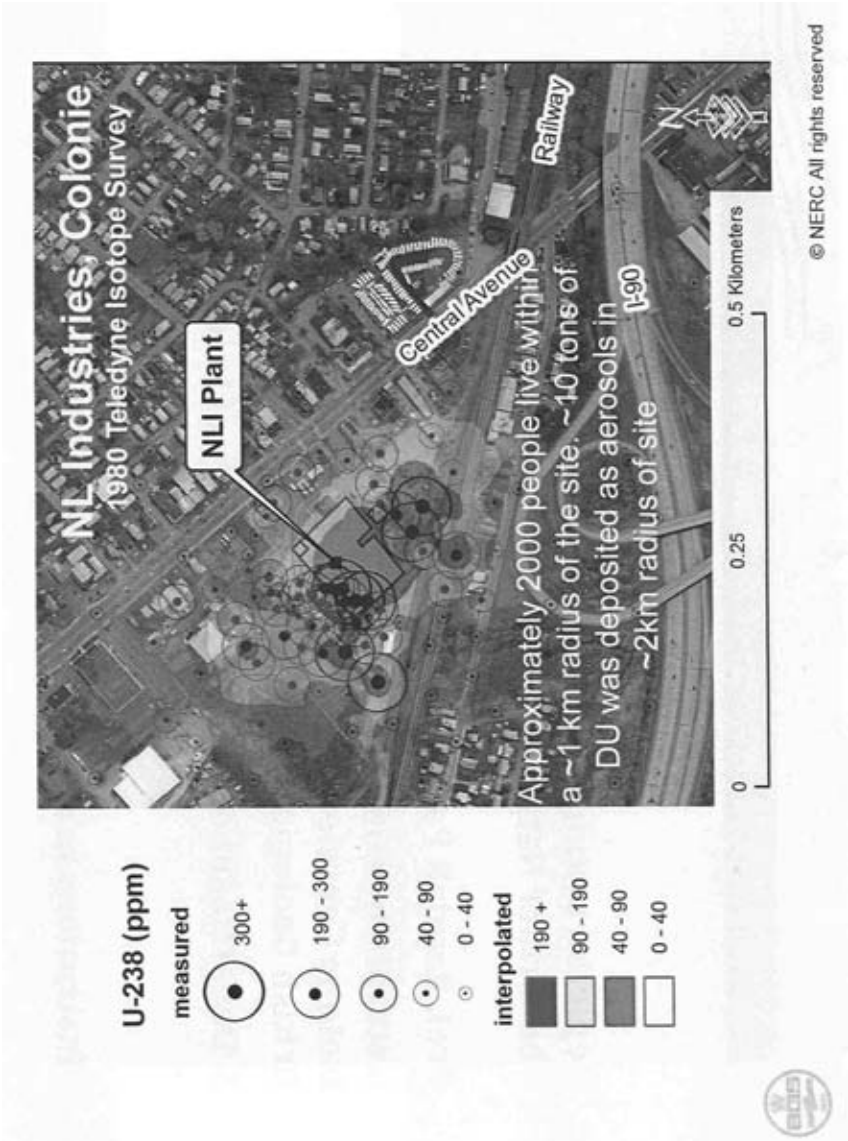
Prof. Randall Parrish

Natural Environment Research Council
Isotope Geoscience Laboratory (NIGL),
British Geological Survey

& Department of Geology, University of Leicester (UK)

Illustrations in support of 12 March 2009 testimony

NATURAL ENVIRONMENT RESEARCH COUNCIL


NL Industries, Colonie
1980 Teledyne Isotope Survey
NLI Plant
Central Avenue
Railway
I-90
Approximately 2000 people live within a ~1 km radius of the site. ~10 tons of DU was deposited as aerosols in ~2km radius of site
0
0.25
0.5 Kilometers
N
U-238 (ppm)
measured
300+
190 - 300
90 - 190
40 - 90
0 - 40
interpolated
190 +
90 - 190
40 - 90
0 - 40
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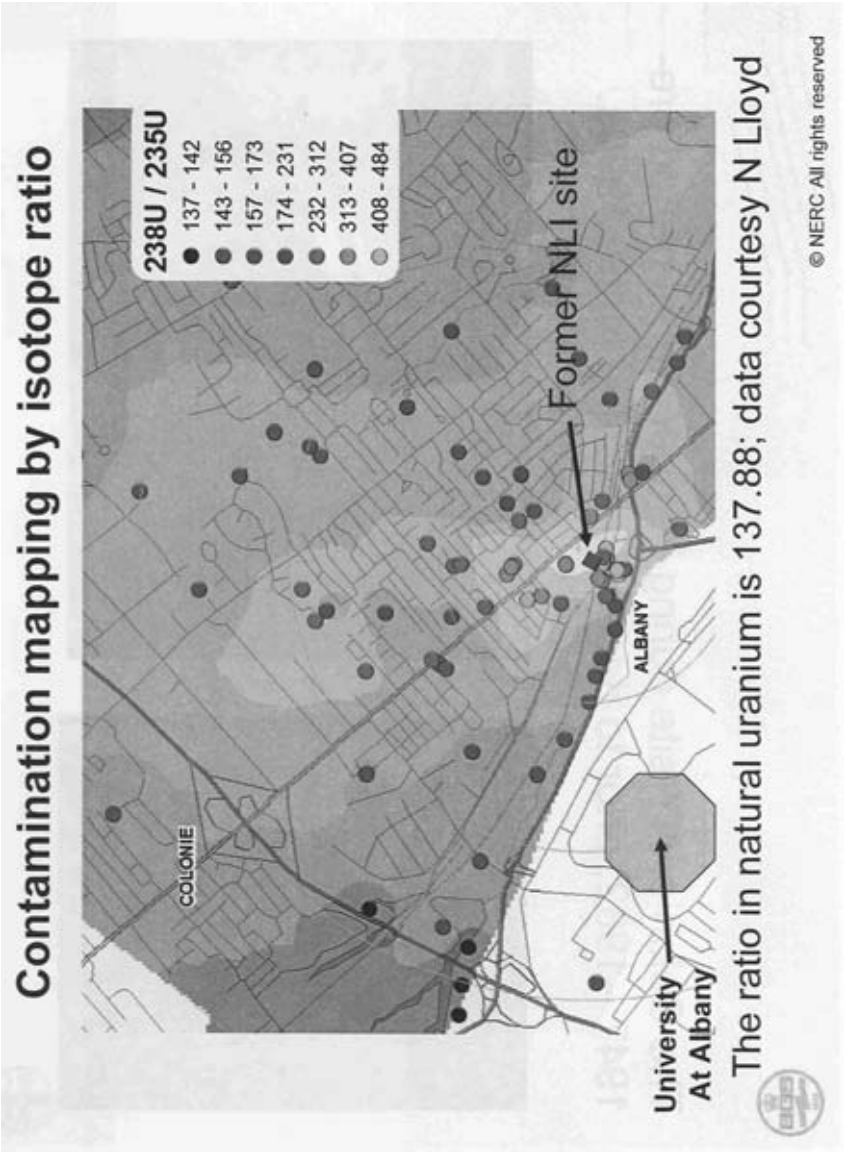
Contamination mapping by isotope ratio
238U / 235U
137 - 142
143 - 156
157 - 173
174 - 231
232 - 312
313 - 407
408 - 484
COLONIE
ALBANY
Former NLI site
University
At Albany
The ratio in natural uranium is 137.88; data courtesy N Lloyd
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The Colonie, NY site during its operational period pre-1947 –1982, prior to decommissioning in the 1990s.

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The Colonie NL site in ~2006 in final stages of remediation by ACE

Huge amount of contaminated building material and soil shipped to radioactive waste disposal sites in western US

DU particles are found in attics, basements, bark, soil near the site in community

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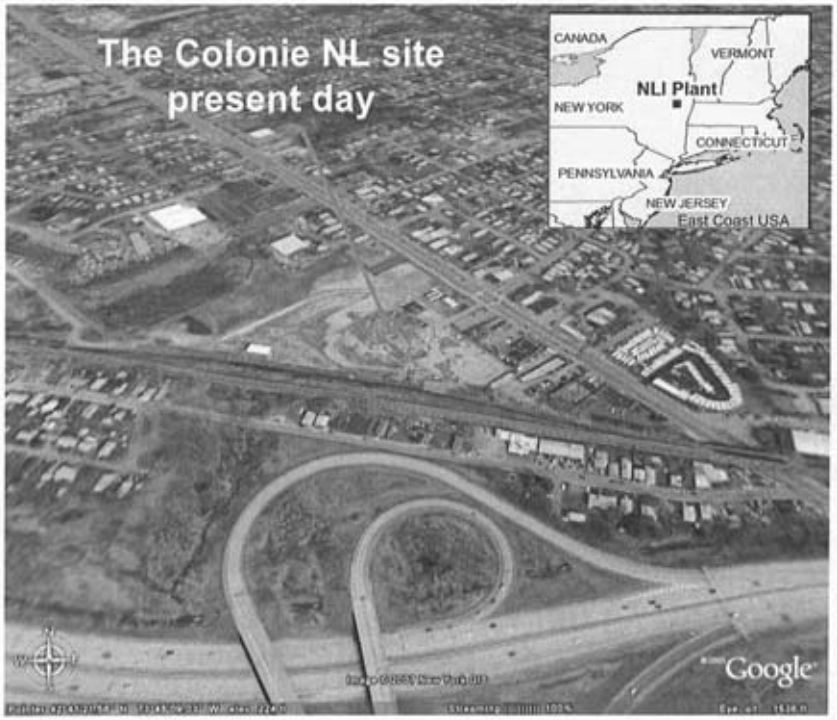

$190M has been spent remediating the site, an amount far larger than the combined resources for DU research worldwide

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A stream containing plant runoff has flowed into Patroon Lake and accumulated for more than 80 years, and it contains an archive of pollution for this time.

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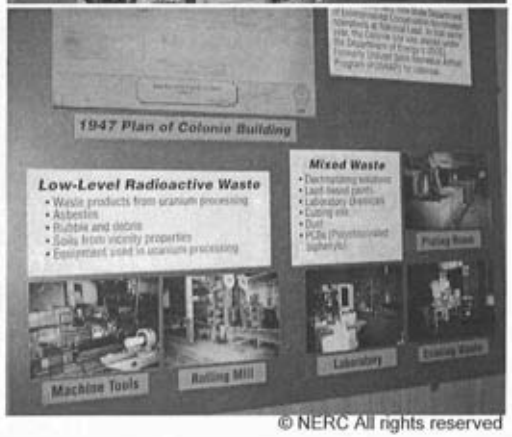
Some photos of the Colonie, NY site and its activities, from archival materials on site, ca. 2006



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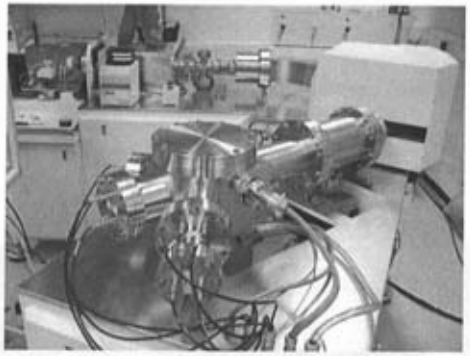
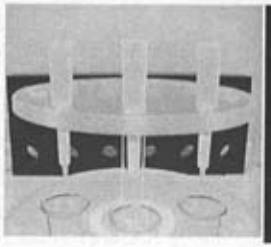
Urinary uranium isotope method at NIGL:

Urine collection in pre-cleaned bottle, away from dust sources



Multicollector ICP-MS analysis

Chemical processing in clean laboratory



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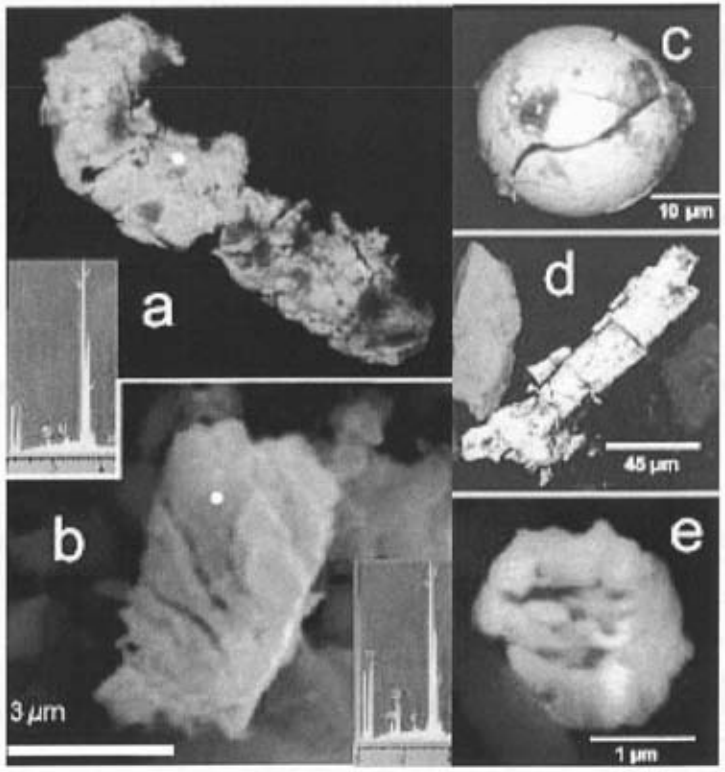
DU oxide particles originating from the NLI plant and recovered from dry household dusts, and identified using scanning electron EDS analysis.

These particles are respirable and are sufficiently small to lodge deep in the lungs.



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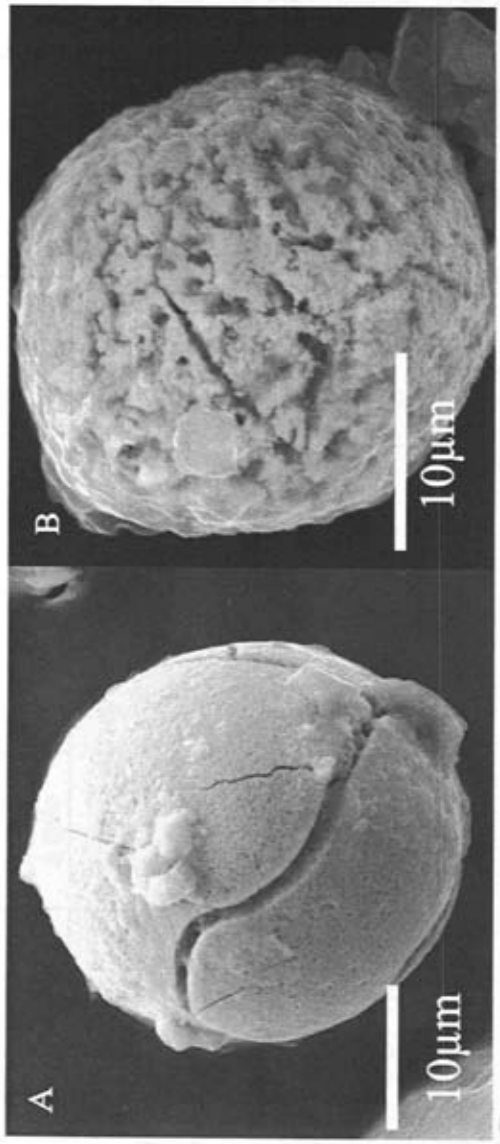
Images of DU oxide particles –
left: house dust (dry, undisturbed)
(right) from soil <10% dissolved after ~25 years
Courtesy Nick Lloyd (PhD student, U Leicester)



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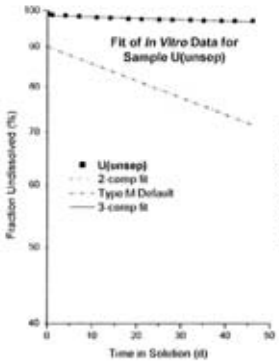
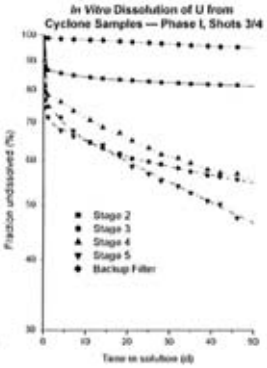
Selected data showing solubility of DU oxide particles illustrating potentially huge variability





US Army Capstone Study, 2005

Experiment	0 days % left	45days % left	1 year % left	10y, 3653d % left	27.4y, 10,000d % left
P1 3/4 BU	100	95.2	72.3	4.3	0.018
U (unsep)	100	96.8	84.9	22.1	1.6
P1 3/4 Stg2	100	56.7	27.4	0.027	4.5E-08
P1 3/4 Stg5	100	48.4	3.3	3.3E-12	2.3E-35
PIII 2I CY-4	100	90.8	89.8	89.8	89.8
PIII 2I CY-5	100	85.6	43.1	15.4	15.4
PIII 2I CY-BU	100	84.4	73.8	19.2	1.42

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Depleted Uranium Oversight Board

The solubility of inhaled DU and its influence on urine excretion

G Etherington
National Radiological Protection Board, Chilton, Didcot, Oxon, OX11 0RQ

1. Introduction

This note briefly discusses the process of absorption of inhaled material from the respiratory tract, and describes how it can be modelled. It then presents some of the available information on absorption of depleted uranium, and describes the effect of variability in absorption on urinary excretion. It is in no way intended to be a comprehensive account; for this, reference should be made to Annexes of the report of the Royal Society Working Group on the Heath Hazards of Depleted Uranium Munitions (RSWGDU) (Royal Society, 2001). Annex A give an account of the current ICRP models used to assess intakes of uranium. In addition, Annexes G and H of the RSWGDU report give summaries of the available information on the absorption characteristics (ie "lung solubility") of particulate DU resulting from penetrator impact and combustion in fires respectively.

2. Absorption from the respiratory tract

Inhaled material is cleared from the respiratory tract by three mechanisms. In regions of the respiratory tract other than the nose, clearance results from a combination of movement of particles towards the gastro-intestinal tract and lymph nodes (*particle transport*), and movement of material from the respiratory tract into the blood and then to body fluids (*absorption*). Material deposited in the nose is cleared by *nose blowing*, particle transport and absorption.

It is generally assumed that :

- all clearance rates are independent of age and sex;
- particle transport rates are the same for all materials;
- absorption into blood, which is material specific, occurs at the same rate in all regions except the front of the nose, where none occurs.

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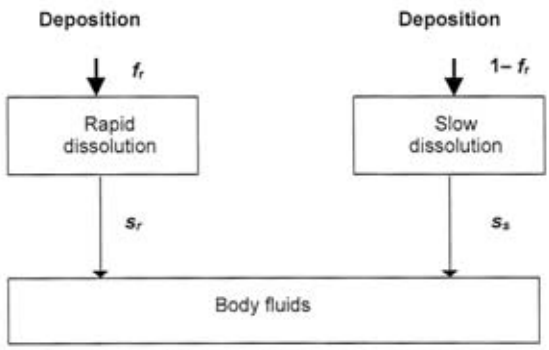
Fractional clearance rates (whether absorption or particle transport) vary with time. However, in order to simplify calculations, most models represent clearance by combinations of compartments that clear at constant rates.

3. Modelling absorption

Absorption to blood is a two-stage process: dissociation of the particles into material that can be absorbed into blood (dissolution); and absorption into blood of soluble material and of material dissociated from particles (uptake). Both stages can be time-dependent. In practice, it is found that dissolution of most materials can be represented by a simple two-compartment model (figure 1). A fixed fraction of deposited material, f_r, is available for rapid dissolution at a rate s_r, while the remaining fraction ($1 - f_r$) dissolves more slowly, at a



rate s_s. Uptake to body fluids of dissolved material can usually be treated as instantaneous. (When this is not the case, the concept of a "bound state" is employed; see Annex A, Royal Society, 2001).

Figure 1. Compartment model describing absorption to blood.

Thus, the absorption behaviour of most materials can be described by making a suitable choice of values for the three absorption parameters, f_r, s_r, and s_s. Some materials are very soluble in the lungs and are absorbed almost instantaneously (eg caesium chloride), and so have an f_r value of 1. Other materials are very insoluble in the lungs (eg plutonium dioxide) and have a very low f_r value (typically 0.001). Three default absorption types have been defined for use when material-specific information is not available, known as Type F ("fast" absorption), Type M ("moderate" absorption) and Type S ("slow" absorption). Absorption parameter values for the three default Types are given in Table 1.

Table 1. Default absorption parameter values for Type F, M, and S materials (ICRP 1994)

Type	F(fast)	M (moderate)	S (slow)

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Fraction dissolved rapidly	f_r	1	0.1	0.001
Dissolution rates:				
Rapid (d^{-1})	s_r	100	100	100
Slow (d^{-1})	s_s	-	0.005	0.0001

A rate constant of 100 d^{-1} corresponds to a half time of ~ 10 minutes; a rate constant of 0.0001 d^{-1} corresponds to a half time of ~ 7000 days.

4. Absorption of depleted uranium

A number of studies have been conducted to determine absorption parameter values for uranium oxides produced during the manufacture of nuclear fuel. Results are summarised in Table 2.

Table 2. Summary of absorption parameter values for uranium oxides

	Absorption parameters			
Compound[a]	f_r	s_r (d^{-1})	s_s (d^{-1})	Reference
UO_4	0.87	0.93	0.024	Ansoborlo et al 2001
UO_3	0.75	14	0.02	Bailey et al 1998
UO_3	0.92	1.4	0.0036	Hodgson et al 2000
UO_3	0.71	0.28	0.0011	Ansoborlo et al 2001
U_3O_8	0.044	0.49	0.00035	Hodgson et al 2000
U_3O_8	0.046	2.3	0.0012	Ansoborlo et al 2001
U_3O_8	0.03	2.1	0.00038	Ansoborlo et al 2001
UO_2 – Non-ceramic	0.011	0.95	0.00061	Hodgson et al 2000
UO_2 – Ceramic	0.008	1.3	0.00026	Hodgson et al 2000
UO_2	0.03	1.3	0.0015	Ansoborlo et al 2001
UO_2	0.01	nd	0.00049	Ansoborlo et al 2001
UO_2	0.01	nd	0.00058	Ansoborlo et al 2001

Note. See (Royal Society, 2001) for full references.

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It can be seen that the different oxides have a very wide range of absorption characteristics. The chemical form of particulate DU produced as a result of its use in munitions depends on the conditions of formation. Particles formed by impacts are reported to be a mixture of U_3O_8 and UO_2 (but predominantly U_3O_8), while combustion produces an oxide which is almost entirely U_3O_8 (Royal Society, 2001). However, there remains uncertainty as to the absorption behaviour of DU formed as a result of its use in munitions, because of factors such as particle size distribution and the presence of other elements.

Human Respiratory Tract Model (HRTM) (ICRP, 1994) parameter values appropriate for a wide range of possible DU exposure scenarios are discussed in the RSWGDU report (Royal Society, 2001). Central estimates of DU parameter values appropriate for Level II or Level III inhalation of resuspension aerosols (impact or combustion) occurring within a vehicle are shown in Table 3. Also shown are parameter values describing the likely upper and lower limits of absorption. Broadly, the parameter values given in Table 3 for "Low absorption" and "High absorption" are equivalent to the values given in Table 15, Appendix 1 of the RSWGDU report for "Worst-case (radiation)" and "Worst-case (chemical toxicity)", respectively. However, there are some small differences in the data given in the two Tables because in this note we are concerned with predicting the upper and lower limits of urinary excretion per unit intake, whereas Table 15, Appendix 1 of the RSWGDU report is concerned with predicting upper limits on dose per unit intake and chemical toxicity.

Table 3. HRTM model parameters for Level II / III inhalation of resuspension DU aerosols (see text)

Parameter	Central estimate	"Low" absorption	"High" absorption
Rapid dissolution fraction, f_r	0.2	0.005	0.5
Rapid dissolution rate, s_r, d^{-1}	1	0.4	14
Slow dissolution rate, s_s, d^{-1}	0.001	0.0001	0.0015
Subject exercise level	Heavy worker	Heavy worker	Heavy worker
Aerosol activity median aerodynamic diameter, µm	5 (default workplace)	5	1
Aerosol geometric standard deviation	2.5 (default)	2.5	4
Particle density ρ, g cm^{-3}	9	9	11
Gut uptake factor, f_1	0.002	0.002	0.02

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5. Urinary excretion of DU

Figure 2 shows daily urinary excretion calculated using the HRTM for the three scenarios described in Table 3. As can be seen, the range spans almost two orders of magnitude at earlier times, but the rates converge at times later than about 500 days.

This figure illustrates the effect on urinary excretion of variability or uncertainty in HRTM model parameters. An additional source of uncertainty in urinary excretion is uncertainties in systemic model parameter values. NRPB is currently planning a study to investigate uncertainties in DU urinary excretion arising from uncertainties and variability in both HRTM and systemic model parameter values.

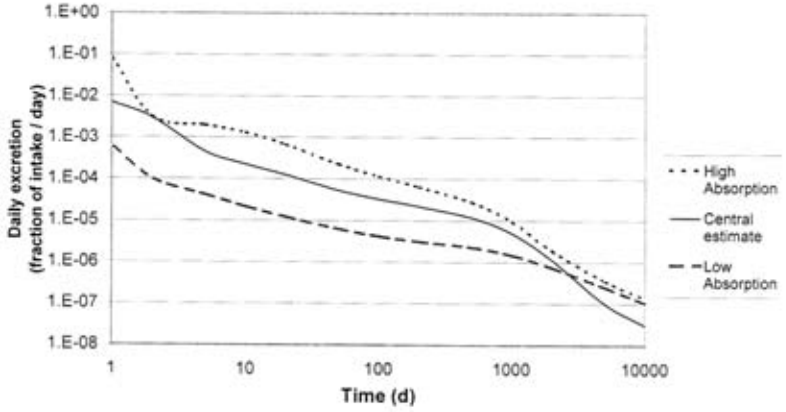

Figure 2. DU urinary excretion rates, calculated using the HRTM using the parameter values given in Table 3.

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References

ICRP (1994). Human Respiratory Tract Model for Radiological Protection. ICRP Publication 66, Annals of the ICRP, **24**, No. 1-3. Oxford, Pergamon Press.

Royal Society (2001). The Health Hazards of Depleted Uranium Munitions, Part 1. Policy Document 6/01. London, Royal Society.

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Paper

DETERMINATION OF $^{238}U/^{235}U$, $^{236}U/^{238}U$ AND URANIUM CONCENTRATION IN URINE USING SF-ICP-MS AND MC-ICP-MS: AN INTERLABORATORY COMPARISON

Randall R. Parrish,* Matthew F. Thirlwall,† Chris Pickford,‡§ Matthew Horstwood,** Axel Gerdes,**†† James Anderson,‡ and David Coggon‡§

Abstract—**Accidental exposure to depleted or enriched uranium may occur in a variety of circumstances. There is a need to quantify such exposure, with the possibility that the testing may post-date exposure by months or years. Therefore, it is important to develop a very sensitive test to measure precisely the isotopic composition of uranium in urine at low levels of concentration. The results of an interlaboratory comparison using sector field (SF)-inductively coupled plasma-mass spectrometry (ICP-MS) and multiple collector (MC)-ICP-MS for the measurement of uranium concentration and $^{235}U/^{238}U$ and $^{236}U/^{238}U$ isotopic ratios of human urine samples are presented. Three urine samples were verified to contain uranium at 1–5 ng L^{-1} and shown to have natural uranium isotopic composition. Portions of these urine batches were doped with depleted uranium (DU) containing small quantities of ^{236}U, and the solutions were split into 100 mL and 400 mL aliquots that were subsequently measured blind by three laboratories. All methods investigated were able to measure accurately $^{236}U/^{238}U$ with precisions of ~0.5% to ~4%, but only selected MC-ICP-MS methods were capable of consistently analyzing $^{236}U/^{238}U$ to reasonable precision at the ~20 fg L^{-1} level of ^{236}U abundance. Isotope dilution using a ^{233}U tracer demonstrates the ability to measure concentrations to better than ±4% with the MC-ICP-MS method, though sample heterogeneity in urine samples was shown to be problematic in some cases. MC-ICP-MS outperformed SF-ICP-MS methods, as was expected. The MC-ICP-MS methodology described is capable of measuring to ~1% precision the $^{236}U/^{238}U$ of any sample of human urine over the entire range of uranium abundance down to <1 ng L^{-1}, and detecting very small amounts of DU contained therein.**

Health Phys. 90(2):127–138; 2006

Key words: accident analysis; uranium; weapons; radiation, ionizing

INTRODUCTION

Depleted uranium (DU) is a by-product of the manufacture of enriched uranium for use as a fuel in nuclear reactors and in nuclear weapons. It has a $^{238}U/^{235}U$ atomic ratio of up to ~500 as compared with 137.88 for natural uranium, and is ~70% more dense than lead. The latter property along with its hardness has been exploited in various specialized applications in engineering. In addition DU has been used militarily in the armor plating of tanks, and in armor-piercing anti-tank weapons. Such weapons were employed by American and British forces in the 1991 Gulf War, by American forces during operations in Bosnia in 1994–1995 and Kosovo in 1999, and by American forces in the conflict in Iraq that began in 2003.

Because of their effectiveness in combat, DU weapons can reduce battlefield casualties among the forces that use them. At the same time, however, they could pose longer term risks to health and the environment from ionizing radiation (DU is a relatively weak alpha emitter) and through chemical toxicity (WHO 2001; Royal Society 2001). As with any hazardous substance, the health risk will depend on the pathway and extent of exposure. While some soldiers have been exposed to DU as a consequence of shrapnel wounds by fragments of metallic DU, the main DU exposure pathways are inhalation of relatively insoluble oxidized uranium particles formed by combustion when a DU round strikes an armored target, and ingestion of DU-contaminated food and water.

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In Britain, there has been concern among some veterans of the campaigns in the Persian Gulf and Balkans that exposure to DU has impaired their health or significantly increased their risk of cancer and other diseases. In response, the British Government in 2002 undertook to provide a scheme of retrospective testing for veterans who wished to know whether and to what extent they had been exposed to DU, and appointed an independent committee (the Depleted Uranium Oversight Board, DUOB, www.duob.org.uk) to oversee development of the testing program. It was agreed by the DUOB at an early stage that the most practical method of assessing past exposure was likely to be by measurement of uranium isotopes and concentrations in urine, this being a non-invasive procedure.

Inhaled particles of uranium oxide may be retained in the lung and associated lymph nodes, where they undergo slow dissolution in tissue fluids over the course of many years (Royal Society 2001). Soluble uranium species will be excreted by the kidney (adding to the normal low-level excretion of uranium derived from dietary sources), though a small proportion will be incorporated into the crystalline bone structure (Leggett and Pellmar 2003). Because the uranium is depleted, the $^{238}U/^{235}U$ ratio in the urine would be elevated. It should therefore be possible to estimate the daily excretion of DU by measuring the $^{236}U/^{235}U$ ratio and overall rate of uranium excretion in urine, provided the isotopic composition of DU is known.

Detection of DU exposure after an interval of 10 to 15 y is methodologically challenging because the total uranium concentration in urine will commonly be less than 10 ng L^{-1} and the perturbation in isotope ratio may be small. Several laboratories have reported measurements of uranium isotope ratios in the urine of Gulf War veterans (Durakovic et al. 2002; Hooper et al. 1999; Gwiazda et al. 2004). However, the analytical methods used in these studies vary greatly, and the ability to make precise and reproducible measurements at low concentrations of uranium in urine has not been demonstrated. In part, these studies (Gwiadza et al. 2004) involved individuals with retained shrapnel whose uranium levels in urine were relatively high.

To help in the planning of the UK DU testing program, we therefore conducted a study to explore the sensitivity and accuracy with which uranium concentrations and isotope ratios can be measured in urine, comparing results from three laboratories based on different analytical techniques, but all using mass spectrometry more advanced than quadrupole ICP-MS. In addition to the $^{238}U/^{235}U$ ratio, we also attempted to assess the $^{236}U/^{238}U$ ratio, since ^{236}U is generally a contaminant in DU (Royal Society 2001); ^{236}U should not be detectable in uranium from natural sources, except at extremely low levels ($^{236}U/^{238}U \leq 10^{-10}$; Berkovits et al. 2000).

MATERIALS AND METHODS

Overview of experimental design

The study involved three laboratories, the United Kingdom Natural Environment Research Council Isotope Geosciences Laboratory (NIGL), Scientifics Ltd. (Harwell), and the Isotope Geochemistry Laboratory of the Geology Department, Royal Holloway University of London (RHUL). Each of these laboratories prepared a batch of urine that was measured to be homogeneous and of natural isotopic composition, within uncertainty. Each laboratory split each batch of urine into three sub-equal portions; one was left untouched, while the other two were spiked with a specially prepared solution of DU (from metal) to achieve target $^{238}U/^{235}U$ isotope ratios specified by the DUOB. Laboratories were told the target ratios only for their own batches of urine and not for those of the other two laboratories. Each laboratory then prepared three separate 500 mL aliquots of each of these three solutions. These were then transported to a central facility (Department of Earth Sciences, University of Oxford) and were coded. A set of nine samples (one from each batch) was then supplied to each laboratory for analysis of the total uranium concentration and the $^{238}U/^{235}U$ and $^{236}U/^{238}U$ (atomic) isotope ratios with 95% confidence intervals. The NIGL and RHUL laboratories were asked to carry out two sets of analyses on each sample, one using 400 mL and one using 100 mL. It was agreed that Harwell would perform two analyses, each on 50 mL aliquots of the samples, consistent with their standard analysis protocols. The results of these "blind" analyses, and also those from preliminary checks that each laboratory made on the spiking solution and in the preparation of its three urine batches, were forwarded to the last author (DC) for statistical analysis in which the codes were broken and the data collated.

Preparation of spiking and reference solutions

Two uranium reference solutions were specially prepared for this project by NIGL, namely natural uranium metal (CRM112a) whose assay and isotopic composition are well established (U.S. DOE 2002), and DU metal supplied by Goodfellow Industries (Cambridge, UK). An appropriate quantity of each was obtained, cleaned in ultrapure water and HNO_3 and dried in clean air conditions. Metals were precisely weighed, dissolved in ultrapure HNO_3 and brought up to a specifically known mass, allowing a calculation of the gravimetric concentration of U in the solution, taking into account the

purity of the assay, if known (i.e., for CRM112a). Dilution was intended to result in a target concentration of 500 pg g^{-1} for the diluted DU solution, termed DU-D, and 10 ng g^{-1} for the natural U solution, termed NU-C. A high purity ^{233}U tracer (from National Physical Laboratory, Teddington, UK) was provided to NIGL by RHUL and its isotopic composition measured and its concentration re-determined by isotope dilution using the CRM112a solution as a reference. To calibrate the concentration and the purity of the assay of the Goodfellow DU solution, admixtures of the ^{233}U tracer and the DU solution were measured by mass spectrometry.

Methods of laboratory analysis

Harwell Scientifics: Sector Field (SF)-ICP-MS. Using standard procedures at the Harwell laboratory, the 500 mL samples were treated as a source of two duplicate, 50-mL samples. The remaining ~400 mL of solution was saved.

After addition of a ^{233}U spike, a phosphate precipitation step in non-acidified urine was carried out, centrifuged, and followed by two washing steps. The phosphate precipitate was then dissolved in nitric acid and deionized water and diluted back to the original volume (50 mL) ready for analysis. Semiconductor grade nitric acid and deionized water were used.

Table 1 lists the instrumental and chemical processing parameters for each of the three laboratories involved in this study. At Harwell, each sample was analyzed using a SF-ICP-MS operated with an ultrasonic nebulizer using a single-collector ion counting detector system, with rapid mass scanning. The concentration of uranium was calculated from the relative response of ^{233}U to ^{238}U, and compared to the response of ^{233}U spiked natural uranium standard with each batch of samples. Typical limits of detection in urine "as analyzed" for ^{235}U and ^{238}U were 0.1 pg L^{-1}. The limit of detection for ^{236}U was typically 5 pg L^{-1}. The total reagent blank was estimated as 5 pg or less for the 50 mL of urine used for analysis.

All isotope composition measurements were normalized relative to the measured $^{238}U/^{235}U$ of a natural uranium reference material (uranium metal EC101 from IRMM, Geel, Belgium), a procedure that also corrects for mass bias (typically 1–2% for the $^{236}U/^{238}U$ ratio), to achieve the natural isotope ratio for $^{238}U/^{235}U$ of 137.9 on standards.

Uncertainties in isotope composition measurement and uranium concentration were estimated from the long-term reproducibility of uranium measurements in synthetic and other urine solutions rather than from individual measurements, and may in low concentration samples be underestimated.

RHUL: Collision cell multicollector (MC)-ICP-MS. Uranium isotopic analysis of urine at RHUL was accomplished by evaporation and ashing of the supplied urine sample followed by chemical separation of uranium using Eichrom TRU resin (Eichrom Europe, Bruz, France). Reagents used were high purity sub-boiling

Table 1. Summary of instrument and chemical procedures parameters.

Laboratory	Harwell	RHUL	NIGL
Instrument	Plasma Trace2 SF-ICP-MS	Micromass Isoprobe MC-ICP-MS Collision cell	VG Elemental P54 MC-ICP-MS Double focusing
Nebulizer	CETAC ultrasonic	ESI PFA50	ESI PFA50
Spray chamber	CETAC desolvating membrane	Aridus desolvating spray chamber	Aridus desolvating spray chamber
Scan mode	E scan	Both magnet static and magnet mass switching	Magnet mass switching
Sensitivity for U	5,000,000 cs^{-1} ppb^{-1}	7,500,000 cs^{-1} ppb^{-1}	3,000,000 cs^{-1} ppb^{-1}
Sample uptake	1 mL min^{-1}	50 μL min^{-1}	50 μL min^{-1}
Number of scans	5 replicates × 10 sweeps	10–15	30
Dwell time per mass			
^{238}U	400 ms	Simultaneous to 235 and 236	12 s, simultaneous to 233, 235, & 236
^{235}U	2,000 ms	10 s	12 s, simultaneous to 238
^{236}U	2,000 ms	10 s	7 s, simultaneous to 233, 238
^{233}U	400 ms	Simultaneous to 235 and 236	12 s, simultaneous to 238
Mass resolution	300	400	400
Detector(s)	Ion counting electron multiplier	Ion counting Daly photomultiplier and multiple Faraday cups	Ion counting Daly photomultiplier and multiple Faraday cups

distilled acids, prepared mainly in-house. Uranium solutions were analyzed on a single focusing MC-ICP-MS with Ar-gas collision cell, with instrumental parameters shown in Table 1.

For each 500-mL urine sample, ~400 mL and ~100 mL urine aliquots were prepared. The ~100 mL aliquot was the second aliquot taken from the sample bottle, and included a rinse of the sample bottle in concentrated HNO_3, which dissolved black particulate residues adhering to the bottle walls. This allowed investigation as to whether significant uranium was held in these particulate residues. Urine aliquots and ^{233}U spiked samples were weighed into quartz-glass beakers and evaporated. Preliminary ashing of urine samples and quartz-glass blanks was carried out on a ceramic hotplate in a fume cupboard at up to 500 °C. Final ashing to a white residue was initially carried out in a furnace at 450 °C for 8–12 h, but samples prepared later were instead treated to 2–3 repeat hotplate ashings interspersed by evaporation with 10–15 mL HNO_3, which appeared to be sufficient to destroy all organic material. Uranium was separated from the resultant solution using two passes through Eichrom TRU resin in disposable polypropylene ion exchange columns, collected into Teflon beakers. Uranium chemical recovery was >70% for samples ashed in the furnace but sometimes as low as 10% for samples ashed on the hotplate. Eluted uranium was converted to nitrate and dissolved in 2% HNO_3 for analysis. Isotopic measurements were made using both static multicollector with mixed ion counting and Faraday detectors, and in magnet switching multiple collection mode. Corrections were made to measured uranium intensities using similar methods to Seth et al. (2003), including a memory correction based on analysis of the 2% HNO_3 used to dissolve the samples.

The limit of detection on a Faraday cup is 83 fg g^{-1} of any uranium isotope in solution (determined by the noise on the Faraday amplifier), and for the Daly ion counting system 1.0 fg g^{-1} in solution, determined by the noise on the 10–50 counts s^{-1} organic memory observed at most high masses (Seth et al. 2003). Uncertainties in the reported isotope ratios were the result of propagating the counting statistics of peak and background measurements together with estimates of uncertainties in the mass bias and Daly gain correction. Errors in concentrations additionally included an estimate of weighing uncertainty. No attempt was made to correct for blank, or to incorporate blank correction uncertainty into the overall uncertainties because of low chemical recoveries. As a result, some of the uncertainties reported may be slightly to somewhat underestimated.

NIGL: Double-focusing multicollector (MC)-ICP-MS. The 400-mL and 100-mL aliquots of samples were acidified and spiked with a ^{233}U tracer. Reagents were purified in-house and supplemented by commercial reagents (Romil Ltd, Cambridge, UK). For 400-mL samples, uranium was co-precipitated with calcium phosphate whereas for 100 mL samples the total urine sample was evaporated to dryness. Dried residues were ashed using concentrated HNO_3 and 30% H_2O_2 on a hotplate with temperatures up to ~170 °C, until nearly white in color. The remaining U-bearing salts were dissolved in 3M HNO_3 and, using Eichrom UTEVA resin, were separated and purified by ion exchange chromatography, and converted to 2% HNO_3 for mass spectrometry. The recovery of uranium from this procedure was mainly 80–100%. Multiple blanks on the two procedures showed a total range from 13–59 pg, and the blank corrections applied to the data were 16 ± 5 pg for co-precipitation and 42 ± 13 pg for evaporation.

Mass spectrometry utilized a double focusing MC-ICP-MS equipped with multiple Faraday cups and an axial ion counting Daly photomultiplier detector set behind the Faraday cup array beyond a 30 cm electrostatic analyzer (ESA), in magnet switching multiple detector mode. Uranium standards (CRM950 and SRMU010) were used to correct for mass bias, abundance sensitivity, hydride production, non-linearity of the ion counting detector, and multiplier gain. Peak switching was employed to measure ^{236}U and ^{235}U in the ion counting system with other peaks measured in Faraday cups.

Uncertainties for final ratios were propagated by quadratic weighted additions of all relevant sources of uncertainty, including uncertainty in the blank. The limits of detection in the measured solutions were estimated as 0.2 ppt for ^{238}U, 0.01 ppt for ^{235}U, and 0.002 ppt for ^{236}U, these being constrained by blank corrections and detector noise.

Predicted values of spiked samples

In attempting to spike solutions to reach the specified "target" values, the three laboratories used their measured urine batch concentrations and the concentration and isotopic composition of the DU-D solution. The best estimate of the composition and concentration of the spiked urines can be calculated using the most precise measurements for the unspiked concentrations of each three unspiked urines and the mass of DU-D added to each. These calculations are outlined in the Appendix, and the predicted values are listed in relevant tables. Harwell did not report predicted values.

RESULTS

Table 2 reports the measurements on the DU-D solution used for spiking the urine batches, with a range from ~460–670 ppt. Harwell only provided limited data on these reference solutions. The differences in measured concentrations of aliquots of DU-D solutions were unexpected. Harwell values are lower than NIGL by an amount similar to other comparable concentration measurements and suggest a bias, further mentioned below. The higher value at RHUL appears to result from either unintended evaporation or heterogeneity in the DU-D solution; its concentration was carefully measured using other standards prior to spiking so that analyses on urine samples are directly comparable.

Table 3 reports the measured concentrations of uranium for the three unspiked batches of urine, with the pre-distribution values being a mean of 2 or 3 measurements. Uranium concentrations reported by RHUL are systematically higher in the 100 mL aliquots compared with the 400 mL aliquots, sometimes by a factor of >2. This is true also for RHUL data for the spiked urine samples discussed later. Our preferred explanation is that higher uranium contents in the 100 mL fractions are due to the dissolution of the particulate organic material in the HNO_3 rinse of the bottle that was incorporated into the 100 mL fraction. If so, the true uranium concentration of the urine sample may be calculated from the total uranium mass in both fractions divided by the total mass of urine: this is reported as "total conc." in Tables 3 and 5. This total uranium content agrees to within ~3% or better with the predicted uranium contents of the spiked samples, and with NIGL measurements that in themselves agree to within ~3% (e.g., samples F and H). This suggests that in some samples a significant fraction of uranium was incorporated into particulate organics that adhered to the sample container walls. The values from Harwell on 50 mL urine aliquots are internally consistent but on average about 10% lower than the other two laboratories, a similar discrepancy as that measured for the uranium concentration of the DU-D solution relative to that at NIGL (Table 2), possibly the result of a systematic bias at Harwell or other unknown factors.

Table 3. Uranium concentration in unspiked urine samples.[a]

Solution	NIGL (pg g^{-1})	Harwell (pg g^{-1})	RHUL (pg g^{-1})
A			
– pre-distribution	1.57 (24–42%)	—	—
– 400 mL	1.51 (92%)	1.4	1.52 (11%)
– 100 mL	1.42 (88%)	1.3	1.74 (27%)
			total conc. = 1.57
F			
– pre-distribution	—	1.1	—
– 400 mL	1.33 (58%)	1.2	0.99 (6%)
– 100 mL	1.31 (65%)	1.2	2.16 (13%)
			total conc. = 1.26
X			
– pre-distribution	—	—	5.10 (86%) n = 1
– 400 mL	5.11 (100%)	4.8	5.08 (89%)
– 100 mL	4.96 (94%)	4.5	5.33 (10%)
			total conc. = 5.14

[a] Batch mean concentrations (excluding the one unsatisfactory measurement) were: A, 1.49 pg g^{-1}; F, 1.18 pg g^{-1}; X, 5.01 pg g^{-1}. % values in brackets for RHUL and NIGL data represent % uranium recovery from the column procedure; Harwell recoveries not provided. Harwell measurements were made on 50 mL aliquots of urine instead of 100 mL or 400 mL. Densities of urine were assumed to be 1.0.

[b] NB 100 mL analyses at RHUL included a rinse of remaining solid residue in the bottle with sub-boiled HNO_3; dissolution of this residue best explains the higher concentrations in the 100 mL fractions. "Total conc" = total pg uranium determined in both fractions divided by total mass of the two fractions.

Table 2. Analysis of spiking solution (DU-D) and CRM112a (NU-C).[a]

Parameter	NIGL	Harwell	RHUL
DU-D spiking solution			
Uranium concentration (pg g^{-1})	502 ± 0.046% (n = 3)	462 (uncertainties not provided)	661.82 ± 0.4% (n = 2) ^{235}U
			670.3 ± 0.4% (n = 1) ^{238}U
^{238}U/^{235}U atomic ratio	286.39 ± 0.132% (n = 6)	291.6 ± 3.0%	286.76 ± 0.047% (n = 2) DS
			286.76 ± 0.16% (n = 6) F,ext
			288.8 ± 0.6% (n = 2) D,ext
^{236}U/^{235}U atomic ratio	0.0001771 ± 0.46% (n = 6)	Not analyzed	0.000176 ± 2.6% (n = 1) D
			0.000177 ± 8% (n = 4) F
^{234}U/^{235}U atomic ratio	0.0000232 ± 0.64% (n = 6)	Not analyzed	0.0000231 ± 2% (n = 3) D
CRM112a solution NU-C			
Uranium concentration (pg g^{-1})	9924 (gravimetric)	Not analyzed	10110 ± 0.4% (n = 1) ^{238}U
^{238}U/^{235}U atomic ratio	137.95 ± 0.24% (n = 6)	Not analyzed	138.08 ± 0.16% (n = 1) F,ext
^{236}U/^{235}U atomic ratio	<4 × 10^{-9}	Not analyzed	<0.00000008 (n = 10) D
			<0.000008 (n = 1) F
^{234}U/^{235}U atomic ratio	0.0000532 ± 3.0% (n = 3)	Not analyzed	Not analyzed

[a] The figures in parentheses are the number of analyses. Uncertainties on Royal Holloway data are observed 2 sd of the population for >1 analysis, or propagated 2 se of a single analysis, whichever is worst. D and F signify minor isotope measurement on the Daly electron multiplier or Faraday cup, respectively. DS signifies mass bias correction using a ^{235}U-^{236}U double spike, ext signifies external mass bias correction using bracketing standards. Concentrations were determined either using a ^{235}U or a ^{236}U spike as indicated.

There was no indication that the blind measurements made after the urine samples had been distributed differed systematically from those made before distribution (in spite of several weeks storage), or that the 400 mL samples provided markedly more reliable measurements than the 100 mL samples (apart from the RHUL caveat above).

Table 4 and Fig. 1 report measured $^{238}U/^{235}U$ atomic ratios in the unspiked batches of urine. Excluding one poor measurement, values ranged from 134.5 to 140.4, with a weighted mean of 137.85 ± 0.34 [2 standard error (SE) weighted mean, $n = 20$], consistent with the natural uranium value. Six analyses fell outside of the natural value within the errors reported, suggesting that uncertainties may have been somewhat underestimated by all laboratories.

Table 5 shows the uranium concentrations measured in spiked samples of urine. Taking the total concentration as measured by pooling the two RHUL measurements, RHUL and NIGL values agree within ~4%, but Harwell values are 9.3 ± 3.3% lower than the mean of NIGL and RHUL measurements. The systematically slightly higher total concentrations measured at RHUL are broadly consistent with the 1.9% higher concentration reported at RHUL for NU-C (Table 2) combined with the fact that RHUL data are not blank-corrected. The differences in concentration between the 100 mL and 400 mL aliquots at RHUL suggest that it may not be easy to reproduce routinely the concentration of uranium in urine by measurement of single aliquots. Agreement to ~2–3% for uranium in urine may be the best reproducibility that can be routinely achieved.

Table 6 presents the measured $^{238}U/^{235}U$ atomic ratios in spiked urine samples. For batch C (spiked with DU-D at NIGL), the predicted ratio and all of the measured ratios, including that obtained before samples were coded and distributed, were higher than the target, a result of adding too much DU-D spike on the basis of a lower quality measurement of unspiked urine uranium concentration. Otherwise, ratios were very close to the target and the "predicted" values. All but one of the NIGL and RHUL results are within ~1% of the batch means for these two laboratories combined, though it is clear that some of the measurements lie outside of agreement at the 95% confidence level, suggesting again a modest underestimation of uncertainty in some analyses. Harwell results showed a wider scatter, with results for a single batch of urine varying by up to 2.5% from the laboratory mean for that batch. When compared with the batch means for NIGL and RHUL combined, 9 of the 14 measurements made by Harwell differed by more than 1%, and six by more than 2%, with the best agreement for those urines having highest uranium concentration (Y, Z).

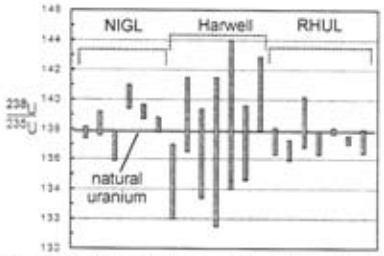

Fig. 1. $^{238}U/^{235}U$ of unspiked samples measured in this study with reported 95% uncertainties. The analyses of the three separate laboratories are identified. The value for natural uranium is indicated as the horizontal line.

Table 4. $^{238}U/^{235}U$ atomic ratio in unspiked urine samples.[a]

Solution	NIGL	Harwell	RHUL
A			
– pre-distribution	137.8 ± 0.4 ($n = 3$)	—	—
– 400 mL	138.4 ± 0.8	134.5 ± 2.5	137.2 ± 0.9
– 100 mL	136.8 ± 1.0	139.0 ± 2.5	136.6 ± 0.7
F			
– pre-distribution	—	136.4 ± 3.0	—
– 400 mL	140.2 ± 0.8	136.5 ± 5.0	138.5 ± 1.7
– 100 mL	[130.9][b]	139.0 ± 5.0	137.1 ± 0.8
X			
– pre-distribution	—	—	137.9 ± 0.2 ($n = 1$)
– 400 mL	139.2 ± 0.5	137.1 ± 2.5	137.3 ± 0.3
– 100 mL	138.3 ± 0.5	140.4 ± 2.5	137.2 ± 0.8
Mean ± 2 sd	138.5 ± 2.3	137.6 ± 4.0	137.4 ± 1.2

[a] Uncertainties are the 95% confidence intervals reported by each laboratory and are propagated 2 se for single analyses. Pre-distribution values are 2 se for 2 or 3 measurements.
[b] Measurement recognized to be unsatisfactory at the time it was made, excluded from the mean value.

Table 5. Uranium concentration in spiked urine samples.[a]

Solution	Predicted[b]	NIGL (pg g^{-1})	Harwell (pg g^{-1})	RHUL (pg g^{-1})
B				
– pre-distribution	1.67	1.61 (n = 3, 43–64%)	—	—
– 400 mL		1.63 (100%)	1.4	1.59 (17%)
– 100 mL		1.49 (100%)	1.4	1.73 (34%)
				total conc. = 1.62
C				
– pre-distribution	1.92	1.93 (52–78%)	—	—
– 400 mL		1.83 (100%)	1.6	1.96 (16%)
– 100 mL		1.76 (83%)	1.7	2.10 (59%)
				total conc. = 1.99
G				
– pre-distribution	N/A	—	1.3	—
– 400 mL		1.27 (72%)	1.2	1.22 (4%)
– 100 mL		1.23 (55%)	1.2	1.60 (10%)
				total conc. = 1.31
H				
– pre-distribution	N/A	—	2.2	—
– 400 mL		2.14 (100%)	2.1	1.85 (12%)
– 100 mL		2.14 (100%)	2.1	3.18 (11%)
				total conc. = 2.17
Y				
– pre-distribution	5.555	—	—	5.65 ± 0.03 (n = 3, 44–90%)
– 400 mL		5.25 (3%)	5.0	5.58 (120%)
– 100 mL		5.38 (100%)	4.9	5.68 (18%)
				total conc. = 5.60
Z				
– pre-distribution	6.032	—	—	6.10 ± 0.02 (n = 2, 57–85%)
– 400 mL		5.93 (100%)	5.4	6.04 (114%)
– 100 mL		5.81 (78%)	5.5	6.23 (7%)
				total conc. = 6.09

[a] Percent values in brackets for RHUL and NIGL data represent % uranium recovery from the procedure. NB 100 mL analyses at RH included a rinse of remaining solid residue in the bottle with sub-boiled HNO_3; dissolution of this residue is the probable cause of the higher concentrations in the 100 mL fractions (see text). "Total conc" in RHUL data = total pg uranium determined in both fractions divided by total mass of the two fractions.
[b] Predicted based on masses of unspiked urine and DU-D used and their concentrations using pre-distribution figures.

Table 6. $^{234}U/^{238}U$ atomic ratio in spiked urine samples.[a]

Solution	Predicted[b]	NIGL	Harwell	RHUL
B (target ratio 140)	141.5			
– pre-distribution		141.1 ± 1.2 (n = 3)	—	—
– 400 mL		140.6 ± 0.5	147.3 ± 2.5	140.1 ± 0.7
– 100 mL		139.1 ± 0.6	144.7 ± 2.5	139.0 ± 0.7
C (target ratio 146)	151.0			
– pre-distribution		154.2 ± 2.1 (n = 3)	—	—
– 400 mL		151.4 ± 0.9	157.9 ± 2.5	154.2 ± 0.6
– 100 mL		151.7 ± 2.4	154.0 ± 2.5	153.8 ± 0.5
G (target ratio 142)	not provided			
– pre-distribution		—	141.9 ± 0.8	—
– 400 mL		139.9 ± 0.8	138.8 ± 5.0	139.8 ± 1.3
– 100 mL		139.4 ± 1.1	144.7 ± 5.0	138.5 ± 1.1
H (target ratio 180)	not provided			
– pre-distribution		—	178.2 ± 2.0	—
– 400 mL		180.6 ± 1.2	171.4 ± 2.5	179.6 ± 1.2
– 100 mL		182.3 ± 7.1	172.0 ± 2.5	174.2 ± 1.7
Y (target ratio 144)	144.0			
– pre-distribution		—	—	143.8 ± 0.2 (n = 3)
– 400 mL		[140.1][c]	145.6 ± 2.5	144.4 ± 0.3
– 100 mL		145.0 ± 0.6	144.1 ± 2.5	143.6 ± 0.6
Z (target ratio 150)	150.0			
– pre-distribution		—	—	150.3 ± 0.2 (n = 2)
– 400 mL		151.2 ± 0.5	153.3 ± 2.5	149.5 ± 0.3
– 100 mL		151.7 ± 1.0	150.9 ± 2.5	149.7 ± 0.6

[a] Uncertainties quoted are propagated 2 se for single analyses, or 2 sd for replicate analyses if worse.
[b] Predicted based on masses of unspiked urine and DU-D used.
[c] Measurement recognized to be unsatisfactory at the time it was made.

Table 7. Comparison of observed and predicted uranium concentrations in spiked urine samples.

	NIGL (pg g^{-1})			Harwell (pg g^{-1})			RHUL (pg g^{-1})		
Solution	Observed[a]	Predicted[b]	Difference %[c]	Observed[a]	Predicted[b]	Difference %[c]	Observed[a]	Predicted[b]	Difference %[c]
B	1.55	1.53	1	1.40	1.67	19	1.62	1.52	7
C	1.80	1.80	0	1.65	1.92	16	1.99	1.86	7
G	1.24	1.21	2	1.20	1.25	4	1.31	1.20	9
H	2.14	2.19	2	2.10	1.90	11	2.17	2.13	2
Y	5.32	5.53	4	4.95	5.51	11	5.60	5.45	3
Z	5.87	6.04	3	5.45	6.10	12	6.09	5.89	3

[a] Mean of blinded measurements on batch excluding those recognized to be unsatisfactory at the time they were made; for RHUL these are the combined total conc. values listed in Table 5.
[b] Predicted from the mean estimate by the laboratory for the isotope ratio of the batch, the mean estimate from all laboratories combined for the uranium concentration in the unspiked urine from which the batch was derived, and values of 502 pg g^{-1} and 286.6 for the uranium concentration and isotope ratio of the spiking solution (see text).
[c] Difference between observed and expected expressed as a percentage of predicted.

Table 8. $^{236}U/^{238}U$ ratio in unspiked and spiked urine samples.

Solution	Predicted[a]	NIGL ($\times 10^{-6}$)[b]	Harwell ($\times 10^{-6}$)	RHUL ($\times 10^{-6}$)
A	0.00			
– pre-distribution		2.5 ± 0.7	—	—
– 400 mL		1.1 ± 0.2	<5	[41 ± 3][c]
– 100 mL		<0.5	<5	[49 ± 5][c]
B	9.2			
– pre-distribution		11 ± 1	—	—
– 400 mL		8.7 ± 0.6	<5	[198 ± 6][c]
– 100 mL		10 ± 1	<5	[1425 ± 10][c]
C	31.7			
– pre-distribution		36 ± 6	—	—
– 400 mL		33 ± 1	23	[42 ± 2][c]
– 100 mL		35 ± 2	25	[364 ± 5][c]
F	0.00			
– pre-distribution		—	<5	—
– 400 mL		1.3 ± 0.2	<5	[15 ± 9][c]
– 100 mL		<0.5	<5	[154 ± 8][c]
G				
– pre-distribution		—	<5	—
– 400 mL		0.4 ± 0.3	<5	[50 ± 7][c]
– 100 mL		<0.5	[37][c]	[307 ± 14][c]
H				
– pre-distribution		—	53	—
– 400 mL		77 ± 3	73	[609 ± 12][c]
– 100 mL		82 ± 2	69	[3762 ± 31][c]
X	0.00			
– pre-distribution		—	—	0.3 ± 0.8
– 400 mL		<0.1	<5	0.2 ± 0.1
– 100 mL		<0.5	<5	[279 ± 11][c]
Y	14.6			
– pre-distribution		—	—	14.8 ± 0.5 $n = 1$
– 400 mL		—	15	14.3 ± 0.2
– 100 mL		13 ± 1	5	[110 ± 3][c]
Z	27.6			
– pre-distribution		—	—	28.3 ± 0.5 $n = 2$
– 400 mL		26 ± 1	28	26.6 ± 0.4
– 100 mL		28 ± 1	49	[410 ± 9][c]

[a] Predicted based on masses of unspiked urine and DU-D used.
[b] No subtraction for blank count rate has been made on 236 mass at NIGL.
[c] Measurement recognized to be unsatisfactory at the time it was made. Uncertainties quoted are propagated 2 se for single analyses, or 2 sd for replicate analyses if worse. Uncertainties for Harwell data were not provided.

Table 7 compares the mean uranium concentrations for spiked urine with the predicted concentrations. The observed and predicted concentrations for NIGL agreed to within 4% (mean 1.8%), at Harwell the agreement was between 4% and 19% (mean 12%), while at RHUL the level of agreement was 2–9% (mean 6%). The systematically higher values at RHUL are largely a function of the higher uranium content of the DU-D solution used at RHUL than the 502 ng L^{-1} assumed in Table 7.

Table 8 shows measured $^{236}U/^{238}U$ ratio in unspiked

and spiked samples in comparison with predicted values. With few exceptions Harwell was unable to measure accurately or precisely the $^{236}U/^{238}U$ ratio. The best data derives from NIGL and selected RHUL analyses.

For RHUL, in spite of some low ^{236}U signal intensities in the blind analyses, ^{236}U intensities were well in excess of the 10 to 16 counts s^{-1} background at this mass, and often greater than ^{238}U intensities in DU-spiked samples pre-distribution. Although cross-contamination from previous ^{236}U spiked samples is a possibility, it is more likely that the poor chemical recovery and inadequate ashing have led to residual sample organic molecularis at mass 236 well in excess of background plus uranium counts. This is a potential source of additional uncertainty that could lead to inaccuracy at very low count rates.

A comparison with the predicted values clearly demonstrates that it is possible to accurately measure $^{236}U/^{238}U$ ratios at low count rates, as portrayed in Fig. 2. In this plot any admixture of two isotopically distinct uranium reservoirs will fall on a straight line with end points at the two end member compositions.

DISCUSSION

In this study the three participating laboratories agreed well in their measurement of urinary $^{238}U/^{235}U$ ratios, although reported uncertainties appear modestly underestimated. The MC-ICP-MS techniques are predictably more precise than the SF-ICP-MS method.

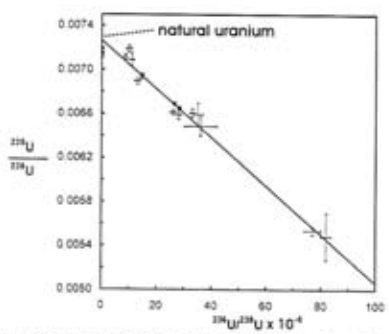

Fig. 2. Measured $^{236}U/^{238}U$ vs. $^{235}U/^{238}U$ in urine samples. Only data for which a laboratory achieved satisfactory measurement of both ratios and reported uncertainties, with the $^{236}U/^{238}U$ ratio above the limit of detection, are shown. The plotted data consist of 15 analyses from NIGL and 5 from RHUL, and while uncertainty estimates provided by the laboratories appear to be underestimated, the scatter about the theoretical mixing line demonstrates accuracy. The value of natural uranium corresponds to the Y-intercept of the mixing line.

Measurements at RHUL for uranium concentration suggest that U-containing particulates may adhere to walls of containers, consistent with the difference in uranium concentration of the 400-mL v. 100-mL aliquots. The implication is that with some chemical procedures, single measurements of an aliquot of urine may not faithfully reflect the uranium concentration of the sample. It is clear that the use of isotope dilution provides a means of more accurate and precise concentration measurements, and when high precision is needed, it is recommended that it be used.

When all of the concentration measurements are summarized (Table 7), the NIGL and RHUL data show good consistency and no apparent bias, whereas Harwell measurements suggest a 9.6 ± 1.4% bias on the low side. This could be a result of miscalibration of either a tracer or reference solution prior to or during the course of this study, or some other unrecognized methodological difference. The results from the 100-mL urine samples did not appear to be markedly less reliable than those from the 400-mL samples, though it is clear that mass spectrometric precision is enhanced with larger ion intensities.

The data suggest that all three of the analytical methods employed in this study are capable of measuring $^{238}U/^{235}U$ ratios to within ±4% in urine with a total uranium concentration as low as 1–5 ng L^{-1}, and most of the time to within ±2.5%. Moreover, with the multi-collector techniques used by NIGL and RHUL, accuracy better than 1.5% (95% confidence) can be achieved with total uranium concentrations as low as 1 ng L^{-1}, and with as little as 100 mL of urine being processed, provided that uranium pre-concentration is utilized with low analytical blanks. This study shows that with appropriate techniques it is possible to identify the presence of DU in urine when the measured $^{238}U/^{235}U$ is as low as 141, a threshold that may decrease with further improvements in measurement. These procedures therefore permit an accurate and precise determination of the $^{238}U/^{235}U$ in urine for essentially the entire range of uranium concentrations in human urine.

Measurements of uranium concentration tended to be less reliable than measurements of $^{238}U/^{235}U$ ratio. The results presented in Tables 3 and 5 suggest that it is possible to measure consistently concentrations to ±4% or better using isotope dilution with a ^{233}U tracer. These levels of reproducibility are substantially lower than those that would be expected using the same techniques on aqueous samples, probably because of inherent particulates in urine.

Our attempts to measure $^{236}U/^{238}U$ were generally successful with MC-ICP-MS methods. The highest sensitivity for ^{236}U measurement is obtained using uranium pre-concentration and MC-ICP-MS. Accurate and consistent results are demonstrated by the excellent inverse correlation between $^{236}U/^{238}U$ and $^{235}U/^{238}U$ as shown in Fig. 2, where the data fit the predicted mixing line between the DU-D spike and natural uranium. The collision cell MC-ICP-MS at RHUL encountered problems with organic interferences on mass 236 with some analyses, and the SF-ICP-MS method had insufficient sensitivity in their smaller urine aliquots. While the $^{236}U/^{238}U$ may not be as useful as the $^{236}U/^{235}U$ ratio when assessing historical exposures to DU, it may provide a useful check against rogue results, and may allow detection of DU sources of variable isotopic composition. It could also be helpful where there was suspicion that an individual had been exposed to enriched as well as depleted uranium.

This contribution is the first to present consistent measurements of $^{236}U/^{238}U$ and $^{236}U/^{235}U$ in human urine samples. The only other published study we are aware of is that of Durakovic et al. (2002), which while presenting $^{236}U/^{238}U$ data in addition to $^{236}U/^{235}U$ data, lacked replicates, had a number of samples with substantial ^{236}U but with natural $^{236}U/^{235}U$ signatures, and had no analysis of DU metal shrapnel to assess comparable accuracy of these urine measurements.

Over the years the threshold for detection of uranium and other transuranic elements in urine has declined markedly (Epov et al. 2005; Schaumlöffel et al. 2005), and the ability to make precise and accurate determinations of the isotopic composition of uranium in urine has steadily improved (Krystek and Ritsema 2002; Westphal et al. 2004). Currently, quadrupole ICP-MS is the most common method, but accurate isotopic measurements are only possible with uranium concentrations exceeding 20 ng L^{-1} and even then the precision is ~10% or worse (Hooper et al. 1999; Becker et al. 2002; Ejnik et al. 2000). The use of uranium chemical separation and thermal ionization mass spectrometry may be capable of increased sensitivity but the only relevant recent study is that of Durakovic et al. (2002), and while it presented measurements of urine containing variable proportions of DU, many analyses were unsuccessful and it lacked replicates and rigorous assessment of uncertainties. More recently, SF-ICP-MS methods like those used by the Harwell laboratory in this study are increasingly being used and have better performance, particularly when uranium separation is used (Krystek and Ritsema 2002; Gwiadza et al. 2004; Pappas et al. 2003; Trešl et al. 2004). Indeed, the Harwell data of this study compares favorably with these other SF-ICP-MS cited studies, even with its lack of uranium chemical separation.

A recent intercomparison of quadrupole ICP-MS, SF-ICP-MS, thermal ionization mass spectrometry (TIMS), and induced neutron activation analysis (INAA) was conducted by the Canadian government (D'Agostino et al. 2002) using a methodology not dissimilar to this study, but with synthetic urine having total uranium concentrations ranging from 25–770 ng L^{-1}, 5–700 times those presented in this paper. The Canadian study showed that both ICP-MS methods (quadrupole ICP-MS and SF-ICP-MS) were able to measure accurately both concentrations and isotopic ratios at these relatively high concentrations of uranium. However, the TIMS method reported inaccurate concentration and isotopic values in a number of samples, with significant underestimation of internal uncertainties. The European Commission is currently conducting interlaboratory tests on uranium isotopes in simulated urine with ~100 ng of contained uranium as part of its Nuclear Signatures Interlaboratory Measurement Evaluation Program (www.irmm.jrc.be/imep/nusimep.html), but it has yet to undertake a study using human urine with "normal" uranium concentrations (<10 ng L^{-1}). On the basis of this study, such a study on low-concentration urine is feasible but will be challenging for many instrumental methodologies.

CONCLUSION

There is as yet no published account of the use of chemical separation of uranium from urine combined with MC-ICP-MS instruments. The data presented in this study show clearly that MC-ICP-MS methods are superior to all of these other methods in that they reproduce concentrations reliably to better than ±5%, $^{236}U/^{238}U$ to better than ±1.5%, and in the case of the NIGL procedure, successful measurement of the low abundance ^{236}U isotope with accurate $^{236}U/^{238}U$. Very significantly, this has been accomplished on samples containing between 0.16–2.4 ng uranium extracted from urine with 1.6–6.0 ng L^{-1} uranium. These results show that with chemical separation combined with MC-ICP-MS techniques, high precision measurement of uranium is feasible with any sample of human urine, even in the low-uranium abundance end of the concentration spectrum.

Relevance to determination of DU exposure

It has been estimated that inhalation of 10 mg of DU together with an ingested dose of 5 mg would lead to an excess lifetime risk of fatal cancer less than 3 per 100,000 (Royal Society 2001). Using biokinetic models (i.e., WHO 2001; Royal Society 2001) and estimates of solubility of uranium oxide and other specific parameters, an inhaled dose of 10 mg of DU might be expected

to cause additional urinary excretion of uranium (above background levels) of >0.3 ng per day 10–15 years after inhalation. Against a background excretion of natural uranium of 10 ng per day, and assuming a $^{238}U/^{235}U$ ratio of 350 for DU, this would produce a $^{238}U/^{235}U$ ratio in urine of approximately 144. Our study suggests that the analytical techniques used by NIGL, RHUL, and to a lesser degree of confidence Harwell, are all sufficiently sensitive to detect a perturbation of the isotope ratio at this level, and as such can be applied to the testing of individuals to assess past DU exposure.

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APPENDIX

Derivation of expected uranium concentrations in spiked urine samples

Define variables as follows:

C_U = total uranium concentration of unspiked urine;
C_D = total uranium concentration of spiking solution (= 502 ng L^{-1});
C_S = total uranium concentration of spiked urine;
R_U = $^{238}U/^{235}U$ isotope ratio of unspiked urine (= 137.9);
R_D = $^{238}U/^{235}U$ isotope ratio of spiking solution (= 286.6);
R_S = $^{238}U/^{235}U$ isotope ratio of spiked urine; and
V = volume of spiking solution per liter of unspiked urine.

$$C_S = \frac{C_U + VC_D}{1 + V} \qquad \text{(A1)}$$

and to a close approximation

$$R_S = \frac{C_U + VC_D}{C_U/R_U + VC_D/R_D} = \frac{R_U R_D (C_U + VC_D)}{R_D C_U + VR_U C_D}$$

$$\rightarrow R_S R_D C_U + VR_S R_U C_D = R_U R_D C_U + VR_U R_D C_D$$

$$\rightarrow V = \frac{(R_U R_D - R_S R_D) C_U}{(R_S R_U - R_U R_D) C_D}.$$

Thus, substituting for V in (A1)

$$C_S = \frac{\left[C_U + \frac{(R_U R_D - R_S R_D)C_U}{(R_S R_U - R_U R_D)}\right]}{\left[1 + \frac{(R_U R_D - R_S R_D)C_U}{(R_S R_U - R_U R_D)C_D}\right]}$$

$$= \frac{C_U C_D (R_S R_U - R_U R_D + R_U R_D - R_S R_D)}{(R_S R_U C_D - R_U R_D C_D + R_U R_D C_U - R_S R_D C_U)}$$

$$= \frac{C_U C_D R_S (R_U - R_D)}{(R_S R_U C_D - R_U R_D C_D + R_U R_D C_U - R_S R_D C_U)}.$$

■■

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Depleted uranium contamination by inhalation exposure and its detection after ~20 years: Implications for human health assessment

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ABSTRACT

Inhaled depleted uranium (DU) aerosols are recognised as a distinct human health hazard and DU has been suggested to be responsible in part for illness in both military and civilian populations that may have been exposed. This study aimed to develop and use a testing procedure capable of detecting an individual's historic milligram-quantity aerosol exposure to DU up to 20 years after the event. This method was applied to individuals associated with or living proximal to a DU munitions plant in Colonie New York that were likely to have had a significant DU aerosol inhalation exposure, in order to improve DU-exposure screening reliability and gain insight into the residence time of DU in humans. We show using sensitive mass spectrometric techniques that when exposure to aerosol has been unambiguous and in sufficient quantity, urinary excretion of DU can be detected more than 20 years after primary DU inhalation contamination ceased, even when DU constitutes only ~1% of the total excreted uranium. It seems reasonable to conclude that a chronically DU-exposed population exists within the contamination 'footprint' of the munitions plant in Colonie, New York. The method allows even a modest DU exposure to be identified where other less sensitive methods would have failed entirely. This should allow better assessment of historical exposure incidence than currently exists.

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Abbreviations: DU, depleted uranium, depleted in the ^{235}U isotope relative to natural uranium; EU, enriched uranium, enriched in the ^{235}U isotope relative to natural uranium; NLI, NL Industries (formerly National Lead Industries); ICP-MS, inductively coupled plasma mass spectrometry; ICP-AES, inductively coupled plasma atomic emission spectrometry; MC-ICP-MS, multicollector inductively coupled plasma mass spectrometry; U-TEVA, Uranium specific tetravalent actinide ion exchange resin (Eichrom Industries); ng L^{-1}, nanograms per litre; IRB, Institutional Review Board.

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1. Introduction

Depleted uranium (DU) is a by-product of the uranium isotope enrichment process, but aside from its ~40% lower radioactivity than purified natural U, it has similar chemical toxicity to enriched or chemically purified natural uranium. When inhaled or ingested in sufficient doses, DU constitutes a distinct health hazard (Royal Society, 2001, 2002; WHO, 2001). DU has been used in military conflicts primarily as armour-penetrating munitions in the Persian Gulf conflict of 1991 and the Balkans (AEPI, 1995; Royal Society, 2001, 2002; WHO, 2001), and in Iraq primarily in 2003. Its use in other conflicts such as Afghanistan in 2003 and southern Lebanon in 2006 has been suggested but remains unsubstantiated (UNEP, 2007).

Uranium occurs naturally in soil (~1–5 mg kg^{-1}) and water (~0.1–5 μg L^{-1}) and the anthropogenic addition to this natural background is insignificant except near point sources of uranium release. For humans, the aerosol exposure pathway is critical to hazard assessment (Royal Society, 2001) in that inhalation exposure to relatively insoluble DU oxide particles represents a potentially long-term reservoir of internal alpha-decay activity that could cause cell damage. Although considerable quantities of either soluble or insoluble natural uranium are ingested regularly by consumption of food and drink, little of this uranium is absorbed into the blood stream (ATSDR, 1999).

It has been alleged that there is or may be a connection between an individual's inhalation exposure to DU aerosols in the military theatre, and the development of multisymptomatic chronic medical conditions often referred to as Gulf War Illness (Jamal, 1998; Duraković, 2003). Attempts to assess the significance of DU to health have been complicated in part by the lack of accurate exposure assessments, although it is clear that in laboratory experiments involving animals or cell cultures, high doses of DU induce cell damage and impair certain body functions (Jamal, 1998; Monleau et al., 2005) and can be cytotoxic and clastogenic (Wise et al., 2007). Thus while the widespread use of DU is acknowledged, the lack of evidence for substantial DU contamination of individuals via inhalation–ingestion (notwithstanding the potential inadequacy of existing DU exposure screening) has so far failed to clarify whether DU plays any role in Gulf War Illness. On this and other grounds the relevance of DU to Gulf War Illness remains in doubt (Wesseley and Freedman, 2006; Ismail and Lewis, 2006). Instead it may be more likely that cytotoxic, clastogenic and teratogenic effects are more likely long term outcomes due to long term exposure to low level radiation or chemically toxic effects of DU (Schmidt, 2004; Bernard et al., 2005; Hindin et al., 2005; Wise et al., 2007).

In the health literature, only one study (Duraković et al., 2002) has claimed to document persistent internal contamination of soldiers by DU from alleged inhalation exposure. However there are many analytical deficiencies to this paper, and the data are unlikely to be reliable, a situation that undermines its conclusion. Most other studies of US or allied soldiers that have DU contamination involve individuals with embedded shrapnel (Hooper et al., 1999; McDiarmid et al., 2000, 2004). Gwiazda et al. (2004) measured uranium isotopes in urine from non-shrapnel-embedded US soldiers that served in the Persian Gulf conflict of 1991 and found some evidence of DU, but the measurements by ICP-MS lacked sensitivity and reproducibility at moderate to low urinary uranium concentrations, and the study involved a small cohort. More recently, the UK government commissioned both a voluntary screening programme of more than 400 individuals potentially having a DU exposure during the period 1991–1997 (DUOB, 2007) and a study by Bland et al. (2007) that tested for DU in spot urine samples of more than 300 personnel involved in Iraq in 2003. Both studies failed to find evidence for DU contamination in any of the tested individuals and both used high sensitivity methodologies at or close to current state of the art. These studies collectively show that DU exposure may be uncommon to rare in military personnel, but because the magnitude of DU inhalation of tested individuals is unknown, they do not provide a quantitative measure of exposure incidence or magnitude. Thus a critical question that remains is the extent to which a significant inhalation exposure of DU metal or DU oxide could be a source of chemical and radiological toxicity in the body.

The potential relationship between DU exposure and illness has also been highlighted in recent years by reports (Hindin et al., 2005; Al-Sadoon et al., 2002) of significant increases in certain cancers and birth defects in southern Iraq, an area where in 1991 DU was used extensively and where civilian chronic exposure to DU dust is potentially significant. Unfortunately, there are no credible studies of DU contamination of Iraqis and thus this apparent increased incidence of cancers and birth defects remains unexplained, with a connection to DU exposure remaining possible but without direct evidence.

With these limitations in mind, a study of a population demonstrably exposed to inhalation exposure of uranium oxide aerosols over a period of time was undertaken to ascertain the potential for detecting DU contamination in human subjects many years after initial exposure.

2. Scope of study

This study investigates a DU contaminated site and a small cohort of individuals that, between 1958 and 1981, resided near to or worked in a uranium processing plant involved in the manufacture of DU and to a lesser extent enriched uranium (EU), near Colonie (Albany) New York (National Lead Industies, NLI). This plant emitted a distinct DU (and possibly minor EU) aerosol plume arising from combustion of metallic uranium milling waste, over a period of decades until plant closure in 1984 (Fig. 1, constructed using data of Jeter and Eagleson, 1980). The data from this study and from additional 2006 soil samples (Lloyd, unpublished data 2007) were integrated to determine that more than 5 metric tons of DU was deposited, primarily by aerosols, in the first 600 m of radius from the plant, and that soils as far as 4 km from the plant have low level DU contamination. It is probable that between 5 and 10 tons of DU aerosol were historically emitted. This quantity is comparable to the total mass of respirable DU particles produced during the entire 1991 Persian Gulf Conflict, considering the proportion of all expended munitions likely to become aerosolised during hard target impact-related combustion.

The temporal record of pollution from the plant is recorded in sediments of a small reservoir nearby (Arnason and

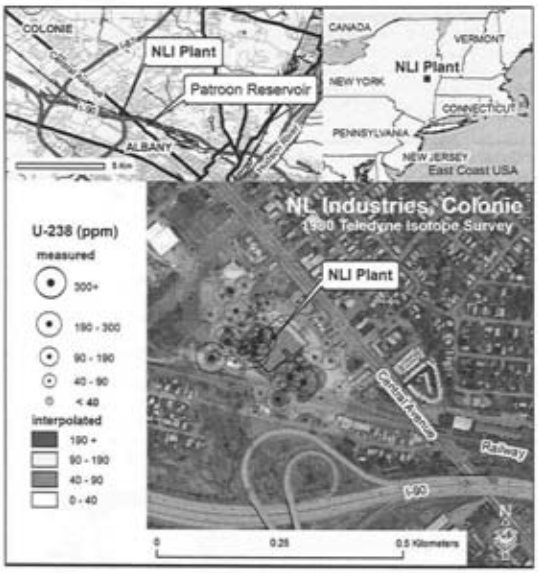

Fig. 1 – Map of the Colonie New York area (in Albany County) showing location, and detailed pattern within the city of the uranium pollution plume from the NLI plant, superimposed upon an aerial view of Colonie. The data used are from the Jeter and Eagleson (1980) study. The figure also uses mapping and photography from New York State public information, http://www.nysgis.state.ny.us/.

Fletcher, 2003). We measured uranium concentration and isotope composition for this sediment record and show that the chronic deposition of substantial amounts of uranium took place during the plant's operation. We also isolated and identified DU oxide particles emitted from the plant but now in soils and household dusts to document the presence and nature of the primary aerosol particles.

Against this background of aerosol deposition, individuals were identified that either worked at the plant or lived or worked in close proximity (<1 km) to the site for more than 5 years during its active phase of operation from 1958 to 1981 and who would have had a clear inhalation exposure. These individuals were tested for DU exposure using our method.

3. History of uranium processing at Colonie

The NL Industries (NLI) plant is located in Colonie, New York, less than 6 km from the State Capitol building in Albany. NLI was involved in the reduction of uranium tetra-fluoride to uranium metal, and fabrication of uranium articles from 1958–1984. These consisted mainly of DU projectiles, but with some enriched uranium for fuel rods prior to 1972 (ATSDR, 2004). A New York State Department of Health draft internal report states that uranium enriched to ≥3% ^{235}U was also processed between 1958 and 1968, and that in 1975 a license amendment restricted the plant to possession of depleted or natural uranium. NLI carried out work with the US Atomic Weapons program from 1958–1968 at its Colonie plant (NYS DOH 1979). After 1968 their primary customer was the US Department of Defence, with contracts primarily for DU penetrators (DOE, 2005).

Fabrication processes at the Colonie plant produced chemically unstable uranium scrap metal, which when finely divided can spontaneously combust. The option chosen by NLI to deal with the uranium waste was to convert it to oxide in a furnace with a filtered exhaust stack. In 1979 the New York State Department of Environment investigated claims that the stack filters were bypassed, and subsequently forced the temporary closure of the plant for excessive emissions of uranium compounds to the atmosphere (Romano, 1982). A soil survey in 1980 conducted by Teledyne Isotopes (Jeter and Eagleson, 1980) found considerable depleted uranium contamination (using gamma-ray spectrometry of soil samples) within 600 m of the plant. The plant was permanently closed in 1984 and the

property was transferred to the federal Department of Energy that proceeded to remediate both the site and more than 50 contaminated nearby residential properties (ATSDR, 2004). The site has now been cleared, and is in the process of advanced remediation by the U.S. Army Corps of Engineers, under the Formerly Utilized Sites Remedial Action Program (FUSRAP, 2005).

4. Methods and materials

4.1. *Analysis of the Jeter and Eagleson (1980) data*

At the direction of state agencies a soil survey was commissioned by NLI in 1980, involving about 240 samples collected in a radius of 600 m of the site, with increasing sampling density closer to the site. Two aliquots of soil were taken for each locality at depths of 0–1.3 cm, and 1.3–5.1 cm and measured by gamma spectrometry for ^{238}U and ^{235}U and expressed as pCuries g^{-1}. We converted these measurements into mg kg^{-1} and contoured the data in the vicinity of the site, as shown in Fig. 1. The minimum integrated deposition of uranium, assuming a dry soil density of 2.0 g cm^{-3}, was 3400 kg of ^{238}U and may be more than 5000 kg due to uncertainties inherent in this calculation. This value does not take into account migration of uranium below the sampled soil profile, deposition outside of the 600 m radius, or the removal of U by runoff during the decades prior to the survey, all of which conspire to increase the estimated mass of uranium pollution.

4.2. *Uranium particles and lake sediments*

Dry dust and soil samples were taken from domestic locations within 1.5 km of the Colonie site. Uranium rich particles from these samples were pre-concentrated by a combination of magnetic separation using a Frantz LB-1 separator and heavy liquid density separation. Uranium oxide particles were identified at high magnification using a scanning electron microscope; their uranium rich oxide composition was confirmed with energy dispersive X-ray (EDX) analysis at the University of Leicester. The oxidation state of uranium oxide particles is difficult to determine because synchrotron X-ray identification is usually required (Salbu et al., 2007), and therefore the exact composition of the particles, in terms of oxidation state, remains uncertain.

Lake sediment cores (mainly mud and silt) from the Patroon Reservoir downstream from the NLI plant that were studied by Arnason and Fletcher (2003) were re-sampled at 5 cm intervals. Sub-samples were dried and pulverised, and dissolved in acid. Uranium concentration profiles were produced using ICP-AES at the University of Leicester and $^{238}U/^{235}U$ isotope signatures using Thermoelemental Excell quadrupole ICP-MS at the British Geological Survey. All data

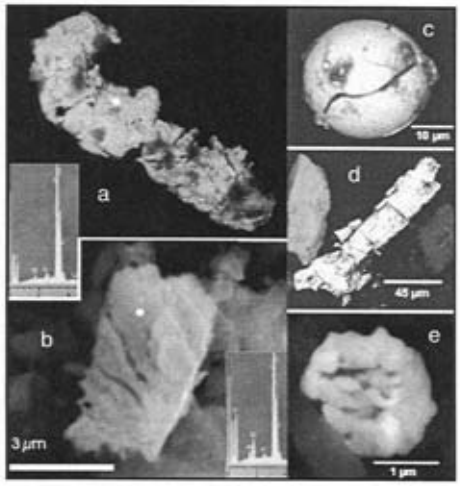

Fig. 2 – Scanning electron photomicrographs of uranium oxide particles from dust samples from residential locations within 400 m of the NLI site illustrating the variety and sizes observed; a,b: energy dispersive X-ray spectrometry (scale in keV) has identified only U, O, and minor Si in the particles (white dot is analysis spot); c, a commonly observed spherical uranium oxide particle suggested to be molten particles quenched in exhaust from the burner stack; d, e: large fragile and very small particles both of uranium oxide.

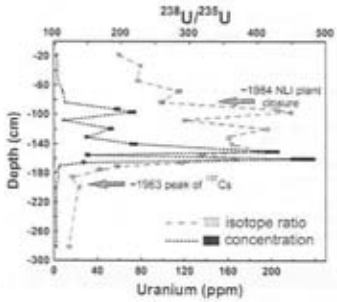

Fig. 3 – Plot of depth (cm) against both U concentration (ppm) and $^{238}U/^{235}U$ of the lake sediments. The peak of ^{137}Cs is shown as a time line approximately 1963, and the rapid decline of U concentration at ~ 90 cm is inferred to coincide with the closure of the plant in ~ 1984. The dip in concentration of U between 140 and 110 cm is probably the result of sediment influx during construction of the adjacent interstate highway. See Table 1 for data.

were corrected for blank contributions, mass bias and dead-time effects. Quality control was ensured with solutions of known natural and depleted uranium isotope signatures.

The core has been subjected to ^{137}Cs and ^{210}Pb measurement and sedimentological analysis in order to place age constraints on the core (J Arnason, personal communication 2006). The ^{137}Cs peak, known to have occurred in 1963, can be placed very close to 200 cm depth in the core.

4.3. Water and urine samples

The scope of sampling was limited to 24 individuals that had either worked in the plant or lived in a contaminated area close to the plant for more than 5 years from 1958 to 1981. The drinking water of most of the tested individuals was also sampled. Such water samples were collected from homes using municipal water supplies and a private well, and placed into pre-cleaned HDPE bottles, and treated similarly to urine in terms of shipment and storage.

The individuals were contacted, and the outline and rationale of the project was explained. Participants signed a consent form, provided information about their employment and/or residential history and agreed to provide a urine sample for analysis. The use of >24 h samples allowed calculations of daily excretion rates to be determined, and provided for replicate analyses where appropriate. Samples were sealed and shipped from the State University of New York at Albany to the UK for testing at the NERC Isotope Geosciences Laboratory. Samples were stored prior to analysis in a cold room at approximately 4 °C and were progressively analysed over the course of several months without any signs of sample deterioration. The samples were never frozen. Approximately 700 ml of urine was used for each analysis.

The method is largely the same as that described by Parrish et al. (2006) and involved pre-cleaning of 24 h sample collection bottles, acidification of urine samples, adding a known quantity of ^{233}U tracer, and chemical co-precipitation of uranium with calcium phosphate upon addition of ammonia to achieve pH 9. The precipitate was separated by pouring off the supernate, re-dissolving in ultrapure nitric acid and hydrogen peroxide, and repeated wet-ashing of the sample in quartz beakers to 240 °C to destroy all organic compounds. For water samples the ^{233}U tracer was added, and about 100 ml of water sample evaporated in quartz beakers. The inorganic salts from both urine and water samples were redissolved in 4M HNO_3 and using U-TEVA resin (Eichrom Industries) uranium was purified and separated from other elements, and taken up in ~1 ml of 2% HNO_3. The chemical procedure was conducted in a class 100 clean laboratory designed for ultra trace analysis. The total procedural blank for the procedure was less than 25 pg U, and its isotopic composition was measured as natural within uncertainty with no detectable ^{236}U. Chemical recoveries varied between 60 and 100%.

Reagent grade nitric acid was sub-boiling distilled in-house using Teflon bottle stills to achieve better than 0.05 pg U/ml blank level. A 99.94% isotopically pure ^{233}U tracer was obtained from the IRMM (Geel Belgium) for isotope dilution determination of U concentration. HDPE urine collection bottles were cleaned with reagent grade nitric acid and rinsed in purified water using a Milli-Q multiple cartridge purification system with RO water as feedstock. Co-precipitating reagents were reagent grade $Ca(NO_3)_2$ and $NH_4(PO_4)\cdot 4H_20$ separately dissolved in 4M HNO_3 and cleaned of contaminant uranium by passing through U-TEVA ion exchange resin in 4M HNO_3 (Eichrom Industries). In house sub-boiling distilled HNO_3 and Romil SPA hydrogen peroxide and Romil SPA ammonia were used for wet-ashing and neutralisation, respectively.

Table 1 – Uranium in lake cores

Depth (cm)	U (ppm)	2 SD	$\frac{^{238}U}{^{235}U}$	2 SD
17	3.6	0.2	197	3
32	4.3	0.2	229	3
52	4.4	0.2	225	3
67	8.4	0.4	285	4
82	10.7	0.5	260	5
92	58.4	2.9	428	4
96	71.8	3.6	449	3
107	9.7	0.5	293	3
119	52.1	2.6	415	3
130	30.1	1.5	358	3
140	73.3	3.7	362	3
150	196.4	9.8	406	3
155	32.0	1.6	319	3
155	30.5	1.5	314	3
160	227.9	11.4	368	3
165	27.6	1.4	289	3
170	6.3	0.3	194	3
170	5.9	0.3	195	4
175	4.2	0.2	169	4
185	4.7	0.2	129	3
199	2.8	0.1	140	2
281	3.5	0.2	125	3

Purified uranium extracted from urine and dissolved in ~1 ml of 2% high purity HNO_3 was introduced into the double-focussing ThermoElemental Axiom MC-ICP-MS using an Aridus desolvating nebulizer to produce a dry U aerosol carried in a stream of argon gas for sample introduction, thus both improving sensitivity and reducing interfering oxide formation. ICP gas flows were optimised to produce the maximum instrumental sensitivity while maintaining flat-topped peak shapes at approximately 400 mass resolution with clear wide separations between peaks. Uranium standards (CRM950 and SRMU010) were used to correct for mass bias, abundance sensitivity, hydride production, non-linearity of the ion counting detector, and multiplier gain. Peak switching was employed to measure ^{234}U, ^{235}U and ^{236}U in the ion counting system with other peaks measured in Faraday cups. The measurement of ^{238}U on both detection systems allowed accurate determination of both major and minor isotope ratios. Purified uranium isotope standards were used extensively for quality control, and an in-house urine sample whose isotope composition was determined to be consistent with the natural value of $^{238}U/^{235}U$ of 137.88 was measured 7 times alongside unknowns using an identical procedure. Repeat measurements of DU-positive samples 6 and 13 were in agreement and the uncertainties quoted for ratios in Table 2 are either the propagated uncertainty of an individual analysis or the weighted mean uncertainty of repeats of the same sample.

Table 2 – Uranium concentration and isotope composition of water and urine

Sample	Weight (g)	[U] (ng/L)	$^{236}U/^{238}U$	2 SD%	$^{235}U/^{238}U$	2 SD%	$^{234}U/^{238}U$	2 SD%	$^{238}U/^{235}U$	2 SD%
Drinking water samples of selected residents										
1, Well	98	570	9.81E–05	5.2	7.27E–03	0.2	b.d.	–	137.64	0.15
2, Mains A	98	81.8	7.94E–05	5.2	7.26E–03	0.2	b.d.	–	137.70	0.17
3, Mains A	99	88.1	7.83E–05	5.2	7.26E–03	1.0	b.d.	–	137.72	0.18
4, Mains A	100	81.8	8.01E–05	5.2	7.26E–03	0.2	b.d.	–	137.77	0.17
5, Mains A	102	6.7	1.55E–04	3.7	7.32E–03	2.0	b.d.	–	136.58	2.03
6, Mains A	102	6.5	nd	–	7.28E–03	0.8	b.d.	–	137.42	0.75
7, Mains W	100	103	8.99E–05	3.4	7.25E–03	0.1	b.d.	–	137.93	0.14
NLI plant workers										
1	755	122	1.01E–05	3.6	2.18E–03	0.09	2.5E–05	0.6	458.65	0.09
2	774	80.4	1.39E–04	3.6	1.40E–02	0.04	6.6E–05	0.6	71.65	0.04
3	760	63.7	9.71E–06	10.2	2.16E–03	0.6	3.0E–05	2	463.87	0.56
4	761	65.8	1.02E–05	6.9	2.20E–03	0.5	2.6E–05	2	454.27	0.54
5	738	66.0	1.24E–05	7.5	2.49E–03	0.6	3.3E–05	5	401.88	0.55
Residents and other worker										
6	723	2.08	7.92E–05	33.2	6.97E–03	1.2	1.4E–06	59	143.39	1.20
7	748	1.89	8.38E–05	3.9	7.25E–03	0.4	b.d.	–	138.01	0.44
8	751	3.40	8.68E–05	3.7	7.25E–03	0.5	b.d.	–	137.95	0.47
9	758	4.13	7.35E–05	10.2	7.25E–03	0.6	b.d.	–	137.93	0.55
10	764	5.42	9.88E–05	10.2	7.24E–03	0.6	b.d.	–	138.08	0.57
11	737	0.94	9.24E–05	10.4	7.21E–03	0.6	b.d.	–	138.61	0.62
12	685	1.85	8.55E–05	11.2	7.18E–03	2.9	b.d.	–	139.25	2.91
13	702	3.74	6.68E–05	6.9	6.61E–03	1.8	4.0E–06	14	151.34	1.75
14	775	2.48	8.46E–05	10.2	7.25E–03	0.6	b.d.	–	137.95	0.59
15	660	1.36	7.02E–05	8.6	7.22E–03	0.9	b.d.	–	138.57	0.93
16	673	0.91	8.36E–05	8.1	7.20E–03	0.6	b.d.	–	138.91	0.60
17	706	5.17	7.29E–05	6.9	7.24E–03	0.5	b.d.	–	138.04	0.53
18	742	2.10	8.42E–05	6.9	7.29E–03	0.5	b.d.	–	137.25	0.55
19	744	2.51	7.94E–05	6.9	7.25E–03	0.5	b.d.	–	137.98	0.54
20	755	1.53	9.49E–05	6.2	7.24E–03	0.9	b.d.	–	138.17	0.89
21	739	1.96	5.44E–05	5.9	7.37E–03	1.2	b.d.	–	135.67	1.20
22	750	1.43	8.86E–05	4.8	7.23E–03	0.6	b.d.	–	138.27	0.57
23	752	4.71	7.05E–05	0.8	7.26E–03	0.1	b.d.	–	137.83	0.13
Internal standard (urine)										
1	742	8.7	2.25E–04	6.0	7.26E–03	0.81	b.d.	–	137.65	0.81
2	250	11.0	2.70E–04	5.2	7.24E–03	0.62	b.d.	–	138.21	0.62
3	250	9.5	2.83E–04	6.4	7.23E–03	0.55	b.d.	–	138.24	0.55
4	250	11.0	2.72E–04	7.3	7.21E–03	0.66	b.d.	–	138.70	0.66
5	250	10.5	2.58E–04	2.0	7.27E–03	0.33	b.d.	–	137.52	0.33
6	265	12.7	2.73E–04	4.1	7.25E–03	0.79	b.d.	–	137.93	0.79

Notes:
n.d, not determined; bd, below detection (see text).
Uncertainty on U concentration estimated at 4% (2SD).
Mains A, mains water supply of part of Albany.
Mains W, mains water supply of part of Watervliet.

5. Results

5.1. Nature of primary aerosols

By subjecting accumulated dry household dusts (with up to ~300 μg g^{-1}U) and contaminated soils to density and magnetic separation techniques followed by imaging using scanning electron microscopy, we identified primary aerosol particles of U oxides in the size range <1–40 μm diameter. These cross both the respirable particle size range (<10 μm) and the "hand to mouth" contact ingestible size range (<250 μm). Many are irregular and/or pitted although some are spherical and resemble fused metal globules, consisting now of primarily oxides of uranium (Fig. 2), consistent with their origin by combustion.

5.2. Anthropogenic uranium isotope signatures of lake sediments

In the U concentration profile in the core (Fig. 3, Table 1), there is a marked drop in concentration between higher values in 100–140 cm depth range; this could be explained by an increase in sedimentation rate that diluted the flux of uranium runoff related to the plant, but this is only one explanation.

In the sediment core, the concentration of uranium generally correlates with isotopic composition (Fig. 3). The highest uranium concentrations, however, have a $^{238}U/^{235}U$ isotopic ratio between 360 and 400 rather than a value closer to ~500 which is considered typical for current end-member DU. This occurs in the section of the core deposited most likely in the late 1960s and earliest 1970s, and could be explained by a mixture of a minor component of enriched uranium mixed with dominant DU. The highest isotope ratio is found between 90 and 120 cm depth in the core and in this section the contaminant may be closer to pure DU with an end member composition close to ~500. The greatest mass of DU appears to have been deposited between 1963 and plant closure in 1984. Since closure the concentration of uranium has dropped to close to background values, but the isotopic composition demonstrates that a significant proportion of the uranium is environmentally "recycled" DU, presumably from runoff derived from already contaminated soils.

5.3. Identification of DU by isotope measurement

Natural uranium has a very specific isotope composition, the value of $^{238}U/^{235}U$, $^{235}U/^{234}U$, $^{234}U/^{238}U$, and $^{236}U/^{238}U$ being 137.88, 0.0072527, 0.00003–0.0002, and $<10^{-10}$, respectively, with only the $^{234}U/^{238}U$ having any natural variability. Enriched uranium has $^{238}U/^{235}U$ much lower than 137.88, and DU much higher, generally close to 500. ^{236}U is effectively absent in natural uranium. The uranium isotope measurements are sufficiently sensitive that if the uncertainty band of a measurement indicates the $^{238}U/^{235}U$ is 139.0 or larger, we are confident the sample is DU-positive, this assessment being based upon approximately 400 urininary uranium measurements of DU-negative samples as part of a related large study (DUOB, 2007). Similarly, when $^{236}U/^{238}U$ has a value larger than 1×10^{-8}, we are confident that it contains either DU or EU due to the fact that both DU munitions and reprocessed EU contain ^{236}U originating from reactor-related neutron capture by ^{235}U.

5.4. Water samples

Table 2 and Fig. 4 show that drinking water samples contain natural uranium, since ^{236}U is absent (i.e. below detection) and the $^{238}U/^{235}U$ is indistinguishable from natural uranium (with a value of 137.88) within 95% confidence limits. The data fall into two different concentration groups of approximately 85 and 6.6 ng L^{-1}, reflecting two distinct sources of municipal water in the Albany, NY area. Other samples are local supplies outside of the immediate vicinity of Albany, with one from a private well, and contain uranium at 570 ng L^{-1}. These data indicate that in spite of the widespread presence of DU in the Albany, NY area, DU contamination is not detectable in the water supply of the city. Because drinking water is regarded as the dominant source of uranium ingestion (Kurttio et al., 2005), it can reasonably be inferred that any anomalous isotopic composition discovered in urine cannot arise from recent ingestion of water.

5.5. Former workers of the NLI plant

Urine samples from five former employees were tested with results shown in Table 2. These individuals worked at the plant for between 5 and 22 years during the active period of uranium processing in jobs ranging from plant floor worker to office worker. None lived near the plant, and so any exposure to uranium is almost certain to have arisen during employment. Their uranium isotopic compositions are highly anomalous, with $^{238}U/^{235}U$ ratios from 72 to 464, the lowest of these clearly including a component of enriched uranium (Table 1). Concentrations of uranium in workers' urine range from 64–122 ng L^{-1}, much higher than the range of residents' urine (0.9–5.4 ng L^{-1}, summarised below), which is a finding consistent with uranium contamination as the dominant contribution to

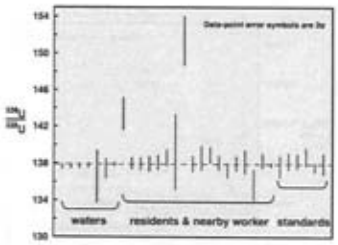

Fig. 4 – Plot of $^{238}U/^{235}U$ of drinking water and resident urine samples and 'standard urine samples' measured in this study, omitting those from factory workers that are off the scale of the diagram (see Table 2). The 'standards' refer to repeat measurements of an internal urine sample known to be of natural isotopic composition, and are shown to illustrate reproducibility.

excreted urine. The predominant source of their drinking water is from municipal sources.

The values of $^{236}U/^{238}U$ for four of the five workers range from 2.5–3.3 × 10^{-5} and are close to the measured composition of DU penetrators as shown by analyses of DU shrapnel ($^{236}U/^{235}U$ and $^{236}U/^{238}U$ of DU of ~500 and 2.5–3.0 × 10^{-5}, respectively, McLaughlin et al., 2003; Trueman et al., 2004). On the $^{236}U/^{238}U$ vs. $^{235}U/^{238}U$ plot shown in Fig. 5, the workers' measurements are similarly distinct from natural uranium.

DU dominates the contamination budget in spite of one worker with evidence of EU with a $^{236}U/^{235}U$ ratio of 72. For example, a mixture of ~2 parts uranium enriched to 3% (a typical value) and ~3 parts DU would produce this value.

5.6. *Residents/worker in close proximity to the NLI plant*

Eighteen individuals were tested who lived in close proximity (1 km) to the plant, or in one case who worked nearby in employment unrelated to NLI. Repeated analysis of a control urine sample with natural isotope composition and similar concentration was also undertaken to demonstrate reproducibility. With a few exceptions, all tested individuals lived or worked near the plant for 10 years or more during the active period of aerosol emissions from 1958 to 1981. Concentrations of urinary uranium vary from 0.9 to 5.4 ng L^{-1} and fall within the normal range for humans. Fourteen individuals returned isotopic ratios that could not be distinguished from natural uranium while four (individuals 6, 11, 13, and 16 in Table 2) had $^{235}U/^{238}U$ values ranging from 138.9 to 151.7, though two of these four are only marginally distinguishable as containing DU (Table 1, Fig. 4). Of these four, only individual 13 lived near the plant while undergoing testing, 11 and 16 moved some distance away by 1986, and individual 6 worked until recently ~200 m from the plant but never lived nearby. These observations suggest strongly that the main DU exposure was via inhalation during the active period of the plant, though some amount of additional exposure by dust resuspension cannot be ruled out. Mass balance calculations using

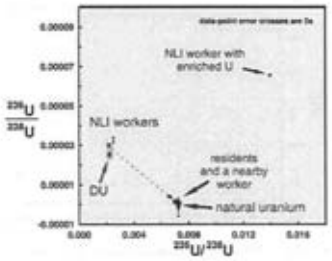

Fig. 5 – Plot of $^{235}U/^{238}U$ vs. $^{236}U/^{238}U$ of tested individuals. The end member composition of DU and the mixing line between natural uranium and DU is shown. Any mixture of two distinct compositions will define a straight line on this plot. Natural uranium contains no ^{236}U and plots as shown.

end-member DU indicate that DU constitutes between 1 and 12% of the excreted uranium in these four contaminated individuals.

The two higher measurements have $^{236}U/^{238}U$ of 1.5–4.0 × 10^{-6} whereas all other urine samples had no detectable ^{236}U. When plotted in Fig. 5, it is clear that these DU-contaminated individuals fall on an array or mixing line between the natural isotope composition and end member DU as represented either by the cluster of workers or the measured composition of DU shrapnel. Although most 'residents' did not have detectable DU, they potentially were contaminated, but to an extent that has not been detected by our measurement threshold of approximately 0.02–0.05 ng L^{-1} of DU, or approximately 1% of the excreted uranium in urine. What level of historic aerosol DU contamination this measurement threshold might represent is discussed below by reference to biokinetic models.

6. Discussion

This study documents residual internal DU contamination in all five former employees and in 10–20% of the cohort of individuals who either lived or worked in close proximity to the plant for at least 5 years during its active phase of emissions. The low number of individuals tested in our cohort precludes a quantitative extrapolation to the nearby population as a whole; this can be done only by testing a larger cohort. However, the detection of anomalous uranium in 100% of workers and up to 20% of our 'residents' cohort is in itself significant, since no previous study has documented evidence of DU exposure to aerosols more than 20 years prior.

The exposure pathway of aerosol deposition in the residential area surrounding the NLI plant occurred from 1958 to 1984, with a major drop in emissions in 1981 when NLI largely stopped manufacturing operations prior to closure in 1984. During the ~23 years of active uranium emissions, many tons of fine uranium, mostly in the form of combusted oxide particles settled downwind from the plant. We have documented DU contamination 5.8 km from the plant using spot soil samples, and it is likely to have travelled even further (Lloyd, unpublished data 2007). Inadvertent inhalation exposure would have been inevitable and may have affected many thousands of people during a period of chronic rather than acute exposure.

The urine from NLI workers is, even now, almost entirely dominated by a combination of DU and EU derived from their exposures while working at the plant. The persistence of high excretion rates of uranium in urine in workers, more than 20 years since active exposure, indicates that the body burden of uranium must still be significant, whether retained in lungs, lymphatic system, kidneys or bone.

The study also detected DU in up to 20% of the 'residential' cohort of 18 individuals. Their route of exposure is likely to have been dominated by inhalation since aerosols were the main source component, but other routes, including ingestion of contaminated soil or dust, may have played an additional role. In the individuals with a DU signature, the DU comprises ~1–12% of the total excreted uranium, the remainder originating from ingestion of natural uranium contained in food and water. The analysis of Albany drinking water clearly

shows that it is not contaminated with DU and that it cannot be linked to the DU contamination.

With the exception of uranium workers (like those in uranium mining and milling, and those employed at NLI), there is little or no evidence of the persistence of any anthropogenic inhalation exposure to uranium in the body beyond 10 years, and even that is poorly documented. Our study clearly shows that a sensitive non-invasive method is available to prove that DU contamination of the body can persist for more than 20 years.

6.1. Health implications

For many years there have been persistent concerns regarding the risk to human health from uranium and other heavy metal pollution in the vicinity of the NLI site, from its airborne uranium emissions and waste dumping. These concerns have been covered by the local media, noted by non-profit organizations, and reinforced by a recent US government Health Consultation assessment of risk (ATSDR, 2004). However, that ATSDR Health Consultation concluded that further investigations were unjustified because it would be impossible to determine the incidence of DU contamination after such a long period of time since the inhalation hazard no longer existed. In contrast this study shows that this is feasible. The results of this study suggest that testing a larger cohort could better determine the incidence of DU contamination in nearby residents and potentially place limits on original exposure quantity. This is a critical piece of information needed to design an appropriate follow-up study to assess the potential health outcomes of the nearby population.

6.2. Estimation of initial inhalation dose

In any analysis of exposure to a toxic substance, it is important to quantify the exposure, if at all possible. For DU, this can be estimated in a model calculation using the (1) rate of excretion of DU, (2) time since exposure, (3) solubility function of inhaled DU particles. By way of illustration using the biokinetic model adopted by the Radiological Protection Board in the UK, as summarised in Royal Society reports (Royal Society, 2001, 2002; also see DUOB, 2007), an initial inhaled dose of oxidized uranium after 10,000 days (~27.4 years) should give rise to a daily uranium excretion of the original amount divided by 10^7; for example an excretion rate of 1.0 ng DU d^{-1} would imply an intake of 10 mg DU 10,000 days earlier. If it is assumed that the individuals' exposure to aerosols can be approximated as taking place around the time of maximum aerosol emission in the period ~1976–1979 (ASTDR, 2004), approximately 10,000 days prior to testing, one can calculate initial exposures using the measured 24 h DU excretion rates. Using the means of 24 h DU excretion for the four DU-positive residents of 0.3 ng DU d^{-1} and for the five workers of 95 ng DU+EU d^{-1}, the calculated cumulative exposure in 1977 would have been approximately 3 mg DU and 950 mg DU+EU, respectively. Given the variability in individuals and a probable variation in DU excretion of an individual from one day to the next, a considerable uncertainty exists for these calculated exposure estimates. However, their general magnitude falls into the Level II and Level I categories of exposure, respectively, referred to by the Royal Society (2001) and are sufficiently high to justify an investigation of the health implications in more detail and scope than has been undertaken to date. The limit of detection of measurements on urine from individuals exposed ~20 years earlier, in combination with this biokinetic model, means that our method should detect virtually all Level I and Level II inhalation exposures, but not most Level III exposures. Of course these predictions of exposure quantity are entirely dependent upon the applicability of the biokinetic models used.

The assumption made in the calculation that intake occurred in a single event in 1977 is meant to illustrate the magnitude of the cumulative initial exposure, rather than detailed estimates applicable to each individual. Individually-tailored calculations based upon known history of exposure would vary but the variation would not materially affect the general magnitude of DU exposure estimation.

It is interesting to compare these results to those of a separate study completed recently in the UK (DUOB, 2007) that measured all (including ^{236}U) uranium isotopes in urine of 466 individuals, mainly veterans of the Persian Gulf conflict of 1991, using methods similar to this study. That study failed to find a single demonstrable DU-positive sample, though the extent to which those tested were actually exposed to DU was not known. It seems a reasonable conclusion that if DU cannot be identified in urine by sensitive methods after a period of 10–20 years, then the exposure for such a tested cohort cannot be assumed to have been significant.

7. Conclusions

The NLI plant in Colonie (Albany), New York emitted many metric tons of uranium aerosols, mainly combusted milling waste, into a mixed residential — commercial area of more than 10 km^2 over a period of 25 years from 1958 to 1982. Inevitably, residents, commercial workers, and NL plant workers were subjected to U inhalation and possibly ingestion exposure. Uranium pollutants comprised EU and DU, the latter being dominant. High sensitivity isotope measurements were made on urine samples from 23 individuals known to have lived or worked over many years in close proximity to the source of emissions to ascertain the extent to which the anthropogenic uranium signal could still be detected. Five factory workers continue to excrete high amounts of uranium dominated by a DU isotopic signature. Of eighteen individuals that either lived or worked near the plant for many years, we have detected DU in up to four, with DU being 1–12% of the excreted uranium. Ingestion of DU-contaminated water can be ruled out as a source of the DU excretion. Estimates of the initial inhalation dose of DU-positive individuals range from up to ~6 mg DU for residents to nearly 1 gram DU for workers. Inferred doses smaller than ~2 mg DU 25 years prior appear at the limit of detection of the methodology. Individuals exposed to substantial quantities of DU aerosols are likely to retain a DU-positive signature for the rest of their lives.

These findings cast new light on an important recommendation of a previous Health Consultation by the US Agency for Toxic Substances and Disease Registry (ATSDR, 2004). That

study concluded that, although plant emissions posed a real health risk, further health assessments would not be justified because of a lack of demonstrated DU exposure in the population. In contrast our method could provide estimates of the incidence and magnitude of DU aerosol inhalation exposure of the residential population, critical data needed in the interpretation of mortality and morbidity data.

A comparison of these data with two recent larger testing programmes of both UK veterans of the 1991 Persian Gulf conflict and the recent conflict in Iraq is revealing. In these UK studies of more than 800 individuals (DUOB, 2007; Bland et al., 2007]) no DU-positive urine sample was found. In the case of Colonie where urinary DU is documented in exposed individuals after 25 years, the simplest conclusion is that if an individual is significantly exposed (i.e. Level II–Level I exposures; Royal Society, 2001), the urine isotope signature will persist for decades.

Acknowledgements

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Precise and accurate isotopic analysis of microscopic uranium-oxide grains using LA-MC-ICP-MS†

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Uranium isotope (^{235}U, ^{236}U, ^{238}U) ratios were determined for microscopic uranium-oxide grains using laser-ablation multi-collector inductively-coupled-plasma mass-spectrometry (LA-MC-ICP-MS). The grains were retrieved from contaminated soil and dust samples. The analytical technique utilised is rapid, requires minimal sample preparation, and is well suited for nuclear forensic applications. Precision and accuracy were assessed by replicate analyses of natural uraninite grains: relative uncertainty for $^{235}U/^{238}U$ is 0.2% (2σ), and the mean is in agreement with the natural ratio. A total of 115 uranium-oxide grains were analysed from environmental samples (soils and dusts); all of these were depleted uranium (DU) from a factory that produced uranium articles. Knowledge of the range of isotope ratios from particles of this controversial contaminant has proven useful when interpreting isotope ratios from bulk samples. Variation of the measured isotope signatures reveals details of the history of uranium processing and emissions.

1. Introduction

Case-study

National Lead Industries (NLI) operated a plant in Colonie (NY, USA), from 1958–1984. The plant processed uranium metals (depleted uranium and some enriched uranium): manufacturing kinetic energy penetrators (munitions), counterweights and radiation shielding from depleted uranium (DU). Scrap metal was combusted in a furnace prior to disposal as uranium-oxide, and this resulted in emissions of uranium-oxide particulate to the environment (at times via an unfiltered chimney).[1] Contamination of the suburban environment surrounding NLI by depleted uranium is evident in air filters, surface soils, reservoir sediments, and the urine of former employees and some residents.[2–7]

It is desirable to know the isotope ratios of the contaminant uranium when assessing bulk samples that comprise both background natural uranium and anthropogenic uranium. Furthermore it is possible that the uranium feedstock(s) used at NLI varied in isotopic composition. DU particulates from air filters collected 15.6 km NNW of NLI in 1979 had variable isotopic composition.[8]

We hypothesise that bulk soil and dust samples aggregate particulates over several decades, and that individual primary uranium-oxide grains from these samples each record the isotopic composition emitted from NLI during a short interval of time.

The bulk environmental samples of interest are contaminated soils (silica-rich medium to fine grained mineral sands with organic matter) and wind-blown dusts, typically comprising up to 500 mg kg^{-1} anthropogenic uranium, as microscopic uranium-oxide particulate in a matrix of natural mineral grains (that comprise trace natural uranium, less than 2.2 mg kg^{-1}). The aim of this study is to analyse the isotopic composition(s) of a population of anthropogenic uranium-oxide grains on an individual particle basis.

Depleted uranium (DU)

DU is the by-product of nuclear enrichment, and is depleted in the fissile isotope ^{235}U, typically (2–3) × 10^{-3} $^{235}U/^{238}U$.[9] The atom ratio, $^{235}U/^{238}U$ (or $n^{235}U/n^{238}U$), of natural uranium has a traditional consensus value 7.253 × 10^{-3} (1/137.88),[9,10] recently recommended as 7.257 × 10^{-3}.[10–13] However, there is evidence of natural isotopic fractionation c. ± 0.009 × 10^{-3} of this value,[14] and one known example (Oklo, Gabon) of sustained natural fission resulting in ^{235}U depletion.[15,16]

A useful fingerprint of anthropogenic contamination is the presence of ^{236}U, which naturally occurs at negligible abundances (in the order of ≈ 10^{-11}–× 10^{-10} $^{236}U/^{238}U$[17,18]). In contrast, DU is typically contaminated by up to 3 × 10^{-3} $^{236}U/^{238}U$ from reprocessed uranium.[8] ‡

Fig. 1 shows a range of $^{236}U/^{238}U$ and $^{235}U/^{238}U$ ratios that have been reported in the literature for DU penetrators. There are

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† Electronic supplementary information (ESI) available: Supplementary data. See DOI: 10.1039/b819373b.

‡ The source of ^{236}U contamination is from reprocessed uranium (neutron capture on ^{235}U in nuclear power or production reactors). Reprocessed uranium can comprise up to 0.5% ^{235}U,[19] typically 0.4–0.6% ^{235}U,[20] which when enriched would produce by-product DU in the order of a part per thousand ^{236}U, with ^{236}U concentrated in the enriched uranium. For DU with 3 × 10^{-3} ^{236}U, the source of ^{236}U is either cross-contamination via enrichment-plant machinery, or blending of virgin uranium with reprocessed uranium, on the order of a percent reprocessed uranium. Presumably the level of contamination depends on the nuclear enrichment facilities' history of handling reprocessed uranium. Civilian uranium reprocessing in the USA ceased in 1977,[21] therefore the abundance of ^{236}U in recently produced DU is likely to be lower.

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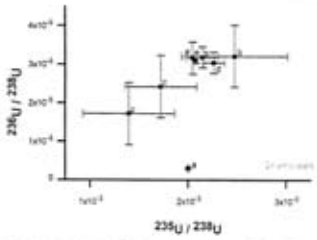

Fig. 1 Isotope ratios of DU penetrators reported in the literature. Measured by gamma-ray spectrometry: a) Trueman *et al.* (uncertainties from counting statistics only);[14] alpha spectrometry: b) McLaughlin *et al.*,[26] c) Pöllänen *et al.*,[15] d) Jia *et al.*,[16] ICP-MS: e) Desideri.[27]

ranges for both these ratios, but the data are scarce and it is not clear if this reflects a continuously variable range, or discrete batches of DU with distinct isotope signatures. Furthermore, it is possible that the isotopic compositions of other DU articles are not represented by these data.

Depleted uranium is also depleted in ^{234}U; literature values for DU munitions range $(0.64–1.1) \times 10^{-5}$ $^{234}U/^{238}U$.[19–23] However, the abundance of this isotope is variable in nature (in the order of 10^{-4}–10^{-5} $^{234}U/^{238}U$) due to alpha recoil effects, and $^{234}U/^{238}U$ is not a reliable measure of low-level anthropogenic contamination.[24,25]

Analytical methods

Radiometric methods of uranium isotopic analysis include alpha and gamma-ray spectrometry. Due to the long half-lives of the uranium isotopes, long counting times (days) are required for precise determination of the minor isotopes. Furthermore, alpha spectrometry requires laborious chemical separation of the analyte from its matrix.

The high-precision analysis of actinide bearing particles by a combination of fission track analysis and thermal ionisation mass spectrometry (FT+ TIMS) was described by Dietz,[2] and is the traditional, but laborious method in nuclear forensics.[28] Fission-track analysis is first used to locate actinide-bearing particles for analysis by TIMS. It is also possible to estimate $^{235}U/^{238}U$ ratios directly by fission-track analysis.[27] Fission-track analysis is time consuming and requires access to neutron irradiation facilities. Digital autoradiography[28] or environmental scanning electron microscopy (SEM) are alternatives for particle location. A disadvantage of TIMS is the requirement for careful chemical separation of the analyte, which may be imperfect and result in poor ionisation and hence precision (risky with only a 'one-shot' analysis per particle).

Inductively-coupled-plasma mass-spectrometry (ICP-MS) offers faster analyses when compared to TIMS, and achieves good precision with multi-collector instruments (MC-ICP-MS). However, as for TIMS, particles of interest need to be manipulated and dissolved prior to analysis, and ideally the analyte is chemically separated from its matrix to avoid isobaric interferences. Hydride formation is also an issue when introducing solution samples, *e.g.* $^{234}U^1H$ on ^{234}U, but this can be minimised by the use of a desolvating nebuliser.

Secondary ion mass spectrometry (SIMS) has been used in the nuclear forensics context for the precise analysis of uranium and plutonium isotope ratios directly from particulates.[29–31] SIMS offers excellent spatial resolution, enabling particle location and sub-sampling.[32]

More recently laser ablation ICP-MS (LA-ICP-MS) has been used,[16–18] a method that also requires only minimal sample preparation. Varga[18] applied LA- sector-field single-collector ICP-MS (LA-SF-SC-ICP-MS) to non-environmental microscopic grains, demonstrating good agreement with solution SF-SC-ICP-MS, obtaining relative uncertainties (2σ) of c. 5% for $^{235}U/^{238}U$.

Multi-collector (MC-) ICP-MS offers superior isotope ratio measurement precision to ICP-MS and SF-SC-ICP-MS, as the isotope signals are measured simultaneously and generally with higher sensitivity. This is especially important for laser ablation, which produces a variable and transient signal. Boulyga and Prohaska[17] used a lengthy screening procedure to identify six micro-samples from Chernobyl contaminated soils, for analysis by LA-MC-ICP-MS, obtaining relative uncertainties (2σ) of 2–3% for $^{235}U/^{238}U$.

The major advantage of both SIMS and LA-ICP-MS is that particles of interest can be selectively sampled directly from solid materials, requiring only minimal sample preparation. However, in practice particles of interest may be very scarce in environmental samples. It is therefore desirable to concentrate these particles prior to analysis, and essential to locate them within the sample mount. The sampling volumes for both techniques are small, enabling replicate analyses of particles, or analysis by other methods.

The NERC Isotope Geosciences Laboratory (NIGL) are experienced users of LA-MC-ICP-MS for U-Pb dating of zircons (trace uranium decay series) from geological samples. We have 'borrowed' these sample preparation and analytical techniques for this novel application. To the best of our knowledge, this paper demonstrates for the first time, the application of high precision isotope ratio LA-MC-ICP-MS analysis to a large population of individual uranium-oxide grains from environmental samples.

2. Experimental

Sample preparation

Samples. A dust and a surface soil sample were collected from residential properties within 200 m of the former NLI site. Aliquots of these materials were analysed by scanning electron microscopy with an energy dispersive X-ray analyser (SEM-EDX: Hitachi S-3600N with Oxford Instruments Inca x-sight), revealing discrete uranium-oxide particles. Bulk uranium concentration and isotopic composition were estimated by quadrupole ICP-MS (VG Elemental PQ ExCell with Cetac Technologies Aridus II desolvating nebuliser) after total dissolution: for the soil 90 ± 9 mg kg^{-1} uranium, $(2.1 \pm 0.1) \times 10^{-3}$ $^{235}U/^{238}U$ (2σ); and for the dust 385 ± 33 mg kg^{-1} uranium, (2.2 ±

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Table 1 Methodology for concentrating uranium-oxide grains from soil and dust sample, and fractions removed

process	criteria	fraction removed
dry	60 °C	moisture
sieve	<250 μm	coarse grains
hand-magnet	magnetic	magnetite, iron
dense-liquid (di-iodomethane)	$\rho > 3.3$ g cm^{-3}	silica and silicates, fine particulate
iodynamic magnetic separation (Frantz LB-1)	0.1–1A	iron-oxides, some zircons
sieve	40 μm	coarse and fine fractions

0.1) × 10^{-3} $^{235}U/^{238}U$. These isotope ratios confirm that the vast majority of the uranium in these samples is from anthropogenic DU contamination.

Pre-concentration. The uranium-oxide particulates were concentrated from the bulk samples using the protocol summarized in Table 1. Dense-liquid (di-iodomethane, ρ 3.3 g cm^{-3}) was used to separate low-density silicates from the bulk samples, recovering dense grains including uranium-oxides (ρ 10.96 g cm^{-3}) greater than about 20 μm diameter.

Grain mounts. Aliquots of the concentrates were mounted in epoxy resin, ensuring separation of grains, and then ground and polished to reveal cross sections (alternatively, they could be adhered whole to the surface of a suitable mount). The mounts were scanned using SEM-EDX to map the uraniferous grains, see Fig. 2. Sample preparation and the grain mapping are moderately time consuming. However, the methodology does produce robust grain mounts with a good density of uraniferous grains, which can be quickly located using the laser ablation system's optical microscope.

Solutions. Solutions were prepared from uraniferous grains from these and two other soil dust samples collected from the vicinity of NLI, for comparison with the laser ablation dataset. Spherical grains that appeared metallic or glassy (anthropogenic in appearance) under an optical microscope were picked from the concentrates (under ethanol) using fine tweezers, and then transferred to a low-tack adhesive (*Glue Dots Repo* ™), as shown in Fig. 3. These mounts were scanned using SEM-EDX, but fewer than 1 in 40 proved to be uraniferous (the others were mostly lead, tin or lead glass).

SEM-EDX analyses show the uraniferous grains were typically comprised of only uranium and oxygen (elemental LLD c.

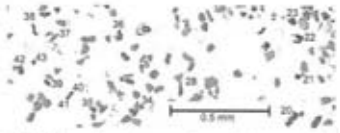

Fig. 2 SEM image of a grain mount surface, overlain by uranium EDX map (highlighting uraniferous grains). Uraniferous grain dimensions for this mount range 12 to 82 μm, mean 36 μm.

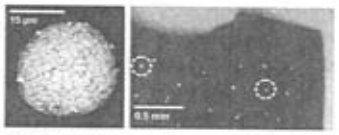

Fig. 3 SEM (uncoated sample, 20 Pa pressure, back scattered electron) image of a typical uranium-oxide sphere, picked from dust concentrate (left). SEM image of a temporary mount, particles with identifiable U Mα X-ray peaks from EDX analysis circled (right).

1%), for this reason, it was not considered necessary to chemically separate the uranium from these solutions. Subsequent analysis of similar grains shows that they are typically polycrystalline UO_2 (unpublished data), and they often include cavities.

Twenty-four uranium-oxide grains were successfully transferred by tweezers into individual pre-leached micro-centrifuge tubes, and then dissolved in ultrapure double-distilled concentrated nitric acid (within a class 100 clean room, typical digest blanks <100 fg U). This method of sample preparation is by comparison with the previous, relatively time-consuming.

Analysis

Mass spectrometry. Analysis was made using a double-focusing MC-ICP-MS instrument (VG Elemental Axiom), coupled with a desolvating nebuliser (Cetac Technologies Aridus) to reduce hydride interference from solutions. Following peak centring, low abundance ^{236}U was measured on a secondary electron multiplier, ^{235}U and ^{238}U on Faraday cups. Abundance sensitivity and mass bias were quantified at the start and end of each analytical run, using a natural uranium solution (U950a).

Solutions. The solutions were diluted in ultrapure 2% $HNO_{3\,(aq)}$ to approximately 25 ng g^{-1} uranium. The sample analyses were bracketed by analyses of a solution of enriched uranium standard reference material U010 that includes ^{236}U (New Brunswick Laboratory).

Laser ablation of grain mounts. The grain mounts were sampled by laser-ablation (New Wave Research LUV266x), using a c. 25 × 14 μm spot, 1 Hz repetition rate at a fluence of c. 68 mJ cm^{-2} (sufficient to give a stable signal within detector range). The output from the desolvating nebuliser provided the carrier-gas flow (c. 1 l min^{-1} Ar_2) for the ablation cell, and was used for the introduction of solution reference materials U950a and U010 at the start and end of each analytical run.

For each analysis, two baselines were measured at half-mass units (217.5 and 216.5), well away from the masses of interest, to record a good instrument baseline. The laser shutter was opened and the ^{235}U signal monitored until approximately stable, prior to acquisition of 30 one-second integrations. These data were output as the mean and standard error of the mean, after rejection (10%, 2σ). The large volume (c. 30 cm^3) of the ablation cell attenuates the pulses of sample from the ablation, and thereby

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minimises the effects of the detector response delays between Faraday cups and electron multiplier. The ^{238}U signal was then monitored for approximately 30 seconds, to allow the passing of 'spikes' from previously ablated material and the return to baseline values, before the next analysis was started.

The ablation protocol used produced irregular conical pits, approximate dimensions 25 × 14 × 1 μm in uranium-oxide sample grains (measured using SEM and Caminex Enterprises Alicona infinite focus microscope). The sampling volume is roughly equivalent to a 9 μm diameter uranium oxide sphere, or 4 ng uranium.

Ablation of the resin gave negligible ^{238}U detector responses (*c.* 3×10^{-5} V using a 10^{11} ohm resistor, *c.f.* 1.6 V from typical samples). Sample grains were bracketed by analyses of natural uraninite grains for quality control. Of the 115 sample grains, 68 were analysed in replicate (up to 21 repeats from a single grain).

Data processing. Corrections were made to the data using U950a as a primary reference material: abundance sensitivity (^{234}U on ^{238}U, *c.* 1.2×10^{-6}); hydride for solutions ($^{238}U^1H/^{238}U$ *c.* 4×10^{-6}, resulting in $^{235}U^1H/^{238}U$ on $^{235}U/^{238}U < 1 \times 10^{-6}$); followed by external correction for $^{235}U/^{238}U$ instrumental response effects[38] (approximated by an exponential mass-bias function[39]). A secondary reference material, U010, was used to correct for bias between the ion counter and Faraday cups. Estimates of uncertainty were propagated from the analytical standard error of the mean (σ_m) and the relative standard deviations of the corrected primary and secondary reference materials.

3. Results

Quality control

Natural uraninite grains were ablated 155 times throughout the four analytical runs for quality control. The data are presented in Fig. 4 (with 8 outliers removed). Following mid-session calibration, the data in the fourth analytical run drift from a significant low bias. Nine of the uraninite data have been used to bracket the remaining sample and quality control data for that interval (as a tertiary reference material). These self-corrected data are highlighted in Fig. 4, and are excluded from the following quality control statistics.

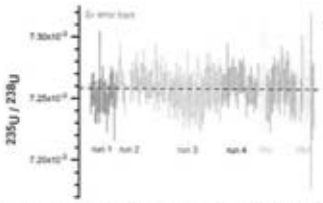

Fig. 4 $^{235}U/^{238}U$ ratios for natural uraninite grains by LA-MC-ICP-MS, from four analytical runs. Nine of the data have been used as reference materials (RM) to correct an observed bias in the second half of run 4.

The remaining data (n = 138) are normally distributed about an arithmetic mean $^{235}U/^{238}U$ (7.259 ± 0.002) × 10^{-3} ($2\sigma_m$). The relative precision for these data is 0.22% (2σ). The mean is within uncertainty of the recently recommended value,[15] within the range of natural variability,[14] or slightly biased when compared to the traditional consensus.[9]

The mean square weighted deviation (MSWD) for these QC data was 1.2, demonstrating that the propagated uncertainty had probably been slightly underestimated.[40] Therefore, the uncertainties for $^{235}U/^{238}U$ have been expanded by 0.1%.

A sample grain (of unknown composition), analysed in replicate during one analytical run (2 outliers excluded, n = 21) has an MSWD of 1.6 for $^{235}U/^{238}U$; demonstrating that the expanded uncertainties are reasonable. For $^{234}U/^{238}U$, an MSWD of 2.6 suggests the uncertainties were underestimated; therefore, they have been expanded by 2%.

The relative expanded uncertainties (2σ) for the sample grain data-points, range from 0.2–1.8% for $^{235}U/^{238}U$, 2.3–4.0% for $^{234}U/^{238}U$, with medians of 0.4 and 2.7% respectively. Compared to the uraninite grains, the sample grains have lower $^{235}U/^{238}U$, and their ablation is more variable and hence signal, resulting in slightly poorer precisions.

Data

The analytical data for the laser ablation of uranium-oxide grains are presented in Fig. 5A, alongside those from analyses of solutions. The solution data show a similar spread of isotopic compositions to the laser ablation data. All these data are expressed as atom ratios.

Fig. 5B shows the data for soils and dusts, and the spread of isotopic compositions from these samples are similar. Particle-solution exchange in the wet soil environment does not explain the spread of data.

4. Discussion

Case-study interpretation

The data confirm the hypothesis that the individual particles of uranium-oxide record a variety of anthropogenic isotopic compositions, which are averaged in bulk soil and dust samples.

All of the uranium-oxide grains analysed are from DU, with $^{235}U/^{238}U$ less than 2.4×10^{-3}. Enriched uranium grains were not observed; these may be very scarce as comparatively little enriched uranium was handled by NLI, and it may have been recycled because of its value. Enriched uranium was evident in one former employee's urine,[4] implying dispersal of some of this material within the plant and possibly further afield.

NLI reduced uranium tetrafluoride (UF_4, greensalt) feedstock during the 1960s and '70s,[5] these may have been from discrete batches with distinct isotope signatures, or an evolving series of isotopic compositions. A number of processes at NLI could also have mixed these isotopic compositions: feedstock storage,

§ It is not clear where the DU feedstock for NLI was sourced. A DoE press release[41] identifies 11 US sites that handled reprocessed uranium, including 3 gaseous diffusion enrichment plants (Oak Ridge, TN; Paducah, KY; Portsmouth, OH) and 1 uranium hexafluoride reduction facility (Fernald, OH). If Fernald produced the UF_4 for NLI, it seems likely that the UF_6 was supplied from neighbouring Portsmouth.

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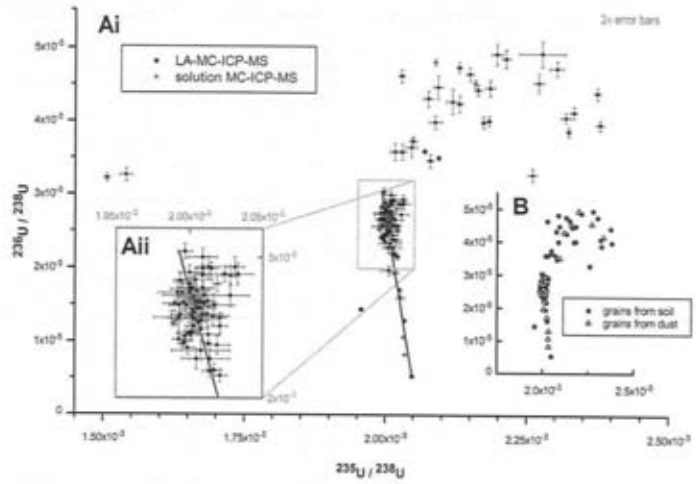

Fig. 5 **A** Isotopic compositions from LA- and solution MC-ICP-MS of individual grains. A mixing line passes through the data up to 3×10^{-4} $^{236}U/^{238}U$ (**Aii** expansion of clustered region showing some deviation of, and scatter away from a simple mixing line). **B** Comparison between analyses of grains from soil and dust samples, showing similar distributions of isotopic compositions.

reduction to uranium metal (derby), castings, machining, shop-floor debris, scrap storage, and finally chip burning (conversion) in the furnace releasing uranium-oxide particulates to the environment.

There is a large spread in ^{236}U abundance, with a reasonably well defined mixing-line from (5–31) $\times 10^{-6}$ $^{236}U/^{238}U$. These data range from (2.05–1.99) $\times 10^{-5}$ $^{235}U/^{238}U$ with increasing $^{236}U/^{238}U$. The data cluster around 2.7×10^{-6} $^{236}U/^{238}U$, 2.0×10^{-5} $^{235}U/^{238}U$. We interpret these ratios to follow either a mixing line between two isotopically discrete batches, or an evolving series of compositions. The former hypothesis seems less likely, as there does not appear to be a second cluster.

There is a scatter of ratios up to 5×10^{-6} $^{236}U/^{238}U$, and up to 2.4×10^{-5} $^{235}U/^{238}U$. These ratios are explained by inhomogeneous mixing (possibly in the NLI conversion furnace) of a continuation of the previous trend with a third component of slightly less depleted uranium. This hypothesised process also appears to affect some of the grains from the clustered region (Figure Aii), drawing them away from the mixing line.

Two grains have distinct isotope signatures with (1.5–1.6) $\times 10^{-6}$ $^{235}U/^{238}U$, and (3.2–3.3) $\times 10^{-4}$ $^{236}U/^{238}U$. The scarcity of these grains suggests that this was a small batch, or that little was released due to improvements in stack filtration.

The isotope signatures revealed by this study are not constrained with respect to age, except for four particles collected by air filters in April and May 1979 and analysed by FT-TIMS[2] (Fig. 6). These ratios fit into the scattered region of our dataset, and support the continuation of the trend of increasing ^{236}U to at least 6×10^{-6} $^{236}U/^{238}U$. These are most likely to have been from emissions at that time. However, the scrap metal may have accumulated for several months before conversion. The isotopic compositions of the uranium materials processed by NLI appear to have been more variable during this period.

It was reported that in 1980, 150 drums of waste uranium had accumulated over several months, and nearly 2 tonnes were converted to oxide in March and April of that year, with the release of only 7.5 g of uranium, thanks to operation of, and improvements to a filtration system, following enforcement action.[40] Extensive uranium contamination of soils is evident by 1980,[8] estimated in the order of 5 tonnes uranium deposited on soils within 1 km^2.[8] The vast majority of the contamination from NLI pre-dates 1980, therefore the sample grains analysed in this study probably also pre-date 1980. Based on the number of grains loosely tied to 1979 (c. 20%), a significant portion of the contamination appears to have been emitted during that period.

We speculate that the feedstock received by NLI evolved through a series of compositions, from 2.05×10^{-5} $^{235}U/^{238}U$ with minor ^{236}U contamination ($<5 \times 10^{-6}$ $^{236}U/^{238}U$), to 1.99×10^{-5} $^{235}U/^{238}U$ with 3×10^{-4} $^{236}U/^{238}U$. Subsequently, and by 1979, the primary NLI feedstock evolved to at least 6×10^{-6} $^{236}U/^{238}U$, but

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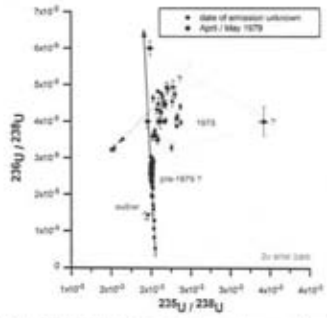

Fig. 6 Speculative explanation of the isotope ratios measured for this case-study. The solid arrow shows the primary NLI feedstock evolving with increasing ^{236}U contamination. A possible secondary feedstock follows the dashed arrow with increasing ^{235}U depletion at the gaseous diffusion plant, leading to the most depleted grains. A scatter of isotopic compositions within the dotted triangular region can be explained by inhomogeneous mixing with 'less depleted' uranium batch(es). The timing is loosely tied by four particles collected by air filters in April and May 1979.[5] A larger dataset could resolve these details.

during that time 'less depleted' uranium was also used. Continued depletion at the gaseous diffusion plant of uranium comprising 2×10^{-5} $^{235}U/^{238}U$, 4×10^{-5} $^{236}U/^{238}U$ could result in the isotope ratios of the most depleted uranium-oxide grains analysed. These interpretations are summarised in Fig. 6.

A chronology for these data could be established using $^{230}Th/^{234}U$, $^{231}Pa/^{235}U$ or possibly $^{232}Th/^{236}U$ dating of particles. The measurements would be technically challenging; with daughter radionuclides in the sub-femtogram range per grain (and are dependent on initial uranium separation). Uranium dating by $^{230}Th/^{234}U$ using ICP-MS has been successfully demonstrated by Varga and Surányi,[46] but improvements in sensitivity would be required for the dating of individual grains.

The spread of $^{235}U/^{238}U$ isotope ratios revealed by this study is matched by those in Fig. 1, but we are able to resolve more information from this large and precise dataset. Some of these DU grains comprise more ^{236}U than previously reported.

These data show that at least some of the DU processed at NLI had low levels of ^{236}U. Therefore, ^{236}U cannot be used as a defining fingerprint of DU contamination if, as for quadrupole ICP-MS, the lower limit of detection of the analytical technique approaches these ratios.

Analytical methodology

Laser ablation allows for the rapid collection of data, when compared to TIMS or solution ICP-MS. A typical sample grain analysis took less than two minutes, and the instrumental productivity (including set-up, reference materials, and particle location), was around 16 minutes per sample grain. Modern MC-ICP-MS systems offer faster set-up times, which could further improve productivity.

Pre-concentration of particles of interest using dense liquid separation was quick and effective, and allows for efficient analysis by laser ablation (or SIMS). However, the methodology does bias the sample by excluding particulates and grains smaller than approximately 20 μm. Smaller grains could be recovered using heavy-liquids with centrifugation,[47] froth-floatation,[48] or inertial separation. Alternatively raw samples may be analysed, but requiring more time searching for the grains of interest and exchanging sample mounts. It is not necessary to embed and polish the particles; they could be adhered to a mount with a clean adhesive, or sampled directly from a swipe sample.

The volume of sample consumed per analysis is small when compared to the volume of the grains of interest, and allows for replicate analyses. The sampling area is similar to the extent of the grains presented on the mount surface. Smaller particles can be analysed, when sufficiently separated from each other, as the uranium content of the resin is indistinguishable from detector noise. However, there is potential for minor additional $^{235}U^1H$ formation with hydrogen liberated from the epoxy resin. Clean mounting material would be necessary for fine particulates, for example carbon planchets. Modern laser systems can also achieve better spatial resolution.

An observed bias in the quality control data for part of one analytical run was corrected by using some of these data as a tertiary standard. There are variations in the uraninite data, and the uncertainties were slightly underestimated, both of which can also be explained by changes in instrument bias between external corrections. This demonstrates the need for more frequent monitoring, preferably by laser ablation of a solid reference material that includes ^{236}U (*e.g.* New Brunswick Laboratory U005-A). These minor issues were not significant to our interpretations of the sample data.

Accuracy was demonstrated by repeat analyses of natural uraninite grains; the mean value agrees with the 'natural ratio'. Relative precision over four analytical runs of 0.2% (2σ) for $^{235}U/^{238}U$ is better or at least comparable to the current methodologies used for nuclear forensic applications. Relative uncertainties (2σ) for the sample grains ranged between 0.2–1.8% for $^{235}U/^{238}U$, and 2.3–4.0% for $^{236}U/^{238}U$. The precision of this method was more than adequate to resolve differences in the isotopic composition of microscopic grains of DU-oxide.

The precision of LA-MC-ICP-MS compares favourably with LA-SF-SC-ICP-MS,[36] and is similar for SIMS analyses of particles from environmental samples.[49,50] It is hard to judge from the literature that achieved by FT-TIMS, although TIMS may offer better analytical precision. However, our method allows the acquisition of large datasets that may be more representative of the samples, the precision is fit-for-purpose, and appears to be a significant way forward for nuclear forensics. For this case-study, a larger dataset could resolve further details regarding the history of uranium processing at NLI (perhaps twice as large, and including sample from other locations for representativity).

5. Conclusions

We have demonstrated the use of LA-MC-ICP-MS to rapidly analyse a large population of microscopic uranium-oxide grains

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for an environmental case-study. It is clear from these and other data that the isotopic compositions of depleted uranium are variable, especially with respect to ^{236}U.

The accuracy and precision analysing $^{235}U/^{238}U$ for natural uranium was excellent. Typical relative uncertainties (2σ) of 0.4% for $^{235}U/^{238}U$ and 2.7% for $^{236}U/^{238}U$, are well-suited to nuclear forensic applications, and are an improvement over single-collector (quadrupole or sector-field) LA-ICP-MS. LA-MC-ICP-MS offers several advantages to nuclear forensics, including fast analysis time, minimal sample preparation, and partial ablation of the sample.

Acknowledgements

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In memoriam Leonard A. Dietz: an inspiration to this study as a pioneer of early TIMS and electron multiplier technologies. He highlighted the contamination of the environment by NLI in 1979, and latterly campaigned against DU munitions.

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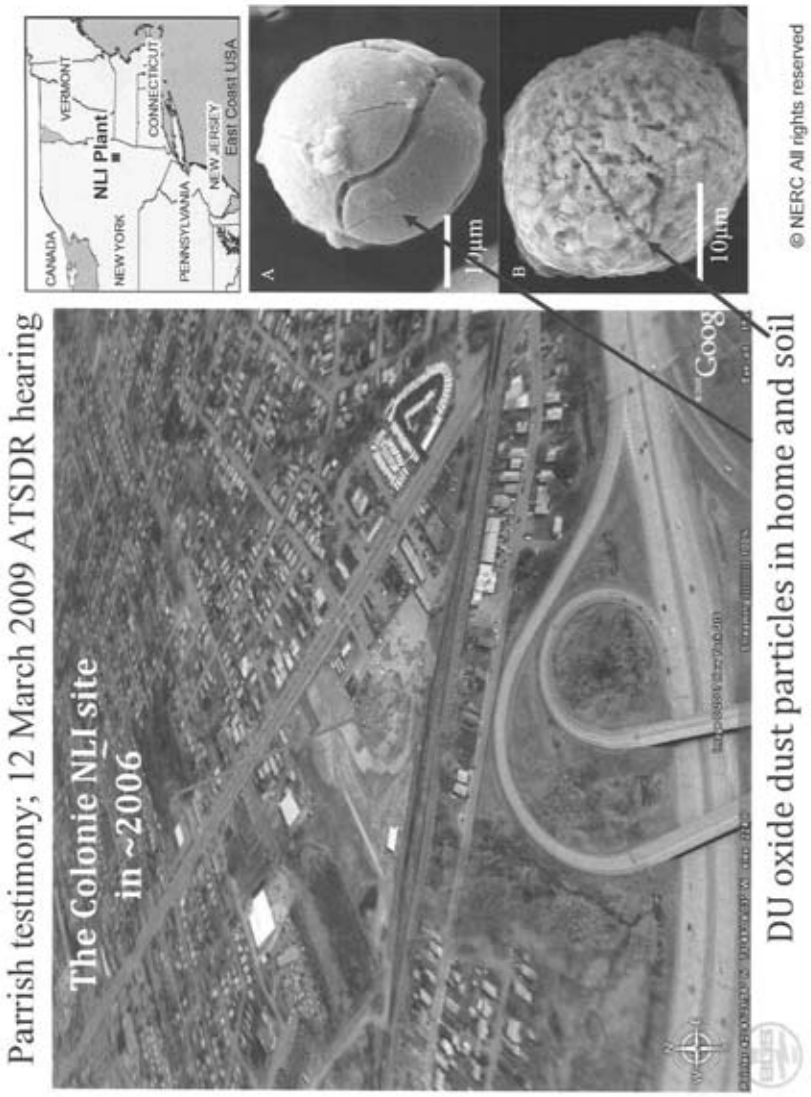
Parrish testimony; 12 March 2009 ATSDR hearing
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DU oxide dust particles in home and soil
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BIOGRAPHY FOR RANDALL R. PARRISH

American by birth (in 1952), the son of parents in the medical business, I lived in the U.S. for all of my youth (Oklahoma, Colorado, Arizona, Vermont). My geoscience career began at Middlebury College (Vermont) during my BA degree studying Geology. I opted to undertake graduate degrees in Canada at the University of British Columbia to study with the late R.L. Armstrong, a most insightful geologist and isotope geochemist. During the period 1974–83 I undertook field work and research in the western Cordillera of Canada (British Columbia mainly) where I combined field work in tectonics with laboratory and theoretical work in the university environment, with a spell teaching at a community college in southern British Columbia. I did my Ph.D. thesis on the rise of the Coast Mountains of British Columbia, which involved a lot of hard field work in remote places. I fortunately escaped any dangerous incidents with bears, rivers, aircraft crashes and so forth that are known in this profession. My first substantial real job was at the Geological Survey of Canada in Ottawa where I was employed from 1983–1996 extending my work that combined geochronology (the dating of rocks and minerals to work out geological history) and field and tectonic studies (in western Cordillera of Canada, much of Canada's vast Precambrian Shield, Saskatchewan, NW Territories, Baffin island, Northern Quebec, Ontario and Quebec, Yukon Territories, but also other studies in the U.S., & Nepalese Himalaya). I also supervised research at Carleton University Ottawa in geoscience. My work in Canada is best known for the tectonic research in British Columbia and for the innovations to mass spectrometry and geochronology methods that I and my colleague the late J. Chris Roddick were largely responsible for, including the synthesis of rare isotopes for geochronology (205Pb).

With the downturn in fiscal climate in Canada in the mid-1990s that required major down-sizing of the public service, I managed change there as Head of the Geochronology Research Facility, but subsequently in 1996 moved to Britain to lead the Natural Environment Research Council's Isotope Geoscience Laboratory, co-sited at the British Geological Survey in Nottinghamshire in a cross appointment arrangement through the University of Leicester, my main employer. This is still my current position. In this capacity I have shouldered a range of responsibilities including re-structuring of the facility, renewing its scientific program and its liaison with the UK geoscience academic community, raising funding for staff growth, program growth, and instrumentation upgrading and expansion (we have 13 mass spectrometers and equipment worth about £6M). Our facility is not a research 'empire' but a collaborative research facility that scientists all over the UK can access—we therefore know how to cooperate and collaborate effectively. Every five years we get put through a very rigorous funding review; each time our performance has improved with the facility now being very stable and well funded. I do a lot of Ph.D. student training both in the field and laboratory environment as part of our remit. My responsibilities expanded in the UK to include a diversified research portfolio extending well beyond traditional geology and geochronology to include heavy metal pollution, different methods of geochronology, innovating methods of analysis in geoscience using laser ablation ICP–MS techniques, climate change, provision of solutions made to a very high calibration standard to worldwide laboratories for interlaboratory comparisons, and lately, applying my analytical and scientific expertise to issues of depleted uranium and health, and the screening of veterans for exposure. I applied my skills to working out a method to detect DU in urine following an exposure more than 20 years prior; this was a major improvement to prior methods. Once I began the depleted uranium and health work, I have tried to make good measurements the cornerstone of the science, let the direction of the work be guided by advances and insights gained through those results, and to follow the science of DU and health until I become satisfied that I have done all that I could to provide insight. This has put me on variable sides of the shifting political fence, with the testimony of this hearing being an interesting collateral task.

I hold research grants in the UK to study a wide variety of problems, mainly involving the evolution of the geology and landscape in the eastern Himalaya, and in improved calibration of the geological time scale through a joint NIGL–MIT–NSF project called EarthTime. My DU research has been funded through piecemeal small grants and contracts, and a funded Ph.D. studentship. I coordinate the thematic research program of the Natural Environment Research Council concerned with depleted uranium and will write a major review report on this topic this year. Our largest contract in the DU business was that to measure uranium isotopes in urine for the Depleted Uranium Oversight Board and we played a part in that major government program funded by the Ministry of Defense. That program was aimed towards the military's duty of care to UK military veterans.

I have led our national facility and worked with its talented staff to move the facility to considerable prominence as an environmental science isotope facility of international stature where a number of research areas are on par with the best world labs. These include the DU work, high precision U–Pb geochronology, laser ablation in situ U–Pb geochronology, multi-element isotope analysis in support of climate research in the recent geological record, and silicon isotope analysis.

In the past five years, I have increasingly been involved with grant proposal adjudication in the UK and elsewhere, editorial duties, and undertaking strategic reviews of facilities, management and operation of portions of large research centers within the UK, including my host institution the British Geological Survey. I consider myself a very good scientific leader and manager gained through experience with colleagues during employment, and guided by common sense. Unusually, I continue to maintain an active role in research and innovative analytical duties; this has extended my period of credibility as a scientist, thankfully!

Further information about our facility is available from *http://www.bgs.ac.uk/nigl/index.htm*

Chair MILLER. Thank you, Professor Parrish. Your use of the phrase "immoral and perverse" made me feel better about perhaps my opening statement being a bit harsh, and I do want to thank you for coming a considerable distance to come to this hearing today.

Dr. PARRISH. It was my pleasure.

Chair MILLER. We have been joined by the Ranking Member of the Full Committee, Mr. Hall. Mr. Hall, do you have any statement?

Mr. HALL. Chair Miller, thank you for having this hearing and bringing these men before us here. I was particularly interested in Sal Mier's testimony, his long-time service at the Centers for Disease Control. I listened to him, and you are welcome to come by my office, and I thank Dr. Broun. I appreciate it. I don't have any questions because I don't know what other questions you will have, but I will try to get back here and listen to one of the other panels, but I thank you very much.

Chair MILLER. Thank you. You don't represent Midlothian, do you?

Mr. HALL. No, but when the legislature is in session, you never know where you are going to be.

Chair MILLER. Mr. Hall covering all bets.

Mr. Camplin.

STATEMENT OF MR. JEFFREY C. CAMPLIN, PRESIDENT, CAMPLIN ENVIRONMENTAL SERVICES, INC.

Mr. CAMPLIN. Good morning. I would like to thank the Subcommittee Members and staff for holding such an important hearing on the lax behavior and misuse of science by ATSDR leadership and staff. My name is Jeffery Camplin and I am President of Camplin Environmental Services Inc., a safety and environmental consulting firm based in Rosemont, Illinois. My chosen research specialty is asbestos. I have been a volunteer for the Illinois Dunesland Preservation Society since 2003 investigating why ATSDR purposely downplays the chronic asbestos exposure of millions of Illinois citizens each year.

My story begins in 1993 when I brought my wife and three kids to Illinois Beach State Park located on the Illinois Lake Michigan shoreline north of Chicago. After building sandcastles and burying each other in the sand, I heard my wife exclaim "Look in the car. It is full of sand. It is in the kids' hair, it is in their ears, it is in

their shoes, it is everywhere.'' Sand eventually ended up in our laundry room as well. Little did I know at the time that my wife along with millions of other families should have been saying, ''Look at the asbestos contamination from the beaches. It is in our car, it is on our kids, it is in our home.''

I have been working for the last six years with Mr. Paul Kakuris, President of the Illinois Dunesland Preservation Society. Our research indicates that ATSDR has violated its mission to serve the public by purposely not using valid science, by not taking responsive public health actions and by providing untrustworthy health information. Specifically, ATSDR has become a complacent agency, choosing to produce outdated, inferior work products when they know more-valid science exists. When ATSDR's ethics and competence are challenged, a great wall of arrogance and denial appears from their leadership to strenuously fend off requests for accountability. ATSDR also takes advantage of the public's gullibility to trust an agency that is ethically bankrupt. The egotistical leadership and complacent culture at this once great agency needs a total overhaul. However, that is not enough.

We are here today to demand accountability for the harm caused to public health by inexcusable and deliberate behavior of ATSDR staff in downplaying elevated levels of toxic microscopic asbestos along the entire Illinois Lake Michigan shoreline. Evidence demonstrates that U.S. EPA and the State of Illinois along with ATSDR bungled the cleanup of an asbestos Superfund site at the south end of Illinois Beach State Park, allowing trillions of asbestos fibers to be released from an unfiltered pipe into Lake Michigan to this very day. Their incompetence also allowed large areas of asbestos-contaminated lake sediments to be dredged and dumped on and offshore at heavily visited public beaches. Federal agencies and the State of Illinois then generated rigged data to conclude the massive asbestos contamination they created was not hazardous to the millions of citizens who frequent these areas. Illinois is well known for nurturing a culture of public officials with less than honest and ethical behavior. Illinois citizens seized upon the opportunity—I am sorry—Illinois officials seized upon the opportunity presented by the complacent culture at ATSDR to protect their unethically symbiotic agendas. They obtained rubber-stamped approval of their intentionally flawed federal and State reports.

In order to conceal the unethical behavior of their staff, ATSDR will tell you the science is still developing while they knowingly continue to use severely flawed and outdated asbestos risk assessments. What they don't tell you is, the current science completely discredits and invalidates all of their past asbestos human health evaluations in Illinois as well as hundreds of other sites throughout the Nation. ATSDR stubbornly refuses to acknowledge this fact.

Just this week ATSDR arrogantly issued another health consultation which intentionally fails to warn the public about deadly microscopic amphibole minerals they found in beach sand and air. Instead, ATSDR recklessly continues to invite families to a shoreline chronically contaminated with asbestos, that is, as long as they don't touch the visible pieces of debris during their visit. Yet there is no recommendation to the public regarding the microscopic asbestos that gets on our kids, gets in our cars, gets in our homes

and ultimately enters our lungs. Maybe Dr. Frumkin can explain his staff's findings that deceitfully concealed the hazard from the public.

Another example of ATSDR's indiscretion includes the review of one of their beach asbestos results in 2006 that the EPA identified as potentially harmful to health. ATSDR dismissed the criticism by the U.S. EPA, stating the beaches were safe anyway.

The fraudulent findings of ATSDR create a welcome permission slip for the continuing dredging of toxic asbestos-contaminated sand in Illinois. Spreading the contaminated dredge material on the shoreline increases the risk of mesothelioma cancer rates in Lake and Cook counties along Lake Michigan that already have elevated mesothelioma rates when compared to national averages. How high must the body count get before ATSDR admits there is a problem?

In 2004, then-Illinois State Senator Barack Obama best summed up our feelings when asked by a reporter about the asbestos contamination along the Illinois shoreline. Our current President said at the time, we can't have our kids swimming in areas that might be contaminated with asbestos, and then he stated they should consider shutting down the asbestos-contaminated shoreline.

Precautionary protections are necessary to address the continuing public health disaster and egregious violations of public trust from getting any worse. The first step is for ATSDR to acknowledge their past studies are flawed. Next, limit the public's exposure to asbestos-laden shoreline beaches until scientifically valid exposure assessments can be completed in an open, inclusive and transparent manner. The final step is to hold all parties liable for their actions. ATSDR officials Mark Johnson, Jim Durant, John Wheeler and Howard Frumkin along with State of Illinois and U.S. EPA officials must be held accountable for their egregious and potentially criminal behavior that resulted in millions of innocent families being unwittingly exposed to deadly amphibole fibers.

On behalf of the Illinois Dunesland Preservation Society and the citizens of Illinois, I want to thank you for this hearing.

[The prepared statement of Mr. Camplin follows:]

PREPARED STATEMENT OF JEFFERY C. CAMPLIN

Good morning. I would like to thank the Subcommittee Members and, staff for holding such an important hearing on the lax behavior and misuse of science by ATSDR/CDC leadership and staff. My name is Jeffery Camplin, and I am President of Camplin Environmental Services, Inc., a safety and environmental consulting firm based in Rosemont, Illinois. My chosen research specialty is asbestos. I have been a volunteer for the Illinois Dunesland Preservation Society since 2003, investigating why ATSDR purposefully downplays the chronic asbestos exposures of millions of Illinois citizens each year.

My story begins in 1993 when I brought my wife and three children (two to three years old) to Illinois Beach State Park, located on the Illinois Lake Michigan shoreline north of Chicago. After building sand castles and burying each other in the sand I heard my wife exclaim, "Look in the car, it's full of sand. It's in the kids' hair, in their ears, and in their shoes . . . it's everywhere." Sand eventually ended up in our laundry room as well. Little did I know at the time that my wife, along with millions of other families, should have been saying, "Look at the asbestos contamination from the beaches. It's in our car, it's on our kids, and it's in our home."

I have been working for the last six years with Mr. Paul Kakuris, President of the Illinois Dunesland Preservation Society. Our research indicates that ATSDR has violated its mission to serve the public by purposefully not using valid science, by

not taking responsive public health actions, and by providing untrustworthy health information. Specifically:

- ATSDR has become a complacent agency, choosing to produce outdated, inferior work products when they know that more valid science exists.
- When ATSDR's ethics and competence are challenged, a great wall of arrogance and denials appears from their leadership to strenuously fend off requests for accountability.
- ATSDR also takes advantage of the public's gullibility to trust in an Agency that is ethically bankrupt.

The egotistical leadership and complacent cultured this once great agency needs a total overhaul. However, that is not enough: **We are here today to demand accountability for the harm caused to public health by the inexcusable and deliberate behavior of ATSDR staff in downplaying elevated levels of toxic microscopic asbestos along the entire Illinois Lake Michigan shoreline.**

Evidence demonstrates the USEPA and the State of Illinois, along with ATSDR, bungled the cleanup of an asbestos Superfund site at the south end of Illinois Beach State Park, allowing trillions of asbestos fibers to be released from an unfiltered pipe into Lake Michigan to this very day. Their incompetency also allowed large areas of asbestos-contaminated lake sediments to be dredged and dumped on and off shore at heavily visited public beaches. Federal agencies and the State of Illinois then generated rigged data to conclude the massive asbestos-contamination they created was not hazardous to the millions of citizens who frequent these areas. Illinois is well known for nurturing a culture of public officials with less than honest and ethical behavior. Illinois officials seized upon the opportunity presented by the complacent culture at ATSDR to protect their unethically symbiotic agendas. They obtained "rubber stamped" approval of their intentionally flawed federal and State reports.

In order to conceal the unethical behavior of their staff, ATSDR will tell you that "the science is still developing" while they knowingly continue to use severely flawed and outdated asbestos risk assessment methods. What they don't tell you is that current science completely discredits and invalidates ALL of their past asbestos human health evaluations in Illinois and at hundreds of others sites throughout the Nation. Yet, ATSDR stubbornly refuses to acknowledge this fact.

Just this week, ATSDR has arrogantly issued another "Health Consultation" which intentionally fails to warn the public about the deadly microscopic amphibole mineral fibers they found in beach sand and air. Instead, ATSDR's recklessly continues to invite families to a shoreline chronically contaminated with asbestos . . . that is as long as they don't touch the visible pieces of asbestos debris during their visit. Yet there is no recommendation to the public regarding the microscopic asbestos that get on our kids, get in our car, get in our homes, and ultimately enters our lungs. Maybe Dr. Frumkin can explain his staff's findings that deceitfully conceal this hazard from the public.

Examples of other indiscretions by ATSDR include:

1. ATSDR generated beach asbestos exposure results in 2006 that the USEPA identified as potentially harmful to human health. ATSDR dismissed the criticism by the USEPA along with our ethics violation charges and published the report stating the beaches were safe anyway.
2. In over a decade of testing, ATSDR has never performed or reviewed any air sampling data that was obtained during the hot, dry, dusty months of June through mid-August. They intentionally test outside the beach season when the beaches are damp and cooler.
3. ATSDR found no elevated risk to human health from the rare but virulent asbestos fiber called tremolite found on Chicago's Oak Street Beach. Tremolite asbestos-contamination has already devastated the town of Libby, Montana with one of the highest mesothelioma cancer rates in the Nation.

The fraudulent findings of ATSDR created a welcome permission slip for the continued dredging of toxic asbestos contaminated sand in Illinois. Spreading the contaminated dredge material on the shoreline increases the risk of mesothelioma cancer rates in Lake and Cook counties along Lake Michigan that are already elevated when compared to the national average. How high must the body count get before ATSDR admits there is a problem?

In 2004, then Illinois State Senator Barrack Obama best summed up our feelings when asked by a reporter about the asbestos contamination along the Illinois shoreline: Our current President said at the time, "*We can't have our kids swimming in*

areas that might be contaminated with asbestos." He then stated they should consider shutting down the asbestos contaminated shoreline.

Precautionary protections are necessary to address this continuing public health disaster and egregious violation of the public trust from getting any worse.

- The first urgent step is for ATSDR to acknowledge that their past studies are flawed.
- Next, limit the public's exposure to the asbestos-laden shoreline beaches until scientifically valid exposure assessments can be completed in an open, inclusive, and transparent manner.
- The final step is to hold all parties liable for their actions. ATSDR officials (Mark Johnson, Jim Durant, John Wheeler, and Howard Frumkin), along with State of Illinois and USEPA officials must be held accountable for their egregious and potentially criminal behavior that has resulted in millions of innocent families being unwittingly exposed to deadly amphibole asbestos fibers.

On behalf of the Illinois Dunesland Preservation Society and the citizens of Illinois, I want to thank you for this opportunity.

I will now address any questions you may have.

Illinois Dunesland Preservation Society

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U. S. House of Representatives
House Subcommittee on Investigations & Oversight
Suite 2321 Rayburn House Office Building
Washington, D.C. 20615-6301

RE: March 12, 2009 Subcommittee Hearing on ATSDR
Illinois Dunesland's Statement on "Human Impacts of Scientific Fraud in ATSDR/CDC's Studies and Consultations"

We would like to thank the subcommittee for choosing to review these important issues. Our country needs to know, in an open and transparent manner, what ATSDR/CDC's scientific fraud translates into and how their arrogant and cavalier behavior has adversely affected humanity. The IMPACT that ATSDR/CDC's scientific fraud has on the public's health and safety has not been FORMALLY addressed by the House Subcommittee on Investigations & Oversight. Further information can be found about these concerns on our web site, http://illinoisdunesland.org/.

President Obama, his family, and millions of others have used the asbestos contaminated Illinois shoreline and believed the "experts'" announcements in the media that the beaches are safe. Therefore, shouldn't the President and the public know about the scientific fraud, those potential exposures, and how they impact their health and safety?

The City of Chicago has concealed from the International Olympic Committee that asbestos has contaminated its beaches http://www.illinoisdunesland.org/pdf/Chicago_Water_Bureau_Asbestos_Study.pdf. Wouldn't the IOC want to know about ATSDR/CDC's scientific fraud and its potential impacts on public health, too?

The exposure of the public to asbestos, including amphiboles, on Illinois's beaches is more than the epidemics in Libby, MT and El Dorado, CA combined. The irony is that the end purpose of ATSDR/CDC is to protect the public's health and safety. EWG (Environmental Working Group in Washington) has found Illinois's Cook and Lake counties along Lake Michigan to rank in the top ten nationally in mesothelioma deaths with no naturally occurring asbestos in the area. The deaths are substantially underestimated.

45 miles of Illinois's (and apparently Indiana's) shoreline on Lake Michigan have been impacted by ATSDR/CDC's misconduct. ATSDR/CDC has continued to cover up the asbestos contamination through conflicts of interest, willful scientific fraud, manipulation of their studies, and through their consultation to other agencies. The manifestation of this behavior impacts the health and safety of millions of people who visit all the asbestos-contaminated beaches in Illinois (and Indiana) and have been exposed to inhaling airborne, microscopic asbestos.

The subcommittee should formally investigate the manifestations on the public health, the intent, and motivations of ATSDR/CDC's "cooked" reports on asbestos. ATSDR/CDC shares

responsibility in the contamination of the entire Illinois/Indiana shoreline because of the agencies' apparent scientific fraud and manipulation of their testing protocols, reports, and consultations. Millions of unwitting beach users are exposed to inhaling invisible, airborne asbestos - including amphiboles. These massive exposures to asbestos affect many millions of people in Illinois and Indiana.

The seriousness of ATSDR/CDC's misbehavior and the resulting exposure of all the people of Illinois/Indiana and the tourists who visit these beaches are incalculable. The agency knowingly allowed their corrupt science and immoral conduct to manifest the deadly results. They failed to protect the public health/safety and the environment which is their responsibility.

John Villarreal lived in one of the coastal towns and walked the beaches several times a month. At 38 years old, he discovered he had mesothelioma and died within two or three years. His only known exposure to asbestos was on the beaches he loved to walk. His case is one of many non-occupational deaths due to asbestos.

Some of the examples of the way ATSDR/CDC "conducted" or "consulted," including activity-based testing are:

- Turning cassette testing units backwards to collect less asbestos
- Placing a weather station near a building to block the true wind velocity during a test; when it is too windy, test results are then further skewed
- Removing testing samples from a study, thereby eliminating their impact
- Extensive conflict of interest between ATSDR/CDC and USEPA; officials would change "hats" and review each others' work (See 2007 & 2008 Inspector General complaints that will be posted on our web site this month.)
- ATSDR/CDC stood by while state agencies only warned the public about chunks of asbestos (RACM) on a fraction of the contaminated beaches while having full knowledge that millions of people were being exposed to inhaling these deadly, invisible fibers when they visited all the beaches and then disturbed the sand. In response to this void, Dunesland's consultant, Jeffery C. Camplin, produced an Asbestos Tips Flyer http://asbestosbeach.com/uploads/IBSP_Asbestos_Flyer_final_version_9-3-04.pdf, warning of airborne asbestos and safety tips to protect the public. The state refused to place the flyer in the information display racks at the state park. Dunesland filed a First Amendment lawsuit http://illinoisdunesland.org/Asbestos2.html in federal court.

It is unconscionable that ATSDR/CDC had years of involvement in lulling other agencies and the citizens of Illinois/Indiana into an apparent false sense of security with their willfully "rigged" science which facilitated millions of people on all Illinois (and apparently Indiana) beaches into being exposed to inhalation of deadly, invisible asbestos fibers, including amphiboles. The resulting contamination has spread over the entire Illinois/Indiana shoreline. ATSDR/CDC and its officials should be held accountable for their actions and the expenditure of millions of tax dollars while willfully carrying out their scientific fraud and ignoring the responsibilities which the agency and officials were charged to perform.

Because of the life-threatening risks to the public health and the growing epidemic of asbestos contamination, we request that the subcommittee hold additional hearings to investigate how ATSDR/CDC's fraudulent practices impact public health and the environment. Further review of the agencies' intent and motivations in committing such practices is imperative. It appears that they have become a puppet of special interests.

Sincerely,

Paul A. Kakuris

2

BIOGRAPHY FOR JEFFERY C. CAMPLIN

Since 1991, Jeff has been President of Camplin Environmental Services, Inc. He is a Certified Safety Professional (CSP) and Certified Professional Environmental Auditor (CPEA). He has been a licensed asbestos professional in the State of Illinois since 1986. Jeff is a nationally recognized safety and health expert who is an accomplished author and public speaker. Jeff has been an instructor of USEPA accredited asbestos abatement training courses for over 20 years.

In 2003, Mr. Camplin became a non-paid consultant for the Illinois Dunesland Preservation Society involved with evaluating issues related to the presence of statistically elevated levels of visible and microscopic asbestos and other amphibole asbestos fibers present in beach sand along the Illinois Lake Michigan shoreline. He determined that asbestos public health assessments published by ATSDR in 2000 and 2006 were not based upon scientifically valid data. Mr. Camplin has challenged several of these ATSDR studies without receiving credible responses from the Agency.

Mr. Camplin has uncovered evidence of ATSDR staff rigging asbestos studies by manipulating sampling protocol, analytical methods, and risk models used in their studies. Examples of this rigging includes sampling during and immediately after rain events, using larger pore sized filter media in violation of standard protocols, and avoiding air sample testing during the hot, dry, beach season of June through mid-August. He also caught ATSDR staff on video violating ethical standards by exposing the unprotected public to high levels of asbestos fibers during ATSDR's activity-based asbestos testing on public beaches. These findings not only discredit health evaluations performed at Illinois Beach State Park and Oak Street Beach (Chicago), but also hundreds of other asbestos health evaluations performed by ATSDR throughout the United States using the same flawed and unscientifically sound protocols.

Mr. Camplin has been interviewed by the USEPA's Inspector General's Office who is currently completing a nearly two-year investigation into the asbestos contamination issues along the Illinois Lake Michigan shoreline. The investigation focuses on the manipulation and rigging of studies by the State of Illinois, USEPA, and ATSDR to fraudulently conclude that the statistically elevated levels of microscopic asbestos fibers present in beach sand is safe for the public to disturb. He seeks to have proper scientifically supported studies performed in the future in an open, publicly inclusive, transparent manner, with independent third party peer review. Mr. Camplin and the Illinois Dunesland Preservation Society also seek to have those members of ATSDR held accountable for their egregious ethical and professional conduct violations during their manipulation of data in the creation of scientifically unsound human health studies.

Chair MILLER. My opening statement seems more and more temperate.

Dr. Hoffman.

STATEMENT OF DR. RONALD HOFFMAN, ALBERT A. AND VERA G. LIST PROFESSOR OF MEDICINE, MOUNT SINAI SCHOOL OF MEDICINE; DIRECTOR, MYELOPROLIFERATIVE DISORDERS PROGRAM, TISCH CANCER INSTITUTE, MOUNT SINAI MEDICAL CENTER

Dr. HOFFMAN. Thank you. For the last 30 years my research and clinical practice have revolved around the investigation of a group of chronic blood disorders termed myeloproliferative disorders, which include polycythemia vera, essential thrombocythemia and primary myelofibrosis. These are serious disorders characterized by excessive production of red cells, platelets and white blood cells and are associated with excessive blood clotting, bleeding and eventual evolution to acute leukemia.

In 2005, a mutation in an intracellular kinase termed JAK2 was found to be present in patients with myeloproliferative disorders and was shown to play a role in the development of this particular group of disorders. The mutation allows blood cell production to occur in myeloproliferative disorders in the absence of signals pro-

vided by hormones that normally control blood cell production leading to the production of too many red cells, white cells or platelets in patients with this disorder. Most importantly for this discussion, the JAK2V617F mutation has been shown to provide an almost foolproof means of diagnosing patients with myeloproliferative neoplasms, since it can be detected using molecular methods in over 95 percent of patients with polycythemia vera. Since there are numerous other causes of too many red cells or polycythemia other than this form of blood cancer, physicians frequently had great difficulty in making this diagnosis. With the advent of the molecular test for JAK2V617F, the accuracy of definitively diagnosing this disorder has been greatly elevated. Although blood cells with JAK2V617F are occasionally observed in patients with other kinds of blood cancers, it is rarely, if ever, observed in normal people.

My first contact with the Agency for Toxic Substances and Disease Registry began in the summer of 2006. Dr. Vince Seaman, an epidemiologist and toxicologist at ATSDR, first called me to ask me some questions about the nature of polycythemia vera and about the possibility of environmental insults increasing the incidence of this blood cancer. I was a bit skeptical about the significance of this polycythemia vera cluster that Dr. Seaman and his colleagues were then investigating in Carbon, Luzerne and Schuylkill counts in eastern Pennsylvania in response to an invitation made by the Pennsylvania Department of Public Health. After a series of phone calls with Dr. Seaman, I gained a greater degree of comfort with these investigations, that this cluster was potentially important from a scientific point of view and that it presented a possible public health danger to the citizens of the State of Pennsylvania. In the past, links between environmental exposures and clusters of polycythemia vera have not been well documented. In my discussions with Dr. Seaman, I emphasized the difficulty of making the clinical diagnosis of polycythemia vera and that the newly described molecular assay would provide a simple, inexpensive means of making this diagnosis with certainty merely by testing blood drawn from the study subjects. Dr. Seaman agreed and we set out to create a means of obtaining blood specimens for subjects who agreed to participate in the study. We proceeded with the JAK2V61 testing due to my belief that these studies were the state-of-the-art in 2009, although there was initial pushback on the part of the Agency and I felt that it was important to do this test to confirm the diagnosis of polycythemia vera. By the end of 2007, these analyses had been completed showing that about 53 percent of the subjects in this study area fulfilled both clinical and molecular diagnostic criteria of having this hematologic cancer. One patient had diagnostic features of polycythemia as determined by a committee of experts but did not have the JAK2 mutation. The confirmed cases appeared to be clustered around numerous EPA Superfund sites and sites of waste coal power plants in the tri-county area. Remarkably, to me, at least, four of the reported cases of polycythemia vera were located along Ben Titus Road, a stretch of about 100 homes scattered along a two-mile stretch. Each of these cases were confirmed to be JAK2V617F positive and therefore to indeed have polycythemia vera. Remarkably, the greatest number of cases of polycythemia vera were in the Tamaqua area, a sparsely

populated area not in the area of greatest population near Wilkes-Barre.

With this data in hand, I and Dr. Seaman wrote an abstract in August 2007 for consideration for presentation at the 2007 meeting of the American Society of Hematology to be held, ironically, in Atlanta, Georgia, in December. Several conference calls were held with numerous members of the ATSDR staff who checked the data and went over the content of the abstract word by word and agreed with the data and conclusions of the abstract vocally during these numerous conversations. The abstract——

Chair MILLER. Dr. Hoffman, there is a five-minute limitation. We are reasonably generous with it. Your whole written statement will be part of the record. Could you summarize in perhaps a paragraph?

Dr. HOFFMAN. Sure. The abstract eventually was accepted by the Society in November of that year and it was accepted as an oral presentation. I then went on to create this presentation that was presented before the Society in December of 2007. A representative of the Agency management team was to appear at the presentation but at the last moment, although he was based in Atlanta, he refused to attend or wasn't able to attend. Several days prior to my presentation at Atlanta, the ATSDR unbeknownst to me issued a press release stating that the abstract presented results that were premature and scientifically flawed. Medical colleagues in Hazleton called me to inform me of this disclaimer because reports had appeared in the local press. I was of course shocked and was incredulous about the lack of forthrightness demonstrated to me by my presumed collaborators at ATSDR. After my arrival in Atlanta I was contacted on my cell phone on repeated occasions by officials at ATSDR requesting that I either withdraw the abstract entirely, state prior to my presentation that the Agency disagreed with my conclusions or present an abridged version of the data. I presented the abstract in its entirety and it was well accepted by the audience at the American Society of Hematology. In order to obtain further peer review, we then went about upon Dr. Seaman's return from a trip to Mozambique on ATSDR business to submit this publication to a peer-review journal. Prior to that submission, the Agency insisted of Dr. Seaman and myself to perform further geospatial analyses which to a statistical point of view confirmed the findings that were present in our abstract showing that there was a higher incidence of polycythemia vera in this area and that those cases were essentially around these areas of high toxic exposure.

From my point of view, the mission of the Agency is to generate and communicate credible scientific information about the relationship between hazardous substances and adverse events that affect human health and to promote responsive public health actions. My experience was that in the case of polycythemia vera in eastern Pennsylvania was that the ATSDR did not accomplish this goal but only accomplished it eventually with relentless prodding to complete the needed investigations. My sense was that if the Agency was left to themselves, they would have preferred to ignore the whole problem. ATSDR seemed to be committed to a course of ignoring and discrediting a mounting body of evidence which sug-

gested the presence of a cluster of polycythemia vera patients in this tri-county area. With the full publication of our paper in February of 2009, the Agency really I think greatly turned around and began to become much more serious about these investigations and hopefully in the future we will be able to expand this area, which I think is of great interest. Thank you for your time.

[The prepared statement of Dr. Hoffman follows:]

PREPARED STATEMENT OF RONALD HOFFMAN

My name is Dr. Ronald Hoffman. I am the Albert A. and Vera G. List Professor of Medicine at the Tisch Cancer Institute of the Mount Sinai School of Medicine in New York, NY. At that institution I am Director of the Myeloproliferative Disorders Program. For over 31 years I have been a practicing clinical hematologist. Hematology is the study of the diseases of the blood. In addition, I am a laboratory based scientist who has investigated the stem cell origins of blood cancers. I am an author of over 400 scientific papers and have served as the President of both the International Society of Experimental Hematology and the American Society of Hematology. I am the lead editor of the textbook *Hematology, Basic Principles and Practice,* which is in its 5th edition and is the leading textbook of hematology in the United States and Europe. I have held prior faculty positions at Yale University School of Medicine, Indiana University School of Medicine, Stanford University School of Medicine and the University Of Illinois College Of Medicine.

For the last 30 years my research and clinical practice has revolved around the investigation of a group of chronic blood cancers, termed the myeloproliferative disorders with include polycythemia vera, essential thrombocythemia and primary myelofibrosis. These disorders are characterized by excessive production of red cells, platelets and white blood cells. These disorders are frequently associated with excessive blood clotting or bleeding and evolution to acute leukemia. These disorders are now known to be blood cancers which originate at the level of blood stem cells. In 2005 a mutation of an intracellular kinase termed JAK2 was found to be present in patients with myeloproliferative disorders. JAK2 is responsible for transmitting signals to blood cell elements inducing them to produce greater numbers of such cells in response to hormones that normally regulate blood cell production. The JAK2 mutation was discovered by a group in France headed by Dr. William Vainchenker. The mutation allows blood cell production to occur in myeloproliferative disorder marrow cells in the absence of the signals provided by the hormones that normally control blood cell production, thereby leading to the production of too many red cells, white cells or platelets in patients with these blood cancers. This JAK2V627F mutation also been shown to provide an almost fool proof means of diagnosing patients with myeloproliferative neoplasms since it can be detected using molecular methods in over 95 percent of patients with polycythemia vera, and 50 percent of patients with essential thrombocythemia and primary myelofibrosis. Previously, polycythemia vera was diagnosed based upon a variety of costly diagnostic tests as well as relatively nonspecific clinical signs and symptoms. Since there are numerous other causes of too many red cells or polycythemia other than this form of blood cancer, physicians frequently had great difficulty in definitively making this diagnosis. With the advent of the molecular test for JAK2V617F, the accuracy of definitively diagnosing polycythemia vera has been greatly enhanced. Although blood cells with the JAK2V617F are occasionally observed in patients with other kinds of blood cancers it is rarely if ever observed in normal people.

My first contact with the Agency for Toxic Substances and Disease Registry (ATSDR) began in the summer in 2006. Dr. Vince Seaman, an epidemiologist and toxicologist at ATSDR first called me to ask me some questions about the nature of polycythemia vera and about the possibility of environmental insults increasing in the incidence of this blood cancer. I had never heard of the ATSDR and at that time had not been previously acquainted with Dr. Seaman. I was a bit skeptical about the significance of a cluster of polycythemia vera patients that Dr. Seaman and his colleagues were then investigating in Carbon, Luzerne and Schuylkill counties in Eastern Pennsylvania in response to an invitation made by the Pennsylvania Department of Public Health. After a series of phone calls with Dr. Seaman, I gained a greater degree of comfort with these investigations and became concerned about this high incidence of polycythemia vera in this area that had been initially identified by the Pennsylvania Department of Public Health. I thought that this cluster was potentially important from a scientific point of view and that it pre-

sented a possible public health danger to the citizens of Pennsylvania. In the past, links between environmental toxic exposures and clusters of polycythemia vera had not been well documented. In my discussions with Dr. Seaman I emphasized the difficulty of making the clinical diagnosis of polycythemia vera and that the newly described molecular assay for JAK2V167F would provide a simple inexpensive means of making this diagnosis with certainty merely by testing blood drawn from the study subjects. Dr. Seaman agreed and we set about to create a means of obtaining blood specimens from the subjects who agreed to participate in the study. Specimens were collected in Tamaqua, shipped to my laboratory and analyzed for JAK2V617F during the period from December 2006 through April 2007. These specimens were shipped in a de-identified manner to my laboratory and the assays were performed without knowledge of the patient source. Initially I had asked that ATSDR to provide some support to cover the expenses for the performance of these assays. To my surprise the Agency administrators were unwilling to supply such funds and were actually resistant to their performance. Their unwillingness to receive input about the significance of the extraordinarily large numbers of patients with this hematological cancer in this small area of Pennsylvania or to consider the value of a molecular epidemiological tool to make their task easier surprised me. Their lack of comfort in collaborating with scientists outside their community or their area of expertise and to readily incorporate new scientific advances into their research efforts while investigating a possible cluster of blood cancer patterns seemed odd, and closed minded in nature. I frequently felt that the members of the Agency management team viewed that this molecular epidemiological approach was overkill and unnecessary since they had already concluded that the cluster was not significant or worthy of further investigation. We proceeded with the JAK2V617F testing without the support of the Agency due to my belief that these studies were the state-of-the-art in 2009 and were required to confirm the diagnosis of polycythemia vera The molecular testing for JAK2V617F was supported with funds that I had received from the Myeloproliferative Disorders Research Foundation for different purposes. The Foundation agreed to this diversion of resources. Dr. Seaman and his team sent us fifty six blood specimens which we evaluated for the JAK2V617F mutation. Over half of these specimens were JAK2V617F positive and an additional five patients from the area were shown to be JAK2V617F positive based upon information present in their medical records; I also assisted ATSDR in establishing a committee of medical experts to examine the medical records of the participants in the study be certain that the clinical characteristics of these individuals were consistent with a diagnosis of polycythemia vera.

By the end of April 2007 these molecular analyses had been completed showing that about 53 percent of the subjects in the study area fulfilled both clinical and molecular diagnostic criteria of having polycythemia vera. One patient had diagnostic features of polycythemia vera as determined by our committee of experts but did not have the JAK2V617F mutation The confirmed cases appeared to be clustered around the EPA superfund sites and sites of waste coal power plants in the tri-county area. Remarkably, four of the reported cases of polycythemia vera were located along Ben Titus Road, a stretch of about 100 homes scattered over a distance of mile; each of these cases was confirmed as being JAK2V617F positive indicating that these patients did indeed have polycythemia vera. Remarkably, the greatest numbers of cases of polycythemia vera were in the Tamaqua area, a sparsely populated area, not in the area of greatest population density near Wilkes-Barre where the cancer registry data (which is based upon diagnoses being made using clinical criteria) had indicated that the greatest numbers of patients had lived. With this data in hand, I and Dr. Seaman wrote an abstract in August 2007 for consideration for presentation at the 2007 meeting of The American Society of Hematology Meeting which was to be held in December 2007 in Atlanta, Georgia. Over 20,000 hematologists from around the world usually attend this meeting. Several conference calls were held with numerous members of the ATSDR staff who checked the data and went over the content of the abstract word by word and agreed with the data and the conclusions of the abstract vocally during these numerous conversations prior to its submission. The abstract was then submitted for consideration for presentation at the American Society of Hematology Meeting. Although numerous ATSDR staff were aware of this submission and its content, Dr. Seaman, without my knowledge, apparently did not have the abstract formally cleared by the Agency. Dr. Seaman explained to me that he was new at the Agency and was not fully aware of the clearance process for documents of this type. This omission was surprising to me and appeared to represent a technicality since so many of the ATSDR staff had gone over the content of this abstract and had already agreed with its content during our numerous phone conversations. In October of 2007 I attended a community meeting dealing with this subject which was organized by the ATSDR

and the Pennsylvania Department of Health in Hazelton, Pennsylvania. Prior to the meeting I had lunch with many of the junior staff of ATSDR who had come to Hazelton. My collaborator at the Agency, Dr. Vince Seaman was noticeably absent. Several weeks prior to the meeting he had been sent to Mozambique for a mandatory training period dealing with agency business. I felt that the timing of Dr. Seaman's trip was odd and showed poor judgment on the part of the Agency. Dr. Seaman had participated in the field of work that led to the report and had the confidence and trust of the community. Many of the community members saw Dr. Seaman as a so called "straight shooter." At the lunch many of the junior staff of the ATSDR bemoaned Dr. Seaman's absence, but were energized by the findings that had resulted from the collaboration between Dr. Seaman and my laboratory . About 75–100 community members attended the meeting and there were a series of presentations, some by the professionals in the community, by ATSDR senior staff and by myself. The conclusions articulated by the ATSDR spokesperson seemed at odds with the results summarized in our abstract that had just been submitted to the American Society of Hematology. The ATSDR claimed that groups of polycythemia vera cases were scattered throughout the tri-county area in no predictable pattern. They also emphasized that only half of the reported cases actually had polycythemia vera based upon our molecular analyses but failed to mention that even with this caveat in mind that the incidence of polycythemia vera was still extraordinarily high in this region. ATSDR appeared to minimize the importance of these findings and concluded that it would be virtually impossible to identify the inciting agent that might possibly have led to the polycythemia vera cluster. The ATSDR spokesperson seemed to feel that this was a fruitless effort and was not really worthy of further attention. I was impressed by the anger of the community at the meeting, there sense of futility and betrayal. At the meeting I mentioned to the audience that we have submitted an abstract to the American Society of Hematology about our findings and that the scientific community would assess the validity of our conclusions. I attempted to inform them that if this material was found scientifically meritorious that the scientific community would demand further investigation of the problem. They appeared skeptical. As I drove back to New York that evening with my scientific colleague at Mount Sinai, Dr. Mingjiang Xu we talked about the experiences of the day. We commented how we felt, that the ATSDR had misinterpreted and prematurely drawn conclusions about the data that we had participated in generating. We commented that many of the ATSDR management were unwilling to think out of the box and how their unwillingness to investigate the unknown or to address difficult problems was the antithesis to the type of scientific investigation that we were so familiar with in the biological and medical sciences. Also we questioned if there was some outside constituency who ATSDR was responding to that made them act like they just wanted this whole matter to go away. Instead of viewing this as a challenging and important scientific problem of possible importance, we felt that they had concluded that it was not important or that it was futile to try to further investigate its origins.. Their lack of familiarity with the power of modern cellular and molecular biology and their unwillingness to apply these tools in an innovative fashion to this problem was surprising to me. I concluded that this type of nihilism was antithetical to the performance of good science.

In the middle of November I was e-mailed by the American Society of Hematology that our abstract had been accepted as an oral presentation. Only 12 percent of the thousands of abstracts submitted to this meeting receive a high enough grade to be presented at an oral session. I immediately informed Vince Seaman of the acceptance. Vince was in Mozambique on assignment but he and several other ATSDR staff members helped me create the presentation and reviewed its content and repeatedly altered the content until they approved it and the written speech that I was to present at the meeting. There were repeated attempts and requests on the part of ATSDR management to avoid showing maps which might indicate a geographic relationship between the cases of polycythemia vera and the known EPA super fund sites.

A representative of the Agency management team was to appear at the presentation but at the last moment, although he was based in Atlanta, he stated that it was not necessary and that he would not be attending. Several days prior to my presentation at the Atlanta meeting the ATSDR—unknownst to me—issued a press release stating that the abstract presented results that were premature and scientifically flawed. Medical colleagues in Hazelton called me and informed me about this disclaimer by the Agency, reports of which had appeared in the local press in Pennsylvania and asked me what I was going to do. I was a bit shocked and was incredulous about the lack of forthrightness demonstrated to me by my presumed scientific collaborators at ATSDR. I told the physicians in Hazelton that I still believed that the data were correct and that I intended to present the information and let

the scientific community evaluate its merit. I must tell you I felt betrayed by the leadership of ATSDR since I had made great efforts to get these leaders involved in the content of the abstract and obtain their approval. After my arrival in Atlanta, I was contacted on my cell phone on repeated occasions by officials of ATSDR requesting that I either withdraw the abstract entirely, state prior to my presentation that the Agency disagreed with my conclusions or present an abridged version of the data. I was intimidated by these frequent calls by government officials which created a great degree of stress and anxiety for me. I was also outraged at this obvious attempt at intimidation. I refused to alter the presentation and presented it in its entirety although ATSDR continued to undermine its validity in the press. I felt justified in these actions since numerous members of the Agency had previously repeatedly approved the content of the abstract. The presentation was well received and the scientific community accepted the possibility that environmental contaminants might play a role in the development of polycythemia vera in the patients in the Tamaqua area.

After receiving this positive feedback from the members of the American Society of Hematology, I realized that the only way that I could further validate the data was for it to be published in a peer reviewed journal so that once and for all this data would be in the public domain and be open to further scientific input and criticism. Upon Dr. Seaman's return from Mozambique we began writing this manuscript. The senior leadership of the Agency continued to doubt these conclusions and insisted that the Agency's biostatisticians perform sophisticated geospatial analyses to further test the validity of our findings. I strongly agreed with their scientific rigor not wanting to be associated with incorrect information. This cluster analysis was done using Satscan, a geospatial software tool developed by the National Cancer Institute for the detection of cancer clusters. The chance of the likelihood of the polycythemia vera cluster being a random event based on the total number of cases in the tri-county area was calculated by the Agency statisticians independently of my input or that of Dr. Seaman. A single statistically significant cluster of polycythemia vera patients ($p<0.001$) was identified near the geographic center of the three counties. The incidence of polycythemia vera in the cluster area was 4.3 times higher than that in the rest of the county. The probability of one finding greater than 15 cases of polycythemia vera in this area and 18 cases in the remainder of the tri-county area was one in 220,000. The probability of the cluster being a random event based on the total number of confirmed cases in the tri-county area was 1/2000. Several sources of hazardous materials were located in or near the high rate area of polycythemia vera. Seven of the 16 waste coal power plants in the United States are located in or within this area or within a few miles of the area. Seven U.S. Environmental Protection Agency super fund sites are contained within this area and another possible cluster area that was identified. This manuscript was completed and revised on numerous occasions with the participation of members of the ATSDR and the Epidemiology Branch of the Pennsylvania Department of Public Health. Numerous revisions were made on the manuscript based upon the suggestions of the ATSDR and the Pennsylvania Department of Public Health without compromising the validity of the information presented. The manuscript was reviewed and revised word by word during several teleconferences. This manuscript was accepted by the peer reviewed journal, Cancer, Epidemiology, Biomarkers and Prevention published in February 2009. During the submission process, a number of minor changes were made in the manuscript to accommodate the Journal's reviewers and specific publication format requirements. This is a routine process and ATSDR did not require the final version of the manuscript to be re-cleared. After the manuscript was published, the chief epidemiologist at the Pennsylvania Department of Health, who had actively participated in the word-by-word editing of the manuscript even though he was not an author, became very upset when he found that the manuscript had been altered. He made numerous calls to high-placed officials at ATSDR in an effort to get them to discredit the manuscript. The ATSDR management resisted these efforts as they recognized that the manuscript contained factual, scientifically valid information and there was no basis for the claims being made by the Pennsylvania Department of Health.

I also participated in a round table discussion of expert researchers convened by ATSDR and the Pennsylvania Department of Public Health in Philadelphia later in 2008 to identify research priorities about further investigating the extent of the cluster of cases of polycythemia vera in the tri-county area and determining possible factors that might have led to this cluster. The data that was presented in the paper published in Cancer, Epidemiology, Biomarkers and Prevention I believe is important and valid. I believe that it provides information which justifies continued realistic concerns that there is a relationship between a cluster of cases of polycythemia vera and serious environmental exposures in the tri-county area. This concern clear-

ly merits careful, additional, detailed objective rigorous scientific investigation to better define the magnitude of this problem and what are the possible causes of such an event. This information is of potential importance not only for the population of this tri-county area but to all citizens of the United States because it provides a possible link between the environment and blood cancers, an association that has not to date been well documented.

ATSDR is the leading federal public health agency responsible for determining human health effects associated with toxic exposures, preventing continued exposures and mitigating associated human health risks at the 1200 National Priorities hazard waste sites targeted for cleanup by the U.S. Environmental Protection Agency. The mission of the ATSDR is stated to be "to generate and communicate credible scientific information about the relationship between hazardous substances and adverse human health effects and to promote responsive public health actions." My experience was that in the case of the polycythemia vera cluster in Eastern Pennsylvania that ATSDR accomplished this goal only because of the relentless prodding to complete the needed investigations due in part to the efforts of some of the talented staff at the Agency working in collaboration with our group at the Mount Sinai School of Medicine in New York and the continued input of the physicians in the tri-county area and of course the residents of this area. My sense was that if the Agency was left to themselves they would have preferred to ignore the whole problem. ATSDR seemed committed to a course of ignoring and discrediting a mounting body of evidence which suggested the presence of a cluster of polycythemia vera patients in the tri-county area. The Agency appeared to be overly responsive to possible outside influences which compromised its ability to evaluate the severity of this problem. Rather than questioning the validity of this cancer cluster in a pro-active manner, their initial response was to discount its significance and to express on numerous occasions the futility in attempting to link the cluster of these cases of polycythemia vera to any specific environmental toxins. This type of work is obviously difficult and time consuming but appears to be the core function of this agency. If the Agency is not willing to evaluate such clusters in a pro-active and objective fashion and closely interact with individuals with different and complementary areas of expertise then the possibility of their accomplishing their stated goals is very small. The scientific nihilism and lack of respect for the integrity of scientific investigation initially displayed by members of the Agency surely compromises the stated mission of this agency. Their unwillingness to look objectively at the compelling data generated by our investigations is puzzling and disturbing to me. The Agency has many talented, skilled energetic professionals in its ranks who have expressed to me frustration and concern about their being held back from fully investigating the polycythemia vera cluster in Pennsylvania. The reasons for these actions and their rationale remain unclear. Most recently the Agency has become increasingly more committed to more vigorously investigating the polycythemia vera cluster and its causes. I congratulate them on this recent change in policy. This behavior is much more appropriate and consistent with the stated mission of the Agency and will likely to lead to a growth of a valid body of information that will provide new insight into the significance of the polycythemia vera cluster in Eastern Pennsylvania and its possible causes. In addition these investigations will likely provide new information about a possible link between blood cancers and environmental toxins. Such information will hopefully be helpful in decreasing in the future the incidence of such deadly cancers in areas of such high risk for exposure to environmental toxins.

BIOGRAPHY FOR RONALD HOFFMAN

Dr. Ronald Hoffman is the Albert A. and Vera G. List Professor of Medicine at the Mount Sinai School of Medicine, and Director of the Myeloproliferative Disorders Program at the Tisch Cancer Institute, Mount Sinai Medical Center. He is the principal investigator of the Myeloproliferative Disorders Research Consortium, with an NCI funded program project dealing with myeloproliferative disorders. His research interests deal with stem cell biology and myeloproliferative disorders. He is a former president of the American Society of Hematology and the International Society of Experimental Hematology.

DISCUSSION

Chair MILLER. I want to thank all the witnesses for your testimony and for appearing here today. We will now recognize each

Member present for five minutes of questioning. The Chair now recognizes himself. I now recognize myself for five minutes of questioning.

EXPLANATIONS OF ATSDR'S DEFICIENCIES

Dr. Hoffman, do you have an impression, an opinion of what accounts for ATSDR's unwillingness to look at the data from the cancer cluster that you looked at? Do you think it is the leadership of ATSDR or do you think it is the culture of ATSDR? Is there external pressure? Is there a reason that comes to your mind to explain their reluctance to acknowledge or find environmental exposure that may cause the cluster, the cancer cluster?

Dr. HOFFMAN. Well, first of all, I want to state that I think there is a number of very talented investigators there and there is a very talented staff so there is a lot of good folks there. My sense is that they felt that it was a futile effort since there were so many environmental toxins in that area to essentially develop a one-to-one relationship between a particular environmental toxin and the development of polycythemia vera. That led to a sense of futility. What was articulated to me on numerous occasions was that even if we found out that the incidence of polycythemia vera was greatest in this area, what were we really going to do about it, could we essentially define an additional—the known agent. That kind of thinking or neolism, I would call it, is very foreign to me because I am used to in a laboratory at least solving or trying to attack very complex scientific problems, and I really thought that that attitude was pervasive, this feeling that one could not identify the toxic agent, and that led to, you know, sort of snowballed into sort of talking away or speaking away or downplaying the significance of this cluster. I think what was also not perceived was the importance of the cluster. The importance of the cluster really went beyond just this particular area because it linked very conclusively, especially with the sophisticated statistical analysis that I congratulate them on performing which was very hard science showing that it was highly unlikely that this was random. So what it really shows is that blood cancers in general could be related to environmental toxins. That is a very important question and observation. The point is, is this a futile event? No, it is not a futile event making this association because if we are aware of this, then we can essentially define the cause of this and hopefully develop chemopreventive agents to prevent additional patients from getting these cancers. So I think they were essentially frozen in time, and because of this sense of futility and perhaps a sense of understanding the whole gamut of hematologic malignancies, they didn't really appreciate the importance of it.

PEER REVIEW

Chair MILLER. Dr. Hoffman, you congratulated ATSDR on their statistical analysis and on the unlikely possibility that it would be random.

Dr. HOFFMAN. Right.

Chair MILLER. You have had your work peer reviewed. I assume you are competent to do peer review. Have you looked at enough of ATSDR's work to know how well it would fare in peer review?

Dr. HOFFMAN. Mr. Miller, I am really not an epidemiologist. I mean, I am a hematologist and a blood scientist. Prior to this interaction which started on 2006, I had never heard of this agency so I am really incapable of evaluating their other work.

Chair MILLER. Do you think that there would be a value in requiring peer review for at least some of their assessments?

Dr. HOFFMAN. I felt from my perspective, I wanted my work evaluated by outside reviewers. I wanted it evaluated and presented at a scientific meeting where I could get feedback from my peers. I also wanted it to go to a scientific journal where people could show me that I was wrong because I was not really interested in presenting or publishing incorrect data. That is the way I was brought up scientifically. I think that is a healthy way to act within any kind of investigative effort if you are going to do real science.

MORE EXPLANATION OF DEFICIENCIES

Chair MILLER. Mr. Mier, you used to work for the CDC. You never heard of ATSDR but you were inclined to assume that they would do reliable work and that assumption you do not think proved to be correct. What do you think is the reason for that? What do you think happened? Why do you think they do not do the job that you thought they would do?

Mr. MIER. You know, I don't know if it is just their reluctance to go after an industry. I know that in Texas, at least my feeling is that there is not much balance between the need to prosper economically, to have jobs, and the need to care for public health and the environment, and in our state my biggest concern is with the State environmental agency and my biggest concern was why ATSDR did not closer evaluate the data that they were looking at upon which to make sweeping generalizations about public health. To me, the air monitoring system was so suspect. I am not a scientist, but based on other scientists that I have dealt with have always told me that, and there is so much tinkering that can be done with the various aspects of the monitoring system. And why they would not—not just ATSDR but the State public health agency with which they have a cooperative agreement with in Texas, why they would not look at the empirical evidence. I always felt that the best monitors were the animals in our community, much better than any mechanical device that we could have, but why they would just not want to look at our animal issues as the potential for a sentinel for human health.

Chair MILLER. My time has expired, and I will try to be reasonably indulgent with the other Members as a result.

Dr. Broun for five minutes.

Mr. BROUN. Thank you, Chair Miller. I appreciate it.

POTENTIAL FIXES

We each have five minutes to ask questions so I am going to ask a pretty broad question of each of you all and so if you would, try to answer it within 30 seconds and we will go forward. If you were

a dictator, how would you fix ATSDR? What would you do? I will start with Mr. Mier.

Mr. MIER. Boy, you know, to me it is a cultural thing. Someone needs to go in there to let them know that——

Chair MILLER. I am sorry, Mr. Mier, your mic is not on.

Mr. MIER. Oh, I am sorry. There is nothing wrong in going after or looking at an illness closely when it might potentially be related to an industry. I think there is a tremendous reluctance to do that. I understand it is a very complicated science but to run away from it and not look at strong empirical evidence, to me I just can't understand that. When I was dealing in my own humble way looking at viruses or bacteria and the issues that I dealt with when I worked with CDC, there was never any quarrel, but the dynamics changed drastically when you point a finger at an industry.

Mr. BROUN. Thank you, Mr. Mier. We need to fix it if there is a problem, which obviously you all think there is a huge problem there. We are trying to look to try to find out—this is an investigation and oversight committee. We need to have some—I would like to hear some suggestions of how to fix the problem and not just wonder. So Professor, do you have any suggestions of how we can fix this problem?

Dr. PARRISH. I mean, I think big organizations have inertia and if you want to change them, I think the first thing I would do if I was dictating would be to—I would clarify what the remit is, what is the mission of the Agency and what is its relationship to other public health agencies and states, for example. I know this because ATSDR bumps up against these other things from time to time. So you need to clarify what your boundaries are, and then I think once you have that mission really clear, you have to recruit the leadership and the senior management team to implement the vision for the Agency and make sure they have the resources so they can actually pursue that mission with vigor. That is what I would do.

Mr. BROUN. Mr. Camplin.

Mr. CAMPLIN. Two things. One, I would recommend that they open up the process a little bit more on the very front end so there is a little bit more agreement and buy-in along the whole way as well as having that third party oversight, the peer review oversight. We have requested that on numerous occasions and it falls upon deaf ears. The other side of it is accountability. There are policies and procedures in place that they are supposed to be following and there doesn't seem to be any kind of accountability and I know in our case at the Illinois Beach State Park, we would love for this committee to request the FBI to meet with myself along with Mr. Paul Kakuris of the Illinois Dunesland Preservation Society so we can turn over evidence of what we believe is criminal activity as well.

Mr. BROUN. Doctor, I would love to talk to you about the JAK2 mutation and all those things as a fellow physician, but again, if you were dictator, what would you do to fix this? And I certainly believe in peer review as a physician. We look at those types of things. And I congratulate you on your research in this—into these blood diseases.

Dr. HOFFMAN. Well, I guess I am a little bit more optimistic about this culture. I think there are—again, I will repeat, there are excellent people there. This is not a deficiency in the talent of the staff. I think what they really need to be is basically cut loose and be told to do good science and unrestricted science. I think the submission of work to peer review journals should be encouraged because once that was accomplished and once the paper was accepted, everything turned around, and in fact when the Pennsylvania Department of Health when they finally saw our manuscript were upset about some of the conclusions that were made. ATSDR to their credit actually said that they weren't going to change or deny anything because they had shown that it was correct and it was peer reviewed. So from my perspective, going through this over a couple of years with them, I think they need consultants that have a lot of scientific information and can bring more to the table and then they should be cut loose to essentially test whether these things are scientifically valid. If not, their resources will be depleted. They have to find out what is really, really important and then they have to go after it as a scientific mission.

Mr. BROUN. Thank you all. Chair, I am about out of time and I just—we are going to submit written questions for you all to look at. I am sure that I look forward to your answers further.

Chair MILLER. Thank you, Dr. Broun. In the last Congress, Mr. Rohrabacher was a Member of the Committee so everyone else's adherence to the five-minute rule looked pretty strict by comparison but if everyone adheres to the five-minute rule, I am going to have to change my own conduct.

Mr. Grayson. Oh, I am sorry. Ms. Dahlkemper is next.

Ms. DAHLKEMPER. Thank you, Mr. Chair.

GEOGRAPHIC PREVALENCE OF DEFICIENCIES

I believe one of the biggest roles of government is public safety, and each of you are from a different area of the country. I am from Pennsylvania where obviously Dr. Hoffman is from, but you are all from different parts of the country and we are seeing sort of a retelling of the story. Do any of you have other areas where you have talked with colleagues kind of dealing with this same type of issue in terms of the conduct of ATSDR? It is open to any of you.

Dr. PARRISH. I will just say, first of all, I don't because I live in the United Kingdom so I will drop out of that.

Mr. CAMPLIN. I will mention that at least on the asbestos side of things, I have talked with many of the people over in Libby, Montana, where there is currently an investigation going on with W.R. Grace and their exposure to asbestos there, and the persons I have talked to, they consider ATSDR and EPA more of the dark side or the evil side than the actual polluters, W.R. Grace themselves. They do not agree with their science and they do not agree with the politics that are there as well.

Ms. DAHLKEMPER. Mr. Mier or Dr. Hoffman, have either one of you had any talk with other colleagues in other areas of the country who have had problems with this agency?

Mr. MIER. I talked to a few in Louisiana and other parts of Texas but frankly, my wife and I have been—we are retired grandparents and we have been so busy researching and addressing this issue

that I haven't spent a lot of time talking to other people except that when I felt that we were going to have the same people looking at it again in the same old way and not getting an objective new look at it, that is when I begged for help from scientists around the country that were familiar with these issues and had them review our draft consultation report.

PUBLIC AWARENESS

Ms. DAHLKEMPER. And my other question to all four of you, I guess, is, the people in the communities where you are dealing with, how much of this information has been put out to the general public, what is the reaction. You know, Mr. Mier, you still live in Midlothian. I mean——

Mr. MIER. I tell you, this is a very sensitive issue in our community. When we are talking about potentially implicating four industries with as many employees and family members as are involved, it is a very sensitive issue and so they are very defensive about pointing any fingers at any of the industries so it is a very sensitive issue to discuss in our community both at city government and even on the school board. So there are very few of us that are actually working on it and addressing it and we are looked at in a very different, negative light, I think but a lot of people in the community, unfortunately, and our only concern frankly is our grandchildren and other children and children yet to be born in our community and that is why are we looking at it. We are not satisfied with the answers that we are getting and we think that there may be some problems and we are not satisfied with the way it has been looked at so far.

Ms. DAHLKEMPER. Thank you for your courage.

Chair MILLER. Each of the witnesses and our Members can make a point of taking the microphone. Although we can hear you, there are others who are watching this on the Internet, et cetera, and it is helpful for recording the hearing later.

Mr. CAMPLIN. I would like to make one point about that. Without a doubt, the public does give the Agency a lot of credibility when they put any kind of report out and so there is a doubt. When we challenge anything that they say, they tend to get the benefit of the doubt and it isn't until we are able to prove motive—because that is what they would say, why would an agency like this, such a prominent agency, put out such faulty reports. And when we explain the motives, then it becomes very clear. But that is one of the problems in the community is, they believe in these agencies. They believe in what this agency at least used to stand for.

Ms. DAHLKEMPER. Yes?

Dr. PARRISH. I mean, I could just say that in the situation of Colonie, New York, the industry that did the polluting is long gone, so it is a legacy issue, and I think generally the health consultation done there added very little new knowledge. It didn't seem—it caused a great deal of frustration in a way because I think expectations were very high that this was going to add new insight, provide solutions and so forth and it basically did none of those things. And so, you know, on the one hand I know there are a lot of people in that area in government and industry that basically would like the whole issue to sort of go away and be buried but on the other

hand, in particular the research that we did certainly served to raise awareness of the issues and, you know, by undermining part of the methodology that ATSDR used in their health consultation, it has actually sort of in a certain portion of the community provided a way forward, I think, for progress in the future that was otherwise completely stalled.

Ms. DAHLKEMPER. Thank you.

Chair MILLER. The gentlelady's time had only expired by a little bit.

Mr. Bilbray.

Mr. BILBRAY. Thank you, Mr. Chair.

Dr. Hoffman, I want to thank you for not just your testimony but also highlighting again that coal-fired power plants leave a legacy of destruction far beyond air pollution and a sad state of affairs, if I may say it again, that while we talk about the executive branch not doing enough oversight here and not looking at this issue, at the same time the legislative branch, this Congress is still buying coal-fired electricity to power our lights overhead, and never pass up a chance to take a cheap shot, so I want to put that out. You know, clean coal is as logical as safe cigarettes, and thank you for bringing up that there are other issues.

ASBESTOS

Mr. Camplin, your work with the asbestos problem here, specifically this site, just for my own information, are we talking short fiber, long fiber or is it a mixture of both at this site that you were working with?

Mr. CAMPLIN. It is not only a mixture of short and long fibers but they are finding predominantly amphibole minerals, which are much, much more toxic, and that is even more disturbing because they put disclaimers in a lot of their reports saying in fact that the risk modeling may significantly underestimate these minerals that are there, so there is some debate on what type of asbestos is toxic. However, what they are finding on the beach there is no debate about it. It is the most virulent, amphibole forms of the mineral.

Mr. BILBRAY. Yes, in California ARB, we found there was a distinct separation that has to be, you know, to really be precise on this. Of course, at the same time we are talking about that, our roads are paved with serpentine, which is all asbestos and everybody that drives down a back road in the Sierra Nevadas is being exposed.

Mr. CAMPLIN. Well, it is the State mineral of California.

Mr. BILBRAY. Yeah. Well, I guess it is appropriate with our air quality. But traditionally with toxicology there are two major measurements. One is level exposure and duration of exposure, and though asbestos is different because certain fibers, certain types can lodge in the lungs and maintain there and continue to irritate and create the problem. Do you think that the Agency might have been using like your instance the short duration of exposure as a justification to reduce the risk level from the toxicology point of view?

Mr. CAMPLIN. It is even more obvious than that. If you were going to test beach activities, I would ask maybe Dr. Frumkin why his team has never reviewed data from June, July or early August,

which we would consider the beach season, and why approximately 30 to 40 percent of the time that they do air monitoring it happens to be either raining or it just did rain. So that alone we think skews the data tremendously, and then getting into their protocols themselves and the outdated risk models they use, that just complicates things even further.

Mr. BILBRAY. Okay. Well, coming from southern California, my perception is it is always raining in your part of the world.

Mr. CAMPLIN. It is.

Mr. BILBRAY. That is the challenge that we get over there.

You know, the Texas model I guess really kind of highlights too the fact that when we get into these groups that somehow when we try to get this agency to straighten out, we are treating a symptom of a deeper problem, and that is, places like Texas not having clean, inexpensive electricity so we can stop drawing on these dirty, cheap sources that create the problem. But I appreciate all your testimony.

LOCAL HEALTH PROTECTION

Mr. Chair, my biggest concern is that when we talk about public health protection as the gentlelady said and we say it is government, I just would like to remind all of us as somebody who comes from a background of being the Agency in the neighborhood, the frontline of health protection is not those of us in the Federal Government. We are the last line of protection. The first line is the local community, the local environmental health department, the local air district, and one of the biggest things I want to do is make sure that the Feds are there to support the local effort. We have seen with Katrina what happens when the locals wait for the Feds to show up, as opposed to what you saw in San Diego during our fires, they kept saying FEMA did so well. It is only because the locals didn't wait for FEMA to do it, FEMA came in and helped, and one of the things I want to make sure is that when we reform this approach that it is one of coming in and helping the local community protect their own neighborhoods as opposed to waiting for the Feds. Because the biggest shock I had when I moved out of San Diego to Washington, D.C., is I look around the environment in this community and the environmental health around this community and let me assure you, I do not want my neighborhoods to be controlled by the people who are taking care of the environment in Washington, D.C., right now, and that is one of those things that I think all of us should work at empowering the local community to address these issues and hopefully we can use this review as a way of doing more of that.

I yield back, Mr. Chair.

Chair MILLER. Thank you, Mr. Bilbray.

Mr. Grayson for five minutes.

VIEQUES, PUERTO RICO

Mr. GRAYSON. Thank you, Mr. Chair. I appreciate the members of this panel and what they have done to highlight the failures of the ATSDR but I would like to talk about a different circumstance that has come up that I think further underlines the situation.

That is the situation that I am talking about regarding Vieques, which is an island off the coast of Puerto Rico. Vieques is a beautiful place. Its economy is based on fishing and tourism, and for 62 years it served as a military testing ground for the Navy. And now it is the subject of a great debate concerning the accuracy of ATSDR testing. The military used among other weapons chemicals such as napalm, Agent Orange and depleted uranium in and around the waters of Vieques. In 2003 the Navy stopped that military testing and the area has become a Superfund site because of the heavy presence of metals and toxins in the area. It is being cleaned up but there is a lot of chemical residue that remains. There are dangerous levels of heavy metals and toxins that have shown up in the crabs, in the fish, in the goats, in the wild horses that roam the island and the vegetation and in the people who live there. The health statistic in Vieques show the consequences of those toxins compared to normal residents of Puerto Rico. Residents of Vieques have a 269 percent increased chance of cancer and a 73 percent increased chance of heart disease and many other health problems. Infant mortality in most of Puerto Rico is decreasing, but in Vieques it is increasing and it has been increasing since 1980. And a 2001 study looking at the hair of the residents in Vieques showed that 73 percent of these human beings were contaminated with aluminum and 30 percent of the children under 10 years old showed toxic levels of mercury.

One of my constituents, Rubin Ojeda, a former fisherman in the area, told me almost every person that he knows in Vieques has cancer or a family member who has cancer or other serious illness. Rubin fished while the Navy dropped bombs around him and he suffers from heart and respiratory disease as well as deafness. His mother has anemia, high blood pressure and diabetes. His uncle died of cancer and several of his fellow fisherman have also died of cancer at young ages. In other words, in Vieques, heavy metal poisons the land and the water and the population carries that poison in its bloodstream and there is no real debate about this anymore.

But somehow when this agency, ATSDR, tested the area, it stated that the poisons in the fish and the crabs and the vegetation somehow posed no threat or no danger to the residents. This agency, which is supposed to protect our children form poisons at Superfund sites, actually wrote that it is safe to eat the seafood from the coastal waters and near-shore lands and that residents have not been exposed to harmful levels of chemicals resulting from Navy training activities. These remarkable statements should not come as a surprise for anybody who actually knows this agency. It is famous for ignoring the dangers of formaldehyde in the trailers used by Katrina victims, and for that the Agency was publicly chided by its own chief toxicologist, who had been cut out of the loop after raising concerns about the scientific basis for the Agency's analysis.

In case after case documented in an excellent report put together by the Science and Technology Oversight and Investigations Subcommittee, this agency has trivialized health concerns and failed to stop the ingestion of poison and the spreading of cancer. In other words, Vieques is not an isolated incident. There is a problem of

leadership, structure and agency culture, and from its inception in the early 1980s this agency has fought with bureaucratic rivals, shortchanged science and public health, and as a result it has let children be poisoned, and this too should come to us as no surprise because the Reagan Administration, which oversaw the creation of this agency, never found an environmental protection that it did not try to dismantle. Despite that origin, there are good and conscientious employees within the Agency and I am hopeful that we can work to restructure this agency so that its leadership is committed to protecting the public from harm. They should at the very least start with the acknowledgement that its work in Vieques is flawed and it should start with a commitment to reassess that site and take into account the various independent studies which show elevated health risks in the area.

You know, we try so hard as Members of Congress to improve people's lives. When I look at what has happened in Vieques, when I see all the health problems that Navy testing there has caused and the health problems that have been perpetuated by the failure of this agency to do anything about it, I am reminded of the Hippocratic oath. Maybe the first thing we should to do as Members of Congress is very simple. The first thing that the government should try to do is very simple: first, do no harm. Thank you.

Chair MILLER. Thank you, Mr. Grayson.

Mr. Tonko is not a Member of this subcommittee. He is a Member of the Full Committee, and as a courtesy the Chair is happy to recognize Mr. Tonko for a round of questioning. He does have a particular interest in this subject today.

COLONIE, NEW YORK

Mr. TONKO. Thank you, Mr. Chair, for this very valuable hearing, and to the panelists, thank you for being here. I represent Colonie, New York, via the 21st Congressional District in New York, and so my questions are directed towards Professor Parrish.

Professor, so I can be perfectly clear on this issue, the ATSDR people, did they test at all, did they use a certain method or did they not test workers and residents?

Dr. PARRISH. They did not test.

Mr. TONKO. So you were the only group that tested?

Dr. PARRISH. That is correct.

Mr. TONKO. And when your system that you offered to ATSDR was exchanged with their people information-wise——

Dr. PARRISH. I have had no contact at all with ATSDR.

Mr. TONKO. None at all?

Dr. PARRISH. None at all.

Mr. TONKO. So did they—do you know if anyone reviewed the system you used?

Dr. PARRISH. Well, our work first went through considerable peer review in the U.K. to do with interlaboratory comparisons and so forth and that work was published in 2006. The method was developed in 2003 and it was applied to basically a very large cohort of U.K. Gulf War veterans in the period 2004 to 2006. So we tested hundreds of U.K. veterans for depleted uranium in their urine during that period of time. I mean, this is the whole reason I started working in Colonie is to pursue this topic that I got involved in in

the U.K. as a result of working with the government to test veterans of the first Gulf War. And what we found in that particular situation is we failed to find a single person who had had a DU positive result. Everybody was normal. And this raised a really important question. The question really was, were the veterans of the 1991 conflict never exposed to DU in the battlefield or were they actually exposed, did they acquire harm, for example, but has it been too long a period of time since the testing in order to detect the signature. So we needed—the reason we went to Colonie was to follow this issue until it logically was concluded, and the reason that Colonie is important is, there is undoubtedly a very significant exposure to a lot of people to the inhalation of depleted uranium oxides is arising because of the manufacturing at the plant, so we knew there was an exposed population, so we went there to try to find out, can we see the signature in their urine? Even after 20 years, and the answer was yes, we could.

Mr. TONKO. Now, my question to you also, were there any opinions offered as to that method by professionals from ATSDR, formal or informal, that were exchanged with you?

Dr. PARRISH. No, because I have had no contact, none whatsoever.

Mr. TONKO. So is there anything that we can do to go forward with the town of Colonie? Should there be any concerns or fears that the town residents—there are some theories that as many as 2,000 homes, if not more, I hear many oftentimes 2,000 homes being in the area of the factory and of course the factory workers, should they still have concerns about depleted uranium?

Dr. PARRISH. Well, let me first say that, you know, I am not a medical doctor so don't misconstrue my opinions here, but I suppose my general view is that the heaviest pollution took place in the 1970s and affected probably in the neighborhood of less than perhaps 1,000 people, and I am sort of drawing a line around, you know, perhaps 600 to 800 meters around the plant, but there were lots of houses and the residential area is extensive. Sorry.

Mr. TONKO. No, I was just going to ask, has the Agency ever contacted you to discuss your findings?

Dr. PARRISH. No, they have not.

Mr. TONKO. Do you think they were aware of your findings?

Dr. PARRISH. They are—I mean, I know that they—people have told me that there has been some contact with ATSDR about my paper but they have not contacted me.

Mr. TONKO. And should the Agency go back to the area?

Dr. PARRISH. Well, I think somebody should go back. If the Agency has got a different attitude, then they should go back and redo some of the work, and some of the things they need to do are to find the people who lived there and were most heavily exposed, regardless of where they live now. They need to find these people. Then they need to do basically a health kind of census, what is the state of health and death results, for example, in the area that is closest to the plant. If there is something untoward going on in terms of that, then they could institute a series of testing programs to find out whether depleted uranium, for example, could be a correlated feature to those health problems. So I think there is a way forward to do this whole program there.

Mr. TONKO. Now, the Agency claims that, in quotes, it ''serves the public by using the best science.'' Have they avoided the best science? Have they used the best science?

Dr. PARRISH. Well, I think my words were, they either chose not to or were unaware of the analysis tools at the time they did their report in order to determine whether people had an exposure. This was possible now. It certainly is possible now. They concluded it wasn't possible——

Mr. TONKO. And if we use——

Dr. PARRISH.—in their report.

Mr. TONKO. I am sorry. If we use your base number of 1,000 for round terms, is there an estimated cost that the Agency should assume will be borne upon it?

Dr. PARRISH. You know, I suppose—I have been asked question and I would have thought that you could commit something like perhaps $1 million or something, and with that sort of money you could undertake a census to find the individuals, look at their health and other death statistics as well as conduct urinary tests for uranium isotope exposure on perhaps several hundred people. You could certainly go some distance to make progress towards the resolution of the issue.

Mr. TONKO. As I understand it, the Federal Government spent nearly $200 million——

Dr. PARRISH. That is correct, on the cleanup.

Mr. TONKO.—on the cleanup. Is that cleanup sufficient? Do you have any sense professionally whether or not——

Dr. PARRISH. I think—the Army Corps of Engineers did the cleanup. I think they did a good job. What they did is remediate the site so that it could then be turned over eventually for some other purpose, but the primary health danger that was at the site arose during the plant's original operation in the 1960s and 1970s and early 1980s and so once the plant stopped operating, the immediate health risk, as I understand it, diminished considerably because emissions of depleted uranium oxide particulates that were inhalable then more or less ceased, and so the ongoing issues relate to sort of secondary ingestion of contaminated soil or perhaps resuspension of dust. But we have also found that there are high levels of settled dust in attics and basements and houses and so forth, and this may be an ongoing health issue. I don't know.

Mr. TONKO. Just one quick final question, and I appreciate your tolerance, Mr. Chair, but it is very important to this community and to the district. There were allegations that the company had bypassed smokestack filters.

Dr. PARRISH. Yes.

Mr. TONKO. Do you have an opinion on that?

Dr. PARRISH. I have been told this is a fact, and I have no doubt that it is.

Mr. TONKO. Well, obviously it is an issue that still needs to be——

Dr. PARRISH. I think the—is it New York Department of Environmental Conservation, I believe, they documented this at the time in the late 1970s so there is no doubt that this has taken place.

Mr. TONKO. Thank you, Professor.

Thank you, Mr. Chair.

Chair MILLER. Thank you, Mr. Tonko. You were still well short of Mr. Rohrabacher's territory.

Dr. Broun, if you would give me the indulgence of just one last question, not a whole other round.

ANIMALS AS SENTINELS OF HUMAN HEALTH

Mr. Mier, Professor Parrish just discussed the willingness of ATSDR to contact him and talk to him. Has ATSDR looked at the animals that were in your film?

Mr. MIER. No, sir.

Chair MILLER. Have you asked them to?

Mr. MIER. Yes, we have.

Chair MILLER. And what did they say?

Mr. MIER. Initially the response was that it wasn't within their mandated domain. Afterwards we were told that neither ATSDR nor the Texas Department of State Health Services had the expertise, and the latest communication was that the Texas Department of Health has contacted a couple of researchers at Texas A&M School of Veterinary Medicine who might be interested in pursuing but that first of all they have to write a proposal and then hopefully seek grant funds to do that.

Chair MILLER. I am not sure that Mr. Mier is the best—Mr. Mier is not a scientist. Perhaps Dr. Hoffman is the best to direct this question to. Is there a value, a recognized value in medical research that effects on animals are an indicator, a sentinel for effects on humans?

Dr. HOFFMAN. In certain situations they are. There is not necessarily 100 percent correlation between the effects on small animals and humans, but I mean, you know, as was shown on that film, I think it is of concern. I mean, I have no idea what the incidence of similar abnormalities are in that area in Texas but obviously that would be of more substantive data to examine.

Chair MILLER. It would get your attention?

Dr. HOFFMAN. Well, as it did in the area in Pennsylvania, yes.

Chair MILLER. Thank you to all the members of this panel for your testimony, for coming here and for answering our questions as well. We will now take a fairly short break before the next panel. Thank you.

[Recess.]

Panel II:

Chair MILLER. I would like to introduce our second panel. Dr. Ronnie Wilson, in addition to being a former country music disc jockey as he told me in the break, probably more pertinent to this hearing was the Ombudsman as ATSDR from 1998 to 2005 and teaches now full time at Central Michigan University. Dr. David Ozonoff is a Professor of Environmental Health at the Boston University School of Public Health, and Dr. Henry S. Cole is the President of Henry S. Cole & Associates, an environmental consulting firm in Upper Marlboro and a former senior scientist with U.S. EPA's Office of Air Quality Planning and Standards. As I said earlier, it is the practice of the Subcommittee to take testimony under

oath. Do any of you have any objection being sworn in, to swearing an oath? No? We also provide that you may be represented by counsel. Do any of you have counsel at today's hearings? All right. If you would now all please stand and raise your right hand? Do you swear to tell the truth and nothing but the truth? Let the record reflect that all of the witnesses answered in the affirmative. Mr. Wilson, you may begin.

STATEMENT OF DR. RONNIE D. WILSON, ASSOCIATE PROFESSOR, CENTRAL MICHIGAN UNIVERSITY; FORMER OMBUDSMAN, AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

Dr. WILSON. Thank you, Mr. Chair. Thank you for the invitation to speak with your committee regarding ATSDR. I am retired now from the government and the Army Reserves, and I am an Associate Professor at Central Michigan University. I hold a degree in journalism, a Juris Doctorate, and a Masters of Science in Administration in Health Services.

I would like to acknowledge the quality science products developed by the professionals within ATSDR who serve the public well in developing toxicological profiles, health education, health studies, emergency response, and public health assessments. However, as my testimony will describe, there are serious problems with and within the Agency.

After serving as the Regional Ombudsman and in enforcement and public affairs role for 23 and a half years with EPA, I became the ATSDR Ombudsman. I was selected to build a neutral force to serve the public in their need to be heard.

In 1999, citizens in Tarpon Springs, Florida, asked me to review whether an appropriate health assessment had been conducted at the Stauffer Chemical Company site. The site had been found to be a public health hazard. The company and community were so hardened in their stance that there was no way to find mutual grounds for an agreement. So after a year of investigating, I published a 196-page report, gathering evidence which the company, the state and ATSDR had never seen. I found that the public health had not been properly studied, and the use of asbestos in vast amounts had not been considered.

After my report was issued, ATSDR moved quickly to review the health of the community and the former workers, finding and a spike of mesothelioma in women who had lived near the plant and the workers who had likely had their health compromised.

This report is used to point out some issues within ATSDR. ATSDR was a wonderful idea, a group of scientists who were independent of EPA to look at the public health around hazardous waste and other kinds of hazardous substance release sites. However, the Agency was never fully staffed or funded and was administratively tethered to the Centers for Disease Control and Prevention, yoking two agencies with different missions. The State's abilities to dictate the Agency's ability to assess the heath of the public was detrimental.

I questioned the author of the original Stauffer Site Public Health Assessment, a State employee, who produced the report pursuant to a cooperative agreement. He drafted the report to meet

the requirements of the state being paid but without looking at the details. He was busy on another site with public and press interest.

In gathering materials for the Stauffer report, I asked the state for information about former employees. Although the public had been given the data, upon advice of the Florida General Counsel, the state would not provide the data to me. I asked if ATSDR had the authority to issue letters commanding the production of information under section 104(e) of the Superfund legislation. No one knew the answer. The CDC General Counsel's office advised that the authority did exist and that a presentation had been made in 1989 regarding the tool.

A 104(e) policy was drafted, went to the CDC General Counsel for review and died because ATSDR was not an enforcement agency. With no policy, the Agency remains unprepared to command the production of data needed to properly assess the public's health.

ATSDR is a dichotomy. In one world are the well-run divisions of the public health, toxicology and education, and I seldom ever heard a complaint about those. Then there was the Division of Health Assessment and Consultation, or DHAC, the largest portion of the Agency, a "fiefdom" managed with an iron fist.

Talented, dedicated professionals in DHAC were not to listen to the public and could not get products to completion. DHAC leadership delayed the completion of Health Assessments until they were worded exactly the way leadership felt things should be, not the way they were. The Division's science officer sought to develop new science to be applied by the assessors, ignoring the established levels of the Division of Toxicology and other science agencies.

One Division leader became concerned about this delay and developed a spread sheet to analyze the days that it took to get a completed public health assessment that was, on average, well over 400 days.

DHAC employees also informed me of the large number of health assessments that were developed at the beginning stages of the Agency. The public's health at this large number of sites was assessed by applying a basic template, documents called interim or temporary assessments. Most of these documents have never been revisited or simply received a permanent cover.

DHAC Leadership presented a beautiful picture to the Agency executives but the public revealed a different story. This conflict led executives to the development of an Ombudsman program, a mechanism to provide the public a voice and a hearing.

The Stauffer report highlights an effective Ombudsman program. The public then had a neutral person they could call with their complaints. By the end of fiscal year 2005, the public complaints to the Ombudsman had dropped as the Agency had begun to actually include the citizens in that decision-making process. However, this favorable report soon ended as the program ceased to exist.

If Congress wishes to impact the health of persons living near or at hazardous waste sites, reorganize ATSDR. My suggestions simply are: legislate a merger for ATSDR and the National Center for Environmental Health, or dictate the separation of the two. Make the Agency independent of CDC. Dictate the establishment of a permanent, independent Ombudsman office for ATSDR and CDC. Restrict the use of cooperative agreements with states to hire con-

tractors and dictate the recovery of the dollars spent for flawed reports.

This concludes my remarks, and I will be happy to answer questions at the end of the session.

[The prepared statement of Dr. Wilson follows:]

PREPARED STATEMENT OF RONNIE D. WILSON

Thank you for your invitation to speak with the Committee regarding ATSDR.

I am retired from the government and the Army Reserves and I am an Associate Professor for Central Michigan University. I hold a Journalism degree, a Juris Doctorate, and a Masters of Science in Administration in Health Services.

I acknowledge the quality science products developed by the professionals within ATSDR who serve the public well in developing toxicological profiles, health education, health studies, emergency response, and public health assessments. However, as my testimony describes, there are serious problems with, and within the Agency.

After serving as the Regional Ombudsman and in enforcement and public affairs roles for 23.5 years with the Environmental Protection Agency, I became the ATSDR Ombudsman. I was selected to build a neutral force to serve the public in their need to be heard.

In 1999, citizens in Tarpon Springs, Florida, asked me to review whether an appropriate health assessment had been conducted at the Stauffer Chemical Company site. The assessment found the site to be a public health hazard. The company and community were so hardened in their stance that there was no way to find mutual grounds of agreement.

After a year of investigating, I published a 196-page report, gathering evidence which the Company, the state and ATSDR had never seen. I found that public health had not been properly studied, and the use of asbestos in vast amounts had not been considered. After my report was issued, ATSDR moved quickly to review the health of the former workers and community, finding and a spike of mesothelioma in women who lived near the plant and that worker health was likely compromised.

The report is used to point out some of the many issues at ATSDR. ATSDR was a wonderful idea, a group of scientists who were independent of EPA to look at the public health around hazardous waste and other kinds of hazardous substance release sites. However, the Agency was never fully staffed or funded and was administratively tethered to the Centers for Disease Control and Prevention, yoking two agencies with very different missions.

The State's ability to dictate to the Agency was detrimental to the assessment of public health.

I questioned the author of the original Stauffer Site Public Health Assessment, a State employee, who produced the report pursuant to a cooperative agreement. He drafted the report to meet the requirements for the state to be paid, without looking into the details. He was busy on another site with public and press interest.

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ATSDR is a dichotomy. In one world is the well-run Divisions of Health Studies, of Toxicology and Education, about which I seldom heard citizen's complaints. Then there was the Division of Health Assessment and Consultation, or DHAC, the largest portion of the Agency, a 'fiefdom,' managed with an iron fist. Talented, dedicated professionals in DHAC were not to listen to the public and could not get products to completion.

DHAC leadership delayed completion of Health Assessments until they were worded the way leadership felt things "should be," not as the facts were. The Division's science officer sought to develop new science to be applied by the assessors, ignoring established levels of the Division of Toxicology and other science agencies. One Division leader became concerned about this delay and developed a spread

sheet to analyze the number of days taken to complete a health assessment, an average of more than 400 days.

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DHAC Leadership presented a beautiful picture to the Agency executives but the public revealed a different story. This conflict led executives to develop an Ombudsman program as a mechanism to provide the public a voice and a hearing.

The Stauffer report highlights an effective Ombudsman program. The public had a neutral person to call to hear their complaints. By the end of FY05, public complaints to the Ombudsman had dropped as the Agency had begun to include the public in the decision-making process. This favorable report soon ended as the program ceased to exist.

If Congress wishes to impact the health of persons living at or near hazardous waste sites, reorganize ATSDR. My suggestions are:

- Legislate a merger for ATSDR and the National Center for Environmental Health, or dictate the separation of the two entities.
- Make the Agency independent of CDC.
- Dictate the establishment of permanent, independent Ombudsman offices for CDC and ATSDR, and
- Restrict the use of cooperative agreements with states as a tool to hire contractor and dictate the recovery of funding not properly earned.

This concludes my remarks. Thank you for your time and consideration of the public and the professionals at ATSDR. I would be happy to answer your questions.

BIOGRAPHY FOR RONNIE D. WILSON

Dr. Ronnie Wilson has become a recognized expert in two fields that impact health services administration. Due to his governmental and legal experience, Dr. Wilson has become known for his ability to assist others in how to avoid negligence or malpractice

Dr. Wilson has been on the staff at Central Michigan, teaching at the graduate (Master's) level since September 1995. Central Michigan University added Dr. Wilson to the full-time staff in 2005 after a 33.5-year career with the Federal Government.

While on loan from the Agency for Toxic Substances and Disease Registry (ATSDR), Dr. Wilson served as the Executive Director of the Delta Regional Authority, a federal/State partnership seeking to improve the lives of 10 million people in eight states along the Mississippi River.

Prior to working with the Delta Regional Authority, Dr. Wilson's most recent position was Ombudsman for the federal agency that conducts health studies around hazardous waste sites. In that role he spent more than a year investigating a waste site in Florida and produced a 196-page report to Congress and the head of the ATSDR. He was given an award by the Florida Sierra Club for his effort to protect the public health and the environment in Florida.

Dr. Wilson came to the ATSDR after more than 23 years with the Environmental Protection Agency (EPA). At EPA he served in a variety of roles, including that of Regional Ombudsman.

On a volunteer basis, Dr. Wilson served as the National Vice President of the Spina Bifida Association of America for two years, as a National Board member for five years.

As an Army Reserve officer, he is the holder of three Meritorious Service Medals, and a Humanitarian Service Medal and he commanded an Army History Detachment. He holds a BS degree in Journalism from Arkansas State University, a Juris Doctorate from Woodrow Wilson College of Law and a Master's of Science in Administration, Health Services, from Central Michigan University.

Chair MILLER. Thank you, Mr. Wilson. Dr. Ozonoff.

STATEMENT OF DR. DAVID OZONOFF, PROFESSOR OF ENVIRONMENTAL HEALTH, BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH

Dr. OZONOFF. Thank you, Chair Miller, Dr. Broun. My name is David Ozonoff. I am a physician and Professor of Environmental Health at Boston University School of Public Health, and by trade over the last 30, 40 years, I am a cancer epidemiologist. At Boston University I was the founding Chair of the department that teaches and researches the effects of chemicals on health, a department which I led for 26 years and where I continue to work as a full professor directing a multi-million dollar research program on health and the environmental effects of chemicals, funded by NIH. I am therefore intimately familiar with the underlying science which is beneath ATSDR's work, and I know its formidable technical difficulty well.

In 1991, Congress asked the GAO to examine how well ATSDR was performing those public health evaluations around Superfund sites that were required by the 1986 SARA legislation, and I was a member of the GAO expert panel whose judgments formed the basis for the report's main findings. Those findings concluded that ATSDR health assessments required more time and care and better consideration of community health concerns, that there should be independent peer review of the assessments, that the contents of the assessments were redundant of EPA reports and not useful to EPA or the community, and that the assessments were incomplete and not reliable for indicating when follow-up studies were needed.

Because of our relationship in the department, we worked there for many years, decades in fact, with community groups around the country, essentially one of the few if not the only academic unit who did that. During that same period of the GAO report, we were engaged by ATSDR via a cooperative agreement to assist them in community involvement activities around several federal facilities.

In the course of that work, we met frequently with community members, both with and without ATSDR at community sites. Our assistance was requested by ATSDR because of persistent complaints. These are complaints that go back to the very inception of the active work of the Agency in 1986, that public health assessments were flawed, unhelpful, and/or misleading. A common view was that somebody else had already shot the arrow, and ATSDR was dutifully painting the target around it.

To prepare for my appearance today and to get as objective a view as I could, I made a number of calls to people both in the environmental health professions and those connected in communities with toxic problems to see what has changed since that experience. The bottom line is this: not very much. The health assessments are somewhat better on average than the earliest years, but they remain extremely uneven. Some are unsatisfactory. The Vieques example, mentioned earlier by Mr. Grayson, is a notorious example whose reputation is now rebounding around the environmental health community.

Recent ones that I have seen are incomplete. They give insufficient weight to the most up-to-date human information, and maybe because I am in epidemiology, I am sensitive about this subject, but they do not pay sufficient attention to epidemiology. And although

the focus of the public health assessment is rightfully on current potential exposures, the reports often do a less-than-satisfactory job of characterizing at least as well as they can past potential exposures. Reports are difficult to read for community members, and they have a one-size-fits-all format which doesn't convey the feeling that the special concerns of the community have been heard or understood.

And while ATSDR provides a short public comment period, the health assessment documents desperately need independent peer review from independent experts. At the very least the reports have a tendency to miss the most current information or adopt lowest common denominator judgments when evidence conflicts. And in addition, there is insufficient breadth and depth of technical expertise among the health assessors. These are a handful of people at each site and with each health assessment who are required to know sciences as disparate as hydrogeology, meteorology, architecture, industrial hygiene, toxicology, epidemiology, sociology, social psychology just to name a few. And as good as some of them are and as truly dreadful as some others are, this is almost an impossible task for one or a few people responsible for drafting the average health assessment.

And not all health assessments are done by ATSDR staff. A serious problem is that a number of states, in fact, almost half of the states I believe, do ATSDR health assessments under cooperative agreement, a practice which carries with it substantial risk which we've seen, realized any number of times, that State-based pressures are going to affect the results.

I have made several concrete suggestions about what to do in my written testimony as well as some more general observations.

So to conclude, I would like to just answer a question that you asked me via letter about my net opinion about whether ATSDR is meeting its mission. In my own view and the view of most community members I consulted, the routine work of ATSDR remains deeply disappointing. I say remains because this is not a new situation, as you have heard. And at the core of it is a deep lost of trust from the communities that ATSDR is supposed to serve. Despite this, I remain strongly of the view that it is vitally important that there continue to be an agency whose job it is to look at community chemical exposures from the public health viewpoint. EPA is primarily a regulatory agency. It is ATSDR's job to ensure that public health activities are effective. To do this, it needs the support and trust of the public to conduct studies and to recommend actions that are focused solely on protecting public health. Public health has the word public in it, and the public indeed should be the main focus of ATSDR's activities.

In the context of the enormous problems that we face today that are in the news every day, ATSDR's problems probably seem minor, and in terms of cost, they are essentially trivial compared to the sums that are being discussed daily. But for the affected communities, they are far from trivial. In some cases, they are matters of life, death, and certainly the happiness of people in those communities.

In 30 or 40 years of observing this, one of the things that I have seen is that chemical contamination doesn't just take lives, as ter-

rible as that is, and as a physician, that causes me great pain to see. But in addition to that it also wrecks lives, something that I have seen all too often. I would be glad to answer questions after the panel has made their statements. And I thank you for your interest in this urgent matter.

[The prepared statement of Dr. Ozonoff follows:]

PREPARED STATEMENT OF DAVID OZONOFF

Chairman Miller, Member Broun and Members of the Subcommittee. My name is David Ozonoff. I am a physician and Professor of Environmental Health in the Department of Environmental Health at the Boston University School of Public Health. I was the founding Chair of the Department that teaches and researches the effects of chemicals on health, a Department which I led for 26 years. I continue at Boston University as a full Professor where I direct a multi-million dollar research program on the health and environmental effects of chemicals, funded by NIH.

By way of background, I received my undergraduate degree in mathematics from the University of Wisconsin in 1962, my MD degree from Cornell in 1967 and my Master of Public Health degree from Johns Hopkins School of Hygiene and Public Health (now the Bloomberg School) in 1968. I spent the first ten years of my career at MIT, where I taught and did research, before moving to Boston University in 1977. The Department I founded there had as its focus understanding the health effects of chemicals on communities. We were then, and remain today, 30 years later, one of the few academic units specializing in this subject. Most investigations of community health effects are carried out in the public sector by State and federal agencies, one of which is ATSDR. In most of our research and technical assistance we have worked closely with communities and while this helped me to see the problem from their perspective, I am also intimately familiar with the underlying science and its formidable technical difficulty. I know quite well that judgments that appear straightforward on the surface are anything but.

Difficult as such work may be, there have been persistent problems with how ATSDR carries it out. In 1991 Congress asked the GAO to examine how well ATSDR was performing the public health evaluations around superfund sites required by the 1986 SARA legislation. Public health assessments are meant to determine if hazardous waste sites were causing harmful exposures to surrounding communities and, if so, whether these exposures should be stopped or reduced. I was a member of the GAO expert panel whose judgments formed the basis for the report's main findings. The GAO concluded that ATSDR health assessments required more time and care on the technical aspects and better consideration of community health concerns; that there should be independent peer review of the assessments; that the contents of the assessments were redundant of EPA efforts and not useful to EPA or the community; and that the assessments were incomplete and not reliable for indicating when follow-up studies were needed. A number of recommendations were made, including that Congress should check back later on progress. I see this hearing as fulfilling that recommendation.

Because of our relationship and reputation working with communities, in the 1990s we were engaged by ATSDR via a Cooperative Agreement to assist them in community involvement activities around several federal facilities. In the course of that work we met frequently with community members at community sites. Dr. Cole, the next panelist, helped us with some of that work. Our assistance was requested because there continued to be persistent complaints from communities that ATSDR's public health assessments were flawed, unhelpful or misleading. A common view was that someone had already shot the arrow and ATSDR was dutifully painting the target around it.

As a result of this background I have seen the problem from several different perspectives, an experience which surely tempers my judgments. I think I have a good feeling for what it is like to be in ATSDR's shoes, always useful for fairness. I also have the advantage of distance from the immediate fray. As my Department grew, my research group expanded greatly and other problems began to claim my attention. As a result I have spent considerably less time in recent years with either the communities served by ATSDR or the Agency itself. I remain close to many community activists and their leaders for whom ATSDR represents, at the least, a serious problem. I have the greatest respect for these residents and activists and for their dedication to making their communities safer for themselves, their families and their neighbors. The toll this takes on them is very large and their stories are heart wrenching. I am not just a scientist but I am a spouse, a father and a grandfather,

and it takes little imagination for me to identify with their concerns. I also know many of the principal players from both the early days of ATSDR and the current leadership. To prepare for my appearance today and to get as objective a view as I could, I made a number of calls to people, both in the environmental health profession and those connected to communities with toxics problems, to see what has changed in recent years.

The bottom line is this: not very much. The health assessments are better on average than in the early years but their quality remains uneven and some are unsatisfactory. Some of the recent ones I have seen are incomplete and do not give sufficient weight to the most up-to-date human information, tending to de-emphasize epidemiology while spending disproportionate time on toxicology and animal evidence. Often much of the detail involves exposure analysis, a function of at least three things: the experience and training of many of the health assessors is more in the area of Earth science and engineering; site-specific detail is available from parallel EPA efforts; and the lack of experience and training that makes assessors more dependent on summary statements like ATSDR toxicology profiles and fact sheets, a number of which are dated or even obsolete. And although the focus of the public health assessments is rightfully on current potential exposures, the reports often do a less than satisfactory job characterizing (or addressing as well as they can) past potential exposures. Finally, the reports are difficult to read for community members and have a one-size-fits-all feel which does not convey the feeling that the special concerns of the community have been heard and understood.

While ATSDR provides a short public comment period on its reports, the health assessment documents need independent peer review from experts. At the very least the reports have a tendency to miss the most current information or adopt lowest common denominator judgments when evidence conflicts. In addition, there is insufficient breadth and depth of technical expertise among the health assessors who are required to know sciences as disparate as hydrogeology, meteorology, architecture, industrial hygiene, toxicology, epidemiology, social psychology and sociology, to name a few. As good as some of them are (or as inadequate as are others), this is almost an impossible task for the one or a few people responsible for drafting the average health assessment. There also needs to be a full review of ATSDR Fact Sheets used for public education for relevance to the concerns of communities and their overall usefulness and appropriateness in specific situations.

Not all health assessments are done by ATSDR staff. The Agency out-sources the health assessment task to a number of states under Cooperative Agreements. This practice is beneficial for building capacity in cash strapped State health departments but carries with it the risk that local pressures from the Governor's office or the legislature will affect the result. ATSDR is not immune to these State-based pressures but they are more distant and ATSDR has a greater chance of independence. I have written about this problem in the past and ask that our paper on the subject be appended to this testimony.

In summary, I would repeat and add to some of the recommendations we made in 1991, including:

- an effective arrangement for independent and timely expert peer review of ATSDR health assessments, consultations and studies.
- an across the board review of the fact sheets and recommendations ATSDR is giving to communities for relevancy to their concerns. It is not uncommon for a community to be told by ATSDR there is no hazard and then to be given advice they should wash their hands and take off their shoes after being in a contaminated outdoor environment.
- an increase in the breadth of scientific talent recruited by the Agency.
- a re-evaluation of the practice of out-sourcing work to State health departments. Perhaps regional style consultation units, based at universities, would be useful.

Finally, you have specifically asked me to give my opinion about whether ATSDR is meeting its mission. Let me try to answer the question by giving you my own view and the view of most community members I consulted. It is this. The routine work of ATSDR *remains* deeply disappointing. ATSDR has acquired, partly on its own, partly for reasons beyond its control, a reputation with communities it will have a difficult time remedying. It is not alone in the government in being a deep disappointment. But it is the disappointment we are here to talk about today.

Disappointment is relative to what one expects. One way to think about this is on the doctor–patient model. A patient with health concerns or complaints expects a doctor to listen, to hear and interpret beyond what's being said, and to be competent—or at least competent enough so the patient will not be able to see obvious

errors. A patient also expects the doctor to be able to do things that make them feel more comfortable if not to make them better. The most damaging thing that can happen to the doctor—patient relationship is loss of trust and faith by the patient. And that is what is at the core of the problem with ATSDR. If a doctor doesn't meet basic expectations the patient will look for another doctor. But there is no other recourse when the patient is a neighborhood and the doctor is ATSDR. This has produced a self-reinforcing feedback loop where ATSDR frankly admits their reluctance to hold public meetings because of the abuse they receive in these settings, opting instead for one-on-one encounters. This is seen as a further withdrawal from the organized community, which responds in kind, increasing the alienation.

This is a difficult situation. But I am strongly of the view that it remains vitally important that there continue to be an agency whose job it is to look at community chemical exposures from the public health point of view. EPA is primarily an environmental regulatory agency, not a public health agency. Public health has the word "public" in it, which implies looking at the situation from the community's standpoint. ATSDR was supposed to step into the gap.

There is no simple technical or legislative fix for what ails ATSDR. The problems are problems of leadership at virtually every level. Presidents from Nixon to Obama have declared we must make an effort to cure cancer in our lifetime. For those whose friends, family and indeed themselves are in the cancer years, this appears to us an important goal. But for my children and grandchildren's sake, I would have also liked to hear that we will *prevent* cancer in our lifetime. ATSDR depends upon advances in basic science to do its job and the recent stimulus package recognized the importance of basic health science to our economy and the terrible cost of dread disease in our communities by injecting badly needed resources into the NIH. Investment in science pays off in many multiples. But left out entirely was money for the science of preventing cancer and other diseases acquired in the environment and workplace. NIOSH got nothing, which means it will get less again this year than last year. The NIH's program for basic science underlying superfund, the Superfund Basic Research Program, got nothing, which means it, too will shrink. CDC and its Center for Environmental Health got nothing. CDC's only stimulus money is for bricks and mortar projects. Bricks and mortar don't prevent cancer. It is a wry adage in the public health community that no Senator champions an agency because his wife didn't get breast cancer or any Congressperson because her child was born healthy. Much of essential public health and its importance remains invisible to the public. Until this changes other things that need to change, like ATSDR, won't.

I'm not talking about money here. The amount involved are almost lost in the accounting noise among the sums we are talking of these days. This is a question of leadership. The unglamorous parts of health science, the parts that are true public health infrastructure and upon which much else depends, like surveillance and vital records, things ATSDR depends upon, have not had the necessary champions. I include those in the private sector, like myself and in Congress but also the Executive Branch. Indeed the Agency needs to signal to you in Congress what must be done. ATSDR is a sister agency of CDC, but the CDC administrator did not visibly, vocally or strenuously fight for it or even her own agency, publicly. Whether she fought these battles internally I don't know, but we needed visible and strong *public* champions for *public* health and we didn't have them. We had a skilled communicator but not a champion. Morale at CDC has dropped precipitously. That's a leadership question. Similarly, ATSDR needs not only the trust and confidence of the communities it is supposed to serve, but its own leadership needs the trust and confidence of the many dedicated professionals in the Agency itself. That's not a question for legislation.

In the context of the enormous problems we face in the economy and foreign policy, ATSDR's problems seem trivial, and in terms of cost they are. But for the affected communities, they are far from trivial. In some cases they are matters of life, death and happiness. If pressed hard to name the single effect of living in a contaminated community I see most consistently, it would be divorce. In a world where the stresses on marriage are already large, the additional burden of worrying about one's family and what might happen to them or coping with what did happen to a child, is too much for too many. Chemical contamination doesn't just *take* lives, as terrible as that is. It can also wreck lives.

I thank you for your attention to this urgent matter, of which the problems at ATSDR are real but only a part.

BIOGRAPHY FOR DAVID OZONOFF

David Ozonoff received his Bachelor's degree in mathematics from the University of Wisconsin in 1962 and his MD degree from Cornell University Medical College

in 1967. In 1968 he received an MPH degree from Johns Hopkins School of Hygiene and Public Health. He then pursued research work at MIT from 1968 to 1977, studying, among other things, the psychophysical difficulties of radiologists when reading chest x-rays. He and his colleagues also published one of the first two-dimensional x-ray reconstructions (CAT scans) in the literature in 1969. He also served as a consultant to the World Health Organization, assisting WHO in the preparation and writing of its contribution to the first International Conference on the Environment which took place in Stockholm in 1972. In 1975 he was a Macy Fellow in the History of Medicine and the Biological Sciences at Harvard, and in 1976 a Mellon Fellow in the History of Public Health at MIT.

In 1977 he moved to the Boston University School of Public Health and in 1983 he became the founding Chair of the Department of Environmental Health, a position he held until 2003 when he became Chair Emeritus He is Professor of Public Health at Boston University School of Public Health, and Professor of Sociomedical Sciences and Community Medicine at Boston University School of Medicine. He directs the Superfund Basic Research Program at Boston University, a $17 million dollar multi-project research effort. He is a Fellow of the Johns Hopkins Society of Scholars and a Fellow of the Collegium Ramazzini.

Dr. Ozonoff's research has centered on epidemiological studies of populations exposed to toxic agents, especially the development of new methods to investigate small exposed populations. He has studied populations around Superfund sites in a number of places, most recently case control and cohort studies in the Upper Cape region of Massachusetts. Dr. Ozonoff frequently serves as advisor or consultant to local, State and federal agencies on matters of health effects from hazardous wastes and contaminated drinking water. He chaired the Water Systems Security Committee of the National Research Council/National Academies of Science and has served on several other NRC panels. He is the author of numerous scientific articles and is on the editorial boards of the *Archives of Environmental Health* and the *American Journal of Industrial Medicine* and is co-Editor-in-Chief of *Environmental Health,* an Open Access international journal.

Chair MILLER. Thank you, Dr. Ozonoff. Dr. Cole, five minutes.

STATEMENT OF DR. HENRY S. COLE, PRESIDENT, HENRY S. COLE & ASSOCIATES, INC., UPPER MARLBORO, MARYLAND

Dr. COLE. Thank you, Chair Miller and Dr. Broun and Members of the Subcommittee for this very important hearing. I am President of Henry S. Cole & Associates, and it is an environmental consulting firm which, among other things, provides scientific support to numerous community organizations on environmental issues.

I received my Ph.D. in meteorology at the University of Wisconsin in 1969, was an Associate Professor of Environmental Sciences at UW–Parkside during the 1970's, and my research into air pollution meteorology led to my appointment to the Wisconsin State Air Pollution Council. From 1977 to 1983 I was senior scientist with U.S. EPA's Office of Air Quality Planning and Standards where my work focused on predicting the impact of source emissions on ambient air. I am giving you this background because it qualifies me to talk about the particular case that I am going to talk about which is Perma-Fix, a facility that processes hazardous and industrial waste in Dayton, Ohio.

Another thing is that ATSDR retained me as a consultant from 1995 to 2003 to investigate the Agency's community involvement practices and to work with the Agency's Community and Tribal Advisory Committee. The purpose of that work was to help them improve that program.

Since 2004, I have provided technical support to a Dayton, Ohio, community organization affected by odors and emissions from an industrial waste processing plant known as Perma-Fix. For years, residents of surrounding low-income neighborhoods complained of noxious odors. These complaints were confirmed by the regional air

pollution control agency which later issued a notice of violations to Perma-Fix. Residents suspect that many illnesses are related to the plant's emissions including nosebleeds, respiratory disease, cardiac disorders, birth defects, and many other symptoms.

In 2004, ATSDR responded to a community petition and agreed to do a health consultation on this case. The consultation was based on a monitoring study of chemicals in community air. The consultation published in December 2008 found that none of the chemicals tested were above levels of concern, and that information on Perma-Fix's waste and processes did not reveal an obvious source for the observed odors. I want to emphasize those two findings.

As a scientist with experience in air pollution meteorology, I found that the limited number of days sampled, only six days sampled, is insufficient to give an accurate representation of long- or short-term concentrations. The waste process emissions and weather all vary from day to day, requiring a far more robust sampling plan. In addition, the consultation also failed to consider the additive effects of pollutants and the fact that the area is non-attainment for ozone and inhalable particulates. Moreover, ATSDR failed to measure or obtain information on the plant's emission rates or to conduct air quality monitoring.

It gets worse. In May 2006, the U.S. Government sued Perma-Fix for its violations of the *Clean Air Act*. The complaint identifies Perma-Fix as a major source of hazardous air pollutions and cites numerous failures to control emission sources. The resulting consent order included a stiff fine and requirements to control emissions. The court docket contains detailed information on the plant's emission sources, and ATSDR officials declined to use this data readily available online despite pleas from the community. They declined to use government information, detailed information, on sources in coming to its conclusion. I feel that that is unconscionable. To find no obvious source for the odors, given that kind of record, is absolutely unconscionable.

The Agency's sole recommendation asking Perma-Fix to voluntarily control solvent releases could have been made back in 2004 without doing a flawed and predictably inconclusive monitoring study. It makes me so frustrated I can't get the word out. Residents were so frustrated that in July 2007 they petitioned the Agency once again, this time to halt all of its work on Perma-Fix unless the Agency negotiated a protocol and process acceptable to the community. They never did that.

Let me just say in concluding that I, too, poll communities that I have worked with, and this agency has no trust. In fact, if you look at the agencies that communicate with networks, they advise communities to be very cautious about cooperating with ATSDR because of these inconclusive studies, and many groups feel that there is more harm done than good. The reason for that is that if a conclusion is inconclusive, that quickly gets translated to mean there is no problem. No evidence is equated with no problem, and that is used as an excuse for inaction. It may have even damaged the government's case. If this health consultation had come out prior to the consent degree in this case, it may have damaged the

case. So one has to wonder about an agency and whether they are fulfilling their mission.

Finally, what has to be done? I think the proverb behind you is very telling. It says, "Where there is no vision, the people perish," Proverbs 29:18. This agency has lost its vision, especially in its dealings with communities, and I think that the first thing that has to be done is to take a close look at the leadership of the Agency and maybe what is needed is a fresh start. Thank you.

[The prepared statement of Dr. Cole follows:]

PREPARED STATEMENT OF HENRY S. COLE

1.0 Introduction:

First, let me thank Chairman Miller, Ranking Member Broun and the other Members of the Subcommittee for the opportunity to present my views on the future of ATSDR.

By way of introduction, I am President of Henry S. Cole & Associates, Incorporated, a Washington, DC area-based environmental consulting company now in its 16th year. I received my Ph.D. in atmospheric sciences at the University of Wisconsin in 1969. My career in atmospheric and environmental sciences is approaching the 40-year mark. During the 1970's, I served as an Associate Professor of environmental Earth sciences at the University of Wisconsin–Parkside and conducted a research project involving air pollution meteorology. From 1977–1983, I then served as senior scientist with U.S. EPA's Office of Air Quality Planning and Standards and Chief of the Modeling Application Section. This section focused on the relationship between sources, emissions, weather conditions and ambient concentrations. From 1983–1993, I served as Science Director of the Clean Water Fund.

My consulting firm, founded in 1993, has provided scientific research and technical advice to support the efforts of dozens of community-based organizations to improve the environmental health and sustainability of their communities. A significant portion of my work has been funded by community-based organizations that receive Superfund Technical Assistant Grants (TAGs) from U.S. EPA. Other clients have included neighborhood associations, State and national environmental organizations and local governments. ATSDR conducted public health assessments and consultations in a number of these communities. An additional line of work is scientific support for companies with technologies that are more sustainable than market standards.

From 1994 to 2003, I served as a consultant to the Agency for Toxic Substances and Disease Registry (ATSDR) in order to help the Agency improve its community involvement programs and practices. In this capacity I provided advice to former Administrator Barry Johnson and prepared a report based on case studies of numerous communities where ATSDR provided health assessments or studies. Finally I served as an advisor to the Agency's "Community and Tribal Subcommittee." The subcommittee included leaders of communities and tribes in which ATSDR had worked. For additional details see attached CV and *www.hcole-environmental.com*.

2.0 Is ATSDR Fulfilling It's Mission?

ATSDR describes it mission in the following way:

> *ATSDR's mission is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related exposures to toxic substances.*

The Oversight Subcommittee has performed a great service by examining ATSDR's handling of the FEMA trailers cased in which hundreds of Katrina victims were exposed to formaldehyde. The Subcommittee report demonstrates that ATSDR was negligent in the conduct of its duty. In its efforts to play down the dangers, the Agency exercised a callous disregard for both science and for the health of those exposed in the trailers.

In my experience, however, the FEMA trailer case is not an isolated case where the Agency has failed to live up to its mission. Unfortunately, the Agency's performance in a substantial number of communities has undermined its most valuable commodities, the ability to provide "trusted health information" and the ability to "prevent harmful exposures" and their effects.

I believe that the Agency has improved the overall quality of its Public Health Assessments[1] and community involvement programs since the early 1990s.[2] However, the Agency will have to make some monumental changes in the conduct of science and in its relationship to communities to warrant its continued use of tax payer dollars. Such changes will require real leadership and a rededication to science and public health *even when the evidence requires expensive corrective measures and opposition by federal agencies or by business. Moreover, uncertainty is not an excuse to play down community concerns, but to dig further and to err on the side of caution.*

3.0 ATSDR's Perma-Fix Health Consultation:

Today, I will focus on a very recent example, of an ATSDR Health Consultation that has failed the Agency's mission—a consultation dealing with a Dayton, Ohio community affected by a plant in their midst that processes industrial and hazardous wastewaters, sludges and oils. The company is Perma-Fix of Dayton (PFD).[3] My association with this case included technical consultation to the Dayton Legal Aid Society in 2004 and pro-bono advice to community leaders.

Let's imagine for the moment that you live in this community, know as Drexel. Your homes and those of your neighbors are small. The community has experienced economic stress for years—not just lately. You have complained to various levels of government for years about the frequent and sometimes overpowering odors that occur when Perma-Fix is processing waste. These odors often make doing something out of doors intolerable and when you get upset enough you call the Regional Air Pollution Control Agency. Although RAPCA inspectors have confirmed the validity and intensity of complaints for many, the problem continues unabated. You also suspect that a high incidence of health problems has something to do with emissions from this plant.[4]

Then, in 2003, your neighborhood group hears about ATSDR, that it's a government agency that can help environmentally stressed communities with various studies. Agency officials respond to a call from the group and your visit the community and appear to be friendly and sympathetic. They tell you how to petition the Agency and with hopes high your community group does so.

Now lets take a look at what actually happened.

ATSDR accepted the community petition and agreed to do a *Health Consultation* in March 2004 based on an *Exposure Investigation*. The purpose of the investigation was to determine whether volatile emissions from Perma-Fix (PFD) were exposing residents to harmful levels of any of 100 chemical species tested. To do this ATSDR conducted an air monitoring program in the neighborhoods surrounding the plant. The number of days utilized in the investigation was extremely low; only six days during the 13-month period from June 2007–June 2008.

More than four years after the petition, ATSDR published its *Health Consultation* document just this past December (2008). The principal findings of the *Health Consultation* on PFD are listed below:

- *Although the data only represent ambient air concentrations during the time of sampling, none of the more than 100 compounds analyzed were detected over health-based values.*

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[1] Under cooperative agreements, Public Health Assessments are often conducted by State Health Departments. I recently reviewed the Ohio Department of Health/ATSDR assessment on the Armco-Hamilton Site in Ohio (former steel mill and coke ovens along the Great Miami River). In my judgment, this assessment did a reasonably good job in scoping out the information existing and referred to U.S. Geological Survey documents which described the vulnerability of groundwater to contamination and the close down-gradient vicinity of the Hamilton North municipal well field. The Health Assessment also recommended that fish be tested for persistent, bio-accumulative contaminants such as PCBs. See: Agency for Toxic Substances and Disease Registry (ATSDR), *Public Health Assessment for Armco-Hamilton Plant*, 2005.

[2] For example, ATSDR adopted a number of ideas from its community and tribal advisory group, including the initiation of health-related Technical Assistance Grants, which allow community organizations to hire independent experts to serve as advisors pertaining to health assessments and health studies.

[3] ATSDR, *Health Consultation, Exposure Investigation Report, Airborne Exposures to Select Volatile Organic Compounds, Perma-Fix Of Dayton, Inc.*, Dec. 15, 2008.

[4] According to the *Health Consultation*, health-related concerns include headaches, nausea, vomiting, nose bleeds, numbness in legs and hands, heart, gastrointestinal and respiratory disorders, burning eyes, sore throats, unexplained rashes, premature births, and birth defects.

- *"The differences between the average concentrations of volatile organic compounds (VOCs) for downwind and upwind samples were not statistically significant. This lack of difference may be due to the small sample size."*[5]
- *ATSDR's review of information on the wastes accepted and the treatment processes used by PFD did not reveal an obvious source for the observed odors in the neighborhood.*
- *ATSDR's outdoor air sampling revealed one compound, ethyl acetate—which has a low odor threshold and the characteristic odor of fingernail polish remover—may be the source of the reported solvent-like odors. That same odor was observed by ATSDR staff while touring the PFD facility and was most noticeable in the filter press room and testing laboratory.*

The sole recommendation found in the *Health Consultation* is as follows:

- *"To reduce solvent-like odors, PFD should determine if there is a source of ethyl acetate in their waste streams and seek to eliminate or treat it if it is present."*

To understand why community members were frustrated and angry we need to look not only at study's outcome (after four years) but also at several inter- related problems including serious deficiencies in the Agency's science, its failure to utilize critical information and its flawed community involvement process.

3.1 Inadequacies in the Exposure Investigation's Monitoring Study

1. The number of sample days (six days over a 13-month period) was woefully inadequate, especially if they are attempting to look at health effects. Both emissions and weather conditions vary—thus a much larger sample (days and locations) is needed to capture the worst cases.[6]
2. The kind of monitoring study conducted by ATSDR should have been supplemented with source testing and air quality modeling. ATSDR officials acknowledged that it did not include source testing. Testing stack and fugitive emissions could have given the Agency much better information on the chemicals being emitted from the plant.
3. Air quality *modeling* can estimate the distribution of concentrations from a source based on pollutant emission rates and multi-year data sets on weather conditions. Although modeling has limitations, the combination of monitoring and modeling provides better information than either alone.
4. Although, the report addresses wind speed and direction, it does not address the stability of the atmosphere (e.g., the presence or absence of temperature inversions). The combination of stable atmosphere with very slow wind speeds has the potential for worst case conditions. It is not certain whether ATSDR's sampling included such conditions. Moreover, as the *Health Consultation* acknowledges, the sample collection length (from two to eleven hours) would not provide information on peak concentrations of relatively short durations.
5. Samples were taken and analyzed on six different days. However, not all of the contaminants were analyzed for each of the six days. Thus the study may have failed to detect certain contaminants on some of the days.

3.2 Problems with the Health Consultation Process

1. Despite repeated requests, the protocol was not provided to the community for review and comment before the study was initiated. The potential deficiencies could have been discussed in advance of the study had a draft been provided in advance. This is a key requirement for effective and respectful public involvement. The *Health Consultation* does not include a response to citizen concerns and recommendations.
2. ATSDR failed to incorporate substantial information pertaining emissions including those of odors and hazardous air pollutants (HAPs) that were available in various notices of government violations and suits filed by a resident and regulatory agencies against Perma-Fix (PFD). These include:

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[5] ATSDR, *Health Consultation*, p. 13.

[6] *The document does not state whether or not the company was notified as to the timing of testing in advance.* Prior notification would have allowed the company to take preventive actions (e.g., not processing certain kinds of wastes) that are not normally employed.

- In 2002, the Regional Air Pollution Control Agency (RAPCA) issued a Notice of Violation to Perma-Fix for the company's failure to comply with RAPCA's previous orders pertaining to odor and emissions controls from a number of sources within the plant.
- In 2005, U.S. EPA filed a "Finding of Violation" in regard to PFD's failure to control a variety of hazardous air pollution (HAP) emission sources regulated under the *Clean Air Act*.
- In May, 2006, the Justice Department in 2006, on behalf of U.S. EPA joined the suit of a local resident for injunctive relief and civil penalties against Perma-Fix for similar violations. The complaint again cited numerous failures to control emissions, e.g., the plant's bio-plant tanks and wastewater treatment plant and other sources. In addition, the company failed to keep records, conduct testing, or apply and receive permits as required by regulations. (See attached copy U.S. Justice Department complaint.)
- In 2007, the parties to the 2006 suit entered into a Consent Decree that imposed a civil penalty of $360,000 and required PDF to (a) identify sources of emissions and odors (b) measure emissions (c) prevent and control emissions and odors and (d) obtain a Title V permit from U.S. EPA.

The filings associated with these complaints as well as a variety of documents (e.g., reports by expert witnesses) were readily available to the Agency online.[7] *The information contained in these sources would have been extremely useful to ATSDR in its design of the monitoring study and in generating a meaningful set of recommendations.* For example, one memorandum contained in the docket provides specific information on waste streams and emission sources. I am also aware that community leaders made numerous attempts to persuade ATSDR officials to obtain and use this data. However, to my knowledge the Agency failed to do so; moreover, the *Health Consultation* is mum on the Agency violations, the federal and citizen litigation and the resulting Consent Decree. (See Attached Documents)

Residents were so frustrated with ATSDR's handling of the study, that in July 2007 they petitioned the Agency once again—this time to *"halt all of its work regarding Perma-Fix until such time as it works out an acceptable protocol and public involvement process with the affected community."*[8] A copy of this letter is attached.

In my judgment, it is unconscionable that the Agency failed to include in its *Consultation* (2008) the list of *uncontrolled* emission sources in the record and the extent which Perma-Fix was taking meaningful steps to meet the requirements of the 2007 Consent Decree. Instead, the *Consultation*'s sole recommendation is of no real consequence or utility. Moreover, it could have been made back in 2004 without expending funds for a predictably inconclusive monitoring study. Most importantly, the tepid recommendation coupled with the implied finding that there is *"no evidence for concern"* can be readily translated to signify, *"no cause for concern."* Had this report been issued earlier, it might have been used to impede the successful federal and citizen litigation against Perma-Fix and the relief it provides.

Thus, it is not surprising that residents of Drexel have grown frustrated and angry and have lost the trust they had in ATSDR. There are many similar stories and word gets around. For example, the Center for Health, Environment and Justice, an organization founded by activist Lois Gibbs, has warned in its publications that communities may opt to boycott ATSDR (and cooperating State health departments) unless the Agency negotiates with the community in good faith regarding study protocols and related issues of public concern.[9]

4.0 Recommendations:

What is needed to create the needed change at ATSDR? First, I would propose that this subcommittee continue its valuable oversight of ATSDR. Secondly, the Subcommittee should press ATSDR to adopt the following policies submit legislation that would mandate the changes if needed.

1. ATSDR should provide *draft protocols* for all exposure investigations and health studies for public review and comment. Upon the request of members

[7] Documents on the case of Fisher and the United States versus Perma-Fix of Dayton are available U.S. District Court, Southern District of Ohio (Dayton), CIVIL DOCKET FOR CASE #: 3:04–cv–00418–MRM.

[8] Letter from Laura J. Rench to Howard Frumkin, Director National Center for Environmental Health and ATSDR, July 25, 2007. (Attached)

[9] Stephen Lester, Center for Health Environment & Justice, *Assessing Health Problems in Local Communities.* Updated April 2007.

of the public the Agency should be required to subject protocols to independent review.

2. ATSDR should undertake the following measures with regard to all community-related *documents*, including health assessments, health studies, health consultations and exposure investigations:
   - Provide drafts of the documents for public review with a minimum 40-day comment period.
   - Upon request, subject the draft to peer review by a group of experts free of ties with ATSDR or facilities which are the subject of the investigation of concern.
   - Upon request, the Agency should hold a public meeting with regard to the draft document.
   - The final document should respond to all community and peer review comments.
3. In formulating its findings and recommendations, ATSDR should utilize *all* pertinent information including federal, State and local agency enforcement actions and evidence contained therein.
4. In any case where the Agency finds that it has insufficient evidence to support a finding (e.g., health effects), it should include clear language warning the public or business leaders *not to equate the absence of evidence signifies an absence of effect or concern. ATSDR should monitor press coverage of all of its community-based documents; where there are indications of confusing statements or misinterpretations, ATSDR should take immediate and public measures to correct such statements.*

5.0 An integrated approach to community restoration and health.

Environmentally stressed communities approach ATSDR and other health agencies because they have serious concerns and badly need help. Low-income, minority and tribal communities often are impacted by a multitude of environmental stresses: e.g., a waste management facility, factory pollution, highly toxic diesel emissions, and unhealthful levels of inhalable particulates and/or ground level ozone. Perhaps there are sewerage related problems. There are other stresses as well—such as unemployment, no access to health care, aging populations, lack of adequate housing, etc. Health agency actions which focus on a single source are poorly equipped to deal with this these situations.

Needs vary from one community to another; i.e., the local health clinic may need expertise to deal with environmental exposures, perhaps a local credit union or pension fund could invest in restoring homes to livability, or perhaps the need is set up volunteers to visit the homes of elderly neighbors on a continuing basis. Such efforts will require a different vision and much greater coordination between programs and agencies. However, there are examples of community-based approaches which attempt to solve problems holistically. For example, in Trenton, a non-profit organization, Isles, Inc. has set up programs to remove lead from home environments and has trained residents to address these problems and to restore dilapidated buildings. These programs have led to employment and entrepreneurial opportunities. Trenton has the potential to bring in up to $2.4 million for green collar jobs and career development activities, many of them connected to restoration and improved environmental health. See *http://www.isles.org/*

This program is by no means unique. In fact, President Obama's economic stimulus package contains funding for community-based training and employment in areas such as weatherization and renewable energy. (See also, *The Green Collar Economy* by Van Jones and Ariane Conrad, 2008 for many examples of community-based initiatives aimed to bring environmental health and economic progress to communities.)

I believe that public health agencies including ATSDR could play an important role in fostering the kind of interagency and inter-departmental coordination that is needed to bring a more holistic and cost-effective approach to community health.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

BARBARA FISHER, Plaintiff, and UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. PERMA-FIX OF DAYTON, INC. Defendant.	Civil Action No. 3:04 CV 00418 Magistrate Judge Michael R. Merz

UNITED STATES' AMENDED COMPLAINT IN INTERVENTION

The United States of America, by the authority of the Attorney General and through its undersigned attorneys, acting at the request of and on the behalf of the Administrator of the United States Environmental Protection Agency ("U.S. EPA"), alleges as follows:

NATURE OF ACTION

1. The United States files this Complaint in Intervention in this citizen's suit brought under Section 304 of the Clean Air Act, as amended ("CAA" or the "Act"), 42 U.S.C. § 7604. Pursuant to Section 304(c)(2) of the Act, 42 U.S.C. § 7604(c)(2), the Administrator of U.S. EPA may intervene as a matter of right at any time in a CAA citizen's suit.

2. The United States seeks injunctive relief and civil penalties against Perma-Fix of

Dayton, Inc. ("Perma-Fix") for violations of the Act, the National Emission Standards for Hazardous Air Pollutants "(NESHAP") for Off-Site Waste Recovery Operations (the "OSWRO regulations") codified at 40 C.F.R. Part 63, Subpart DD; the general NESHAP regulations at 40 C.F.R. Part 63, Subpart A; the State Operating Permit Program regulations at 40 C.F.R. Part 70; and provisions in the federally enforceable Ohio State Implementation Plan ("SIP") adopted pursuant to Section 110 of the Act, 42 U.S.C. § 7410. The violations alleged herein occurred or are occurring at Perma-Fix's industrial waste processing facility in Dayton, Ohio.

JURISDICTION, VENUE AND AUTHORITY

3. This Court has jurisdiction of the subject matter of this action pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 28 U.S.C. §§ 1331, 1345 and 1355.

4. Venue is proper in this district pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and 28 U.S.C. §§ 1391(b) and (c) and 1395(a), because the violations alleged herein occurred in or are occurring at Perma-Fix's Dayton, Ohio facility which is located within this district and because Perma-Fix resides within this judicial district.

5. The Attorney General is authorized to bring this action pursuant to Sections 113(b) and 305 of the Act, 42 U.S.C. §§ 7413(b) and 7605, and 28 U.S.C. §§ 516 and 519.

NOTICES

6. The United States has provided notice of this action to the Ohio Environmental Protection Agency ("Ohio EPA"), in accordance with Section 113(b) of the Act, 42 U.S.C. § 7413(b).

7. Pursuant to Section 113(a)(1) of the Act, 42 U.S.C. § 7413(a)(1), on March 15, 2006 U.S. EPA issued a written Notice of Violation ("NOV") to Perma-Fix advising the company that it

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00285 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

violated and was in violation of relevant requirements of the Ohio SIP.

DEFENDANT

8. Defendant Perma-Fix of Dayton, Inc. is a corporation organized under the laws of the State of Ohio. Perma-Fix owns and operates an industrial facility located at 300 South West End Avenue in Dayton, Ohio (the "Facility"), at which it processes and treats industrial wastewaters, used oil and hazardous and non-hazardous waste received from off-site sources. At the Dayton Facility, Perma-Fix owns and operates, among other things, a biological treatment plant (the "Bioplant") that uses micro-organisms to oxidize contaminants in wastewater into more benign compounds before the wastewater is discharged into an adjacent publicly-owned wastewater treatment plant.

STATUTORY AND REGULATORY BACKGROUND

9. The Clean Air Act establishes a regulatory scheme designed to protect and enhance the quality of the nation's air so as to promote the public health and welfare and the productive capacity of its population. Section 101(b)(1) of the CAA, 42 U.S.C. § 7401(b)(1).

10. Section 112(d) of the Act as amended, 42 U.S.C. § 7412(d), directs U.S. EPA to promulgate regulations establishing emission standards for categories or subcategories of major sources of hazardous air pollutants ("HAPs").

11. As amended, Section 112(a) of the Act, 42 U.S.C. § 7412(a), defines "major source" to mean any stationary source (or group of sources located in a contiguous area and under common control) that emits or has the potential to emit, in the aggregate, 10 tons per year or more of any hazardous air pollutant, as such pollutants are listed pursuant to Section 112(b) of the Act, or 25 tons per year or more of any combination of HAPs.

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00286 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

The OSWRO NESHAP Regulations

12. On July 1, 1996, U.S. EPA promulgated National Emission Standards for Hazardous Air Pollutants ("NESHAP") for Off-Site Waste Recovery Operations ("OSWRO"), 61 Fed. Reg. 34140. Amended OSWRO NESHAP regulations were promulgated on July 20, 1999. 64 Fed. Reg. 38950. The OSWRO regulations are codified at 40 C.F.R. Part 63, Subpart DD.

13. Pursuant to 40 C.F.R. § 63.680(a), the OSWRO regulations apply to owners and operators of any plant site that is a "major source" of "hazardous air pollutants" and that receives off-site material such as wastewater, used oil or used solvents for processing in one of the waste management or recovery operations listed in 40 C.F.R. § 63.680 (a)(2)(i) through (vi).

14. The OSWRO NESHAP regulation at 40 C.F.R. § 63.680(a)(1) defines "major source" by reference to the general NESHAP definition at 40 C.F.R. § 63.2, which tracks the statutory definition in Section 112(a) of the Act, 42 U.S.C. § 7412(a). "Hazardous air pollutants" covered by the NESHAP are listed in Table 1 of the OSWRO regulations and include, without limitation, xylene, styrene, toluene, methyl ethyl ketone and benzene.

15. Waste management or recovery operations in 40 C.F.R. § 63.680 (a)(2)(i) through (vi) include certain hazardous waste handling and used oil recycling operations, as well as wastewater treatment operations where the treatment of wastewater received from off-site sources is a predominant activity at the site and the operation is also regulated under the Clean Water Act.

16. The OSWRO regulations define "affected sources" in 40 C.F.R. § 63.680(c) to include the entire group of "off-site material management units" that are associated with an operation covered by 40 C.F.R. § 63.680 (a)(2)(i) through (vi).

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00287 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

17. Pursuant to 40 C.F.R. §§ 63.6(b) and 63.680(e)(2), the date for compliance with the OSWRO NESHAP for a new affected source that commenced construction after October 13, 1994 is the date of initial startup of the new operation or July 1, 1996, whichever is later. 1 8 .

Pursuant to 40 C.F.R. § 63.6(c)(5), existing sources which become affected sources by reason of the new operation have three years and seven months from the date of startup of the new operation within which to comply with the NESHAP. 61 Fed. Reg. 34140, 34159 (July 1, 1996); 64 Fed. Reg. 38950, 38952 (July 20, 1999).

19. Owners and operators of affected sources must control air emissions from each off-site material management unit in accordance with the standards specified in the OSWRO regulations at 40 C.F.R. §§ 63.685 through 63.689.

20. The OSWRO regulations at 40 C.F.R. § 63.685(b) establish emission control requirements for tanks that are part of off-site material management units. Tanks must meet either Level 1 or Level 2 control requirements, depending on the tank's size and the off-site material's maximum hazardous air pollutant vapor pressure. 40 C.F.R. §§ 63.685(c)(1) and 63.694(j) describe procedures to be used to determine maximum hazardous air pollutant vapor pressure for off-site material managed in tanks. Level 1 controls for tanks are prescribed in 40 C.F.R. § 63.685(c); Level 2 controls are prescribed in 40 C.F.R. § 63.685(d).

21. 40 C.F.R. § 63.693(f)(2) requires owners or operators using a vapor incinerator (also known as a thermal oxidizer) as a control device to perform an initial performance test or design analysis to demonstrate that the vapor incinerator achieves the performance requirements in 40 C.F.R. § 63.693(f)(1).

22. The OSWRO regulation at 40 C.F.R. § 63.689(c) applies to "transfer systems" and

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00288 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

requires the owner or operator of such systems to control emissions by using one of the transfer systems specified in 40 C.F.R. § 63.689(c)(1) through (c)(3).

23. 40 C.F.R. § 63.695(c)(1)(i) provides that owners or operators required to operate closed vent systems as part of their Level 1 or 2 controls must monitor the system's components and connections at initial startup and each year thereafter to demonstrate that the system operates with no detectable organic emissions.

24. 40 C.F.R. § 63.695(e) provides that owners and operators of control devices required under 40 C.F.R. § 63.693 must monitor such devices in accordance with the requirements of 40 C.F.R. § 63.695(e)(1) through (e)(7).

25. 40 C.F.R. § 63.695(e)(2) provides that owners and operators of control devices required under 40 C.F.R. § 63.693 must calculate and record daily average values for each monitored operating parameter associated with that control device.

26. The OSWRO NESHAP contains various recordkeeping and reporting provisions, including, but not limited to, requirements in 40 C.F.R. §§ 63.696(g), 63.697(a)(2), and 63.697(b)(4).

The General NESHAP Regulations

27. Pursuant to Table 2 of the OSWRO NESHAP, certain provisions of the general NESHAP regulation at 40 C.F.R. Part 63, Subpart A are made applicable to sources covered by the OSWRO NESHAP.

28. 40 C.F.R § 63.5(b)(3) of the General NESHAP regulations, which is applicable to sources covered by the OSWRO NESHAP, provides that no person may construct a new source that causes the facility to become a major source subject to a NESHAP standard without obtaining written approval in advance from the U.S EPA Administrator.

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00289 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

29. 40 C.F.R. § 63.6(e)(3), which is also applicable to sources covered by the OSWRO regulations, requires the owner or operator of the source to develop and implement a Startup, Shutdown and Malfunction Plan ("SSM Plan") that describes procedures for operating and maintaining the source, including a corrective action plan for malfunctioning process, control and monitoring equipment used to comply with a relevant standard.

30. 40 C.F.R. § 63.10(b)(2)(i), which is also applicable to sources covered by the OSWRO regulations, requires the owner or operator to keep records of the occurrence and duration of each startup, shutdown and malfunction of its process equipment.

31. 40 C.F.R. § 63.10(b)(2)(ii), which is also applicable to sources covered by the OSWRO regulations, requires the owner or operator to keep records of the occurrence and duration of each malfunction of required control equipment.

32. 40 C.F.R. § 63.10(b)(2)(vi), which is also applicable to sources covered by the OSWRO regulations, requires the owner or operator to keep records of each period during which a continuous monitoring system ("CMS") is malfunctioning or inoperative.

The Title V Permit Regulations

33. Section 502(b) of the Act, 42 U.S.C. § 7661a(b), required the Administrator of U.S. EPA to promulgate regulations establishing the minimum elements of a Title V permit program to be administered by any air pollution control agency, including the elements specified in 42 U.S.C. Sections 502(b)(1) through (10) of the Act, 42 U.S.C. § 7661a(b)(1) through (10).

34. In accordance with 42 U.S.C. § 7661a(b), U.S. EPA has promulgated State Operating Permit Program regulations, which are codified at 40 C.F.R. Part 70.

35. 40 C.F.R. § 70.5 requires owners or operators of major sources to submit timely and

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00290 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

complete applications for Title V permits. 40 C.F.R. § 70.7(b) prohibits such owners or operators from operating until an application for a Title V permit has been submitted.

36. Section 502(d) of the Act, 42 U.S.C § 7661a(d) required the Governor of each State to develop and submit to the Administrator of EPA for approval a permit program meeting the requirements of 42 U.S.C. § 7661a(b)(1) through (10).

37. Ohio submitted a Title V permit program to the Administrator, which was approved on August 15, 1995. 60 Fed. Reg. 42045.

38. Pursuant to Section 502(a) of the Act, 42 U.S.C. § 7661a(a), after the effective date of any State's Title V permit program approved by U.S EPA, it is unlawful to operate a major source in such State except in compliance with a Title V permit.

The State Implementation Plan

39. Section 110 of the Act, 42 U.S.C. § 7410, requires each State to adopt and submit to U.S. EPA for approval a State Implementation Plan ("SIP") which, inter alia, includes a permit program to regulate the construction and modification of any stationary source of air pollution as necessary to assure that National Ambient Air Quality Standards are achieved. Pursuant to Section 113(a) and (b) of the Act, 42 U.S.C. § 7413(a) and (b), upon approval by U.S. EPA, SIP requirements are federally enforceable under Section 113. See 40 C.F.R. § 52.23.

40. Pursuant to Section 110 of the Act, 42 U.S.C. § 7410, on October 31, 1980, U.S. EPA approved Ohio Administrative Code ("Ohio Admin. Code") Chapter 3745-31 as part of the federally enforceable SIP for Ohio. See 45 Fed. Reg. 72119. Since then, U.S. EPA has approved several revisions to Chapter 3745-31 which regulates Permits to Install("PTI") new or modified sources of air pollutants. Ohio Admin. Code Chapter 3745-31 was substantially revised and approved as a

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00291 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

revision to the SIP on September 8, 1993. See 58 Fed. Reg. 47211.

41. Ohio Admin. Code § 3745-31-02(A) states that no person shall cause, permit or allow the installation of a new source of air pollutants or allow the modification of an air contaminant source without first obtaining a Permit to Install the new source from the director of the Ohio EPA.

42. Ohio Admin. Code § 3745-31-05(A)(3) provides that the director of the Ohio EPA shall issue a PTI only if the director determines that the installation or modification and operation of the air contaminant source will employ best available technology ("BAT").

Information Requests Under Section 114 of the Act

43. Section 114(a) of the Act, 42 U.S.C. § 7414(a), authorizes the Administrator of U.S. EPA to require persons who own or operate emission sources to provide such information as the Administrator may reasonably require for purposes of determining compliance with the Act.

44. Section 113(b) of the Act, 42 U.S.C. § 7413(b), authorizes the United States to commence a civil action for a permanent or temporary injunction when a person is in violation of any requirement or prohibition in the CAA or in any applicable standard, implementation plan or permit. Pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), and the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, as amended by the Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, and 69 Fed. Reg. 7121 (February 13, 2004), persons who violate the Act or an applicable standard, plan or permit are liable for a civil penalty of up to $27,500 per day for violations occurring between January 30, 1997 through March 15, 2004 and $32,500 per day for violations occurring after March 15, 2004.

GENERAL ALLEGATIONS

45. Perma-Fix is a "person" within the meaning of Section 302(e) of the Act, 42 U.S.C.

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00292 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

§ 7602(e).

46. Perma-Fix is an "owner" and "operator" of the Dayton Facility, which is a "major source" of HAPs and includes "affected sources" as those terms are defined in Sections 112, 113(b), 302 and 501 of the Act, 42 U.S.C. §§ 7412, 7413(b), 7602 and 7661, and 40 C.F.R. §§ 63.2, 63.680(c) and 70.2.

47. At all times relevant to this Complaint, Perma-Fix received industrial wastewater, used oil and other hazardous and non-hazardous waste from off-site sources and conducted various of the waste management and recovery operations listed in 40 C.F.R. § 63.680(a)(2)(i) through (vi).

48. Perma-Fix commenced construction of the Bioplant at its Dayton Facility in 2000 and started up operation of the Bioplant on or about November 17, 2000. The initial Bioplant operation included off-site material management units (tanks) T-801D, T-801E, a Biological Sequential Batch Reactor ("BioSBR"), a Biological Variable Depth Reactor ("BioVDR"), and an Activated Sludge and Utility Clarifier. Tanks T-801D, T-801E and the Activated Sludge and Utility Clarifier tanks were taken out of service in April 2001 and June 2002, respectively. Tanks T-901A, T-901B and T-901C were added as part of a Bioplant expansion in November 2001.

49. Since startup of the Bioplant operation on November 17, 2000, the offsite material management units at the Perma-Fix Facility have had a potential to emit greater than 25 tons per year ("TPY")of hazardous air pollutants.

50. Upon startup of the Bioplant, the Perma-Fix Facility became a "major source" of hazardous air pollutants as that term is defined in Section 112(a) of the Act, 42 U.S.C. § 7412(a) and the regulations at 40 C.F.R.§ 63.680(a)(1) and 40 C.F.R. §§ 63.2 and 70.2.

51. Pursuant to 40 C.F.R. § 63.6(b), Bioplant units T-801D, T-801E, the BioSBR, the

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00293 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

BioVDR, and the Activated Sludge and Utility Clarifier were required to comply with the OSWRO NESHAP regulations at the time of startup of these units on or about November 17, 2000.

52. Pursuant to 40 C.F.R § 63.6(b), Bioplant tanks T-901A, T-901B and T-901C were required to comply with the OSWRO regulations at the time of startup of these units in November 2001.

53. Before and after startup of the Bioplant, Perma-Fix operated other wastewater treatment equipment, a used oil recovery operation and a hazardous waste handling (fuel bulking) operation at its Dayton Facility. These operations are "affected sources" as defined in 40 C.F.R. § 63.680.

54. Perma-Fix has maintained and continues to maintain certain of the foregoing used oil and wastewater operations in Building B and certain of the foregoing wastewater and solid waste operations in Building G at its facility, among other operations. Pursuant to 40 C.F.R. § 63.6(c)(5), the compliance date for these existing sources was June 17, 2004, which was three years and seven months after startup of the Bioplant. See 61 Fed. Reg. 34140, 34159 (July 1, 1996); 64 Fed. Reg. 38950, 38953 (July 20, 1999).

55. Perma-Fix has also owned and operated a transfer system as part of its hazardous waste management operation. The OSWRO NESHAP compliance date for this existing source is also June 17, 2004. The system, which involves pumping hazardous waste from tanks and drums into tanker trucks, is subject to regulation under 40 C.F.R. § 63.689(c)(2).

56. Perma-Fix began construction of a regenerative thermal oxidizer in August 2002. This unit, which began operation on November 6, 2002, is a vapor incinerator that controls emissions from Bioplant tanks BioSBR and BioVDR, among other units. At the same time, a closed vent system was

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00294 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

installed between the vapor incinerator and the BioSBR and BioVDR tanks, to control emissions from these units.

57. Perma-Fix became obligated to comply with the maintenance, recordkeeping and reporting requirements relating to the vapor incinerator (thermal oxidizer) upon startup of this equipment in November 2002.

FIRST CLAIM FOR RELIEF
(Violations of the OSWRO NESHAP Regulations)

58. The allegations in Paragraphs 1 through 57 are realleged and incorporated herein by reference.

59. From November 2000 to at least July 2005, Perma-Fix failed to determine the maximum hazardous vapor pressure of off-site material in Bioplant tanks, in violation of 40 C.F.R. § 63.685(c)(1).

60. From November 2000 to April 2001, Perma-Fix failed to control emissions from Bioplant tanks T-801D and T-801E, in violation of 40 C.F.R. § 63.685(c)(2).

61. From November 2000 to November 2002 when the regenerative thermal oxidizer began operation, Perma-Fix failed to control emissions from the Bioplant Activated Sludge and Utility Clarifier tanks, in violation of 40 C.F.R. § 63.685(c)(2).

62. From November 2001 to at least July 2004 when conservation vents were installed on these tanks, Perma-Fix failed to control emissions from Bioplant tanks T-901A, T-901B and T-901C, in violation of 40 C.F.R. § 63.685(c)(2).

63. From November 2000 to at least November 2002, Perma-Fix failed to control emissions from Bioplant tanks BioSBR and BioVDR, in violation of 40 C.F.R. § 63.685(c)(2).

64. From June 2004 to at least July 2005, Perma-Fix failed to control emissions from

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00295 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

various wastewater treatment and oil recovery tanks, including, without limitation, used oil tanks T1, T2, G1, G2, T-808 and the oil/water separator.

65. From June 2004 to at least July 2005, Perma-Fix failed to control emissions from management units associated with its hazardous waste transfer operation, in violation of 40 C.F.R. § 63.689(c)(2).

66. From January 30, 2001 to at least July 2005, Perma-Fix failed to submit startup, shutdown and malfunction ("SSM") reports for each affected source on a semi-annual basis, in violation of 40 C.F.R. § 63.697(a)(2).

67. From November 2002 to at least July 2005, Perma-Fix failed to perform an initial performance test or design analysis on its vapor incinerator, in violation of 40 C.F.R. § 63.693(f)(2).

68. From November 2002 to March 2004 and from March 2005 to at least July 2005, Perma-Fix failed to monitor its closed vent system to demonstrate that the system operated with no detectable emissions, in violation of 40 C.F.R. § 63.695(c)(1)(i) and (ii).

69. From November 2002 to at least July 2005, Perma-Fix failed to calculate daily average values for each monitored operating parameter (of its thermal oxidizer), in violation of 40 C.F.R. § 63.695(e)(2).

70. From at least June 2003 to at least July 2005, Perma-Fix failed to submit semi-annual reports summarizing excursions as defined in 40 C.F.R. § 63.695(e)(4), in violation of 40 C.F.R. § 63.697(b)(4).

71. From November 2002 to at least July 2005, Perma-Fix failed to record descriptions of planned routine maintenance operations that would cause a control device (here the thermal oxidizer) not to meet applicable requirements, in violation of 40 C.F.R. § 63.696(g).

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00296 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

72. Unless restrained by an order of this Court pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), Perma-Fix will continue to violate applicable provisions of the OSWRO NESHAP at its Dayton Facility.

73. Pursuant to Section 113(b) of the Act and the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, as amended by 31 U.S.C. § 3701, Perma-Fix is subject to civil penalties for each violation in the preceding paragraphs occurring within five years before the date of filing of this Complaint. Penalties for such violations are up to $27,500 per day through March 15, 2004 and up to $32,500 per day for each violation after March 15, 2004.

SECOND CLAIM FOR RELIEF
(Violations of the General NESHAP Regulations)

74. The allegations in paragraphs 1 through 57 are realleged and incorporated herein by reference.

75. Perma-Fix failed to obtain prior written approval from the Administrator of U.S. EPA prior to constructing the Bioplant, in violation of 40 C.F.R. § 63.5(b)(3).

76. From November 2000 to at least July 2005, Perma-Fix failed to develop and implement an SSM Plan that describes operating and maintenance procedures for each of its affected sources, in violation of 40 C.F.R. § 63.6(e)(3).

77. From November 2000 to at least July 2005, Perma-Fix failed to keep records of the occurrence and duration of each startup, shutdown and malfunction of its process equipment, in violation of 40 C.F.R. § 63.10(b)(2)(i).

78. From November 2002 to at least July 2005, Perma-Fix failed to keep records of the occurrence and duration of each startup, shutdown and malfunction of required control and monitoring equipment, in violation of 40 C.F.R. § 63.10(b)(2)(ii).

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00297 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

79. From November 2002 to at least July 2005, Perma-Fix failed to keep records of each period when its CMS was malfunctioning or inoperative, in violation of 40 C.F.R. § 63.10(b)(2)(vi).

80. Unless restrained by an order of this Court pursuant to Section 113(b) of the CAA, 42 U.S.C. § 7413(b), Perma-Fix will continue to violate applicable provisions of the General NESHAP regulations at its Dayton facility.

81. Pursuant to Section 113(b) of the Act and 28 U.S.C. § 2461, as amended by 31 U.S.C. § 3701, Perma-Fix is subject to civil penalties for each violation in the preceding paragraphs occurring within five years before the date of filing of this Complaint. Penalties for such violations are up to $27,500 per day through March 15, 2004 and $32,500 per day for each violation after March 15, 2004.

THIRD CLAIM FOR RELIEF
(Title V Permit)

82. The allegations in paragraphs 1 through 57 are realleged and incorporated herein by reference.

83. From November 2000 to the present time, Perma-Fix failed to submit an application for and operated a major source without a Title V permit, in violation of Section 502(a) of the Act, 42 U.S.C. § 7661a(a), and 40 C.F.R. §§ 70.5(a) and 70.7(b), and Ohio Admin. Code Chapter 3745-77.

84. Unless restrained by an order of this Court pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), Perma-Fix will continue to violate the foregoing provisions of the Act and the regulations.

85. Pursuant to Section 113(b) of the Act, Perma-Fix is subject to civil penalties for violations of the foregoing provisions occurring within five years before filing of this Complaint. Penalties for such violations are up to $27,500 per day for violations occurring before March 15,

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00298 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

2004 and up to $32,500 for violations after March 15, 2004.

FOURTH CLAIM FOR RELIEF
(SIP Violations)

86. From at least 1987 and continuing to the present time, Perma-Fix failed to apply for and obtain Permits to Install prior to installing various new emission sources at its Dayton facility, including, without limitation, sources that are part of the used oil and wastewater operations in Buildings B and G, in violation of Ohio Admin. Code 3745-31-02.

87. From November 2000 and continuing to the present time, Perma-Fix failed to apply for and obtain PTIs prior to installing various new emission sources at the Bioplant, in violation of Ohio Admin. Code 3745-31-02.

88. Unless restrained by an order of this Court pursuant to Section 113(b) of the Act, 42 U.S.C. § 7413(b), Perma-Fix will continue to violate applicable provisions of the Ohio SIP.

89. Pursuant to Section 113(b) of the Act and 28 U.S.C. § 2461, as amended by 31 U.S.C. § 3701, Perma-Fix is subject to civil penalties for each violation in the preceding paragraphs occurring within five years before filing of this Complaint. Penalties for these violations are up to $27,500 per day for violations occurring through March 15, 2004 and up to $32,000 per day for each violation occurring after March 15, 2004.

FIFTH CLAIM FOR RELIEF
(Section 114 Request)

90. From October 3, 2003 to January 14, 2004, Perma-Fix failed to respond to a July 26, 2002 information request issued by U.S. EPA, as modified on August 14, 2003, in violation of Section 114(a) of the Act, 42 U.S.C. § 7414(a).

91. For the violations referred to in the preceding paragraph, pursuant to Section 113(b)

VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00299 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

of the Act, Perma-Fix is subject to civil penalties of up to $27,500 a day.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff-Intervenor United States respectfully requests that this Court:

1. Enjoin Perma-Fix to take all action necessary to come into and maintain compliance with the Clean Air Act, the OSWRO NESHAP, the applicable provisions of the general NESHAP and State Operating Permit Program regulations and Ohio Admin. Code § 3745-31-02 of the Ohio SIP.

2. Assess civil penalties of up to $27,500 per day for each violation by Perma-Fix of the Clean Air Act and the applicable regulations through March 15, 2004 and up to $32,500 per day for each violation after March 15, 2004.

3. Grant such other and further relief as the court may deem appropriate.

Respectfully submitted,

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VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00300 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

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VerDate 11-MAY-2000 19:54 Dec 21, 2009 Jkt 047718 PO 00000 Frm 00301 Fmt 6633 Sfmt 6602 C:\DWORK\I&O09\031209\47718 SCIENCE1 PsN: SCIENCE1

CERTIFICATE OF SERVICE

I hereby certify that on August 24, 2006, I electronically filed the foregoing **United States' Amended Complaint In Intervention** in Barbara Fisher and the United States v. Perma-Fix of Dayton, Inc., #3:04-cv-00418, with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

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July 25, 2007
Laura J. Rench
8280 West Third St.
New Lebanon, Ohio 45345

Howard Frumkin, M.D., Dr. P.H.
Director, National Center for Environmental Health
Agency for Toxic Substances and Disease Registry

Dear Dr. Frumkin,

I am writing on behalf of the Citizens for the Responsible Destruction of Chemical Weapons and the community surrounding Perma Fix of Dayton, to express our serious concerns regarding ATSDR's recent air monitoring. Following our phone conference of July 10, 2007 we decided to formally ask that ATSDR halt its study.

We do so because we have growing doubts about the scientific validity of the study and its ability to reliably assess the hazards associated with Perma Fix's odors and emissions. Secondly we have been unable to get answers to our questions or the detailed answers necessary for our scientific advisors to evaluate the design of the study. We have asked for such information, including a study protocol repeatedly. In fact, ATSDR broke its promise to provide a copy of the "final protocol to the community members, members of CRDCW, Perma Fix representatives, local, local, state and federal agencies, Jefferson Township Trustees and any other stakeholders who are interested." This promise was made in a letter from ATSDR to Mike Turner (dated Jan. 10, 2006, see Attachment 1). Despite its failure to deliver the protocol as promised, the Agency proceeded with its investigation.

Frankly, we were both surprised and disappointed in ATSDR's responses to our questions on the July 10 phone conference. Although ATSDR's air monitoring expert did provide some information, ATSDR's convener abruptly cut off the discussion before we received answers to questions important to both community members and our advisors.

What we did learn further eroded our confidence:

- The Agency did not test emission sources at the facility
- Agency representatives appeared not to have a complete understanding of waste handling practices and the range of hazardous chemicals contained in the wastes at the plant. Such information would have been helpful to ATSDR in designing the study and interpreting the results.

- The Agency acknowledged that it had not obtained extremely critical information contained in public records stemming from litigation against Perma Fix. ATSDR officials could have easily obtained this information by logging onto U.S. District Court Southern District and then go to the docket for the case. The case is Fisher v. Perma Fix. The case # is 3:04CV00418. For example, one memorandum contained in the docket highlights sources and provides specific info about P.F.D.'s waste streams and sources of air pollution. All of which is extremely important to this investigation and to ATSDR's planned Public Health Consultation.

Presumably ATSDR undertakes exposure studies and Public Health Consultations to provide important information and advice to the public. These studies take on special meaning because they are official pronouncements of the U.S. Department of Health and Human Services. It is essential that such studies be conducted in a scientific manner – which means that they are conducted openly with the public and scientists are given an opportunity to review and comment on protocols prior to the conduct of an experiment. It is also essential that the public agencies such as ATSDR have credibility and the confidence of the public. Sadly, this is not the case with regard ATSDR's work regarding air emissions and odors in our community.

For these reasons, we are asking that ATSDR halt all of its work regarding Perma Fix until such time as it works out an acceptable protocol and public involvement process with the affected community.

We are willing to participate in discussions toward this end and look forward to your response.

Sincerely,

Laura J. Rench
Petioner
Citizens For the Responsible Destruction of Chemical Weapons
Members of community surrounding Perma Fix of Dayton

CCs:Honorable Michael R.Turner, Senator Tom Roberts, Commissioner Deborah Lieberman, Ellis Jacobs, Dr. Henry S.Cole, Susan Robinson

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

August 2, 2007

Laura J. Rench
8280 West Third Street
New Lebanon, Ohio 45345

Dear Ms. Rench:

Thank you for your correspondence of July 25, 2007, expressing your concerns over the recent air monitoring being done in your community by the Agency for Toxic Substances and Disease Registry. I am sorry you are dissatisfied with this project and I am asking my staff to look into this matter. I assure you that my staff and I take our commitment to the public's health seriously. I will provide a full, more detailed response to your letter after I have consulted with staff.

Thank you for bringing this matter to my attention.

Sincerely,

Howard Frumkin, M.D., Dr.P.H.
Director, National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry

cc:
Rep. Michael R. Turner
Sen. Tom Roberts
Commissioner Deborah Lieberman
Mr. Ellis Jacobs
Dr. Henry S. Cole
Ms. Susan Robinson

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

August 8, 2007

Laura J. Rench
8280 West Third St.
New Lebanon, Ohio 45345

Dear Ms. Rench:

Thank you for your July 25, 2007 letter regarding the work the Agency for Toxic Substances and Disease Registry (ATSDR) is performing in the Drexel community. It is important for our agency to receive your comments so that we can better understand how to serve the community and other communities who are advocating for a healthy environment. So let me sincerely express our appreciation for your efforts on behalf of the community.

We understand that you remain concerned about the course of action we have chosen to respond to concerns from citizens regarding odors and emissions from the Perma Fix facility. ATDSR staff decided to conduct an *exposure investigation* because we did not have enough data to determine if the community is being impacted by air emissions from the facility. Exposure investigations have been used successfully in other communities to enable the agency to determine if an immediate health hazard is present. If the exposure investigation indicates a hazard, then we will recommend actions to reduce the hazard and possibly to conduct other public health activities. Exposure investigations are based on reliable scientific analysis and use approved standard methodologies. Environmental testing of potentially contaminated air, soil, or water provides important information during an exposure investigation. ATSDR investigators focus environmental testing on where people live, spend time and play, or might come in contact with contaminants under investigation. Because sampling at the source does not provide concentrations of contaminants to which people are exposed, ATSDR does not conduct sampling of industrial stacks. That type of sampling is typically performed by regulatory agencies.

Our primary goal is to serve the Drexel community members. The exposure investigation benefits the community by providing a more timely answer to health concerns than other more lengthy studies. We have received support from a number of members of the Drexel community for our course of action, including residents near the plant and elected officials. This support, in addition to our desire to protect the community, remains a key factor in our decision to proceed with the exposure investigation.

Again, we want to express our sincere respect for the issues raised in your letter, and I would like now to respond to some of your specific concerns. First, we apologize if we were not clear in our January 10, 2006 letter that we intended to share the protocol when we presented the results of our investigation, rather than before we began the investigation. Our air monitoring experts have been diligent in selecting locations for sampling based on air modeling, extensive review of odor surveillance logs, and in collaboration with the Regional Air Pollution Control Agency.

You also mentioned that you felt a discussion of your concerns with the protocol was cut short in a phone call with our team on July 10th. I understand that unfortunately two of the members of the team could only spend an hour that day talking with you and that they did let you know that the call would need to be focused and limited to an hour. The team has expressed to me that they hope they have made it clear that they are available to continue discussions, so I am directing them to be vigilant in setting up such phone meetings. Because the team plans to fully present the exposure investigation protocol in their final report, it would be advantageous to focus on the other issues that you have noted would increase your confidence in our work if addressed.

Towards resolving those issues, included here are additional responses to specific points you have raised. In your letter, you express concern that we are missing critical information available from your court case that may be important for our investigation. You could greatly assist our work if you can provide the specific information and documents from your legal case as discussed on the July 10, 2007 conference call and in a follow-up email on July 12, 2007. Additionally, I understand that on July 12th the team sent you the list of chemicals included in their testing plans and their associated laboratory analytical methods. We would welcome input on any chemical your experts believe would not be captured by those analytical methods.

We look forward to receiving any information you would like to share regarding your court case and input on our laboratory analytical methods. We need the information as soon as possible so we can make any necessary adjustments to our sampling protocol to ensure the most comprehensive exposure characterization. In order to remain on schedule, so we can provide the community with our results as soon as possible, we can only wait until August 24, 2007 to receive your information before proceeding with the next phase of our investigation.

Ms. Rench, we appreciate your advocacy on behalf of the community and we share your desire to make sure the community enjoys a healthy environment and is treated in a fair manner. It is our intention to continue our dialogue with you and the community to address any issues that would undermine confidence in our work. The most important step in this process is keeping our channels of communication open and to move our work forward as quickly as possible, so that if additional steps to protect the community are indicated, we can take them together.

Page 3 – Ms. Rench

Thank you again for your work in the Drexel neighborhood and your willingness to participate in our activities to protect the health of community members.

Sincerely,

Howard Frumkin, M.D., Dr.P.H.
Director, National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry

cc:
Rep. Michael R. Turner
Sen. Tom Roberts
Commissioner Deborah Lieberman
Mr. Ellis Jacobs
Dr. Henry S. Cole
Dr. William Cibulas
Dr. Sharon Williams-Fleetwood
Ms. Susan Robinson
Ms. Susan Moore

BIOGRAPHY FOR HENRY S. COLE

Henry S. Cole, Ph.D., the President of Henry S. Cole & Associates, is an environmental and atmospheric scientist with broad and in-depth experience on issues involving air pollution, involving facility emissions, air pollution meteorology and source receptor relationships. His experience includes a wide range of pollutants and sources including landfills, incinerators, power plants, cement kilns, and industrial plants. Dr. Cole has a broad and interdisciplinary background in environmental Earth sciences as well as atmospheric sciences which enables him to provide scientific support and expert opinion on the transport and fate of contaminants in the environment. Dr. Cole is a professional member of the American Meteorological Association and the American Chemical Society and has won awards from the U.S. Environmental Protection Agency, Sierra Club, and Clean Water Action.

Education

Cole earned his BS with high honors at Rutgers University College of Agriculture (1965) with majors in soil science and meteorology. He obtained his Ph.D. in meteorology at the University of Wisconsin in 1969 and received broad training in atmospheric sciences including dynamics, thermodynamics, climatology, micrometeorology, and physical meteorology.

Faculty Research and Teaching

As a faculty member of the University of Wisconsin–Parkside (1969–1977) Cole conducted EPA-sponsored research on the air pollution problems affecting the Chicago-Milwaukee L, Michigan shoreline corridor. He co-authored some of the earliest and most referenced journal articles on the impact and modeling of shoreline sources (e.g., power plants, urban emissions). (See Publications List). Cole taught a variety of courses including meteorology, environmental Earth sciences, and air pollution meteorology. He received tenure and promotion to Associate Professor in 1976. During this period, Cole served as a member of the Wisconsin State Air Pollution Control Council.

U.S. EPA Senior Scientist

During the period 1977–1983, Dr. Cole served as a senior scientist in U.S. EPA's Office of Air Quality Planning and Standards (Monitoring, Data and Analysis Division). In this capacity, Cole directed the Modeling Application Section of the Source Receptor Analysis Branch. This Section used point/stationary source, urban, and re-

gional modeling to develop emission limits and ambient air strategies as part of the regulatory process. In position as Section Chief, Dr. Cole supervised staff in their application of numerous point source, urban source, and regional air quality models.

Clean Water Action

From 1983–1993, Cole served as Science Director of Clean Water Fund Action, a national environmental public interest organization headquartered in Washington, DC. Cole authored a number of studies on EPA's Superfund program, the impacts of municipal waste incinerators and on the Nation's mercury problem. During this period Cole frequently provided testimony to Congressional committees on issues pertaining to Superfund cleanups, mercury emissions, solid waste management policies, and pollution prevention (e.g., alternatives to PCE-based dry cleaning).

DISCUSSION

Chair MILLER. Thank you, Dr. Cole. Mr. Mier testified—you all were all here for the earlier panel. Mr. Mier testified, showed photographs of animals in his community in Midlothian, Texas, and said ATSDR was not interested in seeing his animals or the pictures of his animals. Dr. Hoffman said that obvious apparent effects on animals would get his attention, and I think if I had noticed that every tadpole near my house had two heads, I would worry a little bit.

MORE ANIMALS AS SENTINELS OF HUMAN HEALTH

Dr. Ozonoff, what is the value or the reliability of effects on animals in predicting as a sentinel or an indicator of what effects there may be on human health?

Dr. OZONOFF. Well, there is a long tradition, actually, in epidemiology of doing epidemiology on animals as well as doing it on people. There are numerous studies in the literature, for example, of trapping small rodents called voles and other small animals around hazardous waste sites, net cropping them to see what the health effects are. In Vietnam, Agent Orange was looked at because—one reason it was looked at was because of epidemiology on dogs, the canine dogs that were in Vietnam. The canary in the coal mine is another classic example. These are all warning flags. They don't give you the answer, but they are like a big sign in the ground that says dig here.

PEER REVIEW

Chair MILLER. Dr. Ozonoff, you have said you were a part of a panel some time ago that recommended that ATSDR health assessments be subject to independent peer review. What has ATSDR's response to that recommendation been?

Dr. OZONOFF. I can't give you a tally on how many of their assessments are peer reviewed. My impression is very few, but that some of them are often on the basis of controversy or pressure. One of the things that we saw in the original GAO panel was that the squeaky wheel got the grease and that health assessments around very active community sites that made a lot of noise were more detailed and got more attention than those that didn't. In fact, some of them in the original batch of 800-some or 700-some under the initial mandate were just cut-and-paste jobs of EPA memos, whereas if there was a community, an active community group very concerned about what was going on, they would get more attention.

Chair MILLER. Dr. Wilson, you were nodding vigorously.

Dr. WILSON. I think that we have enough fingers and toes to calculate the number of health assessments and consultations that routinely are peer reviewed. I recommended in my Stauffer report that a new health assessment be conducted and that it be peer reviewed, and that was looked at as way out of proportion for what could and should be done. I recommend that all of them have the peer-review process. We are already spending well over 400 days. If we just speed up a little bit, we will have time to do peer review within that 400 days and still get a better quality product.

INFORMATION ACCESS

Chair MILLER. Dr. Wilson testified to the unwillingness of ATSDR to push to get information, to get documents. What would be the effect of the lack of those documents or what might be the effect? Dr. Ozonoff, how important is it that they get the information that might be available to other agencies or in the private sector?

Dr. OZONOFF. Well, I think there is an interesting pattern that emerges when you look at the health assessments. There is a lot of emphasis on exposure pathways, analyzing exposure, and to some extent toxicology, and a lot of that is a function of the fact that those documents are easy to get. The EPA has got a lot of exposure information, so that is available to them. And a lot of ATSDR health assessors sit actually in EPA regional offices so that there is not so much independence between those two, and it is one reason that I think EPA doesn't find the health assessments very useful because they are redundant of documents that are with EPA.

When it comes to documents that are health related, I think there is just not enough effort expended to get the documentation both about community concerns—EPA often will be very frank with both State agencies and communities in saying that they don't want to have public meetings with communities because of the abuse that they suffer when they are at public meetings, so they meet on them one on one. This is a self-fulfilling prophecy. This is the Agency withdrawing from the community because of the community's response, the community then seeing that the Agency is withdrawing, and it becomes a self-reinforcing cycle. This is no way to get the kind of information that we are talking about.

DIFFICULTY WITH EPIDEMIOLOGY

Chair MILLER. One more question, although the red light is on. Dr. Ozonoff, your testimony was probably more critical than my opening statement, although perhaps more elegantly put than jackleg science. What is the effect on the health of human beings from a pattern of inconclusive studies?

Dr. OZONOFF. You are asking me a question that I am very conflicted about because I understand from my own work how difficult it is to do these studies. One of the things that I have said during my career that gets quoted most often essentially started out as a joke, and like a lot of jokes there is a grain of truth to it, which is that a definition of a public health catastrophe is a health effect

so powerful that even an epidemiological study can detect it. Epidemiology, you know, is not a very sensitive tool. It is a very blunt instrument to try and figure out what is going on.

But I think that what Dr. Cole said is exactly right. The contention that this is inconclusive or that we don't see anything or that there doesn't appear to be something going on is really interpreted as a statement that nothing is going on, but the absence of evidence is evidence of absence. And that is particularly harmful to these communities who then get no follow-up.

So I don't know what we would find if we followed up on these communities. That is part of the problem which is that it remains invisible.

Chair MILLER. Dr. Cole, you were raising your hand that you wanted to chime in despite the fact——

Dr. COLE. Yeah, I do want to——

Chair MILLER.—that the red light is on.

Dr. COLE.—chime in because there is a question of what you do when there is scientific uncertainty, when there are a lot of symptoms, when the data is sparse, when the resources don't produce the evidence that you are really looking for, yet there is a sense that there really is a problem. In those instances, I believe that the public health model, and this is a public health agency, is to err on the side of caution and to act preventively. We don't have to wait, do we, until there are corpses, until there are people and families that are suffering?

Let me give you one very specific thing that could have been done at Perma-Fix had there been a different mindset and perhaps a slightly different mission at ATSDR. Had they looked at all of the data, they would have found that there were a lot of hazardous wastes coming into that facility, Perma-Fix, that contained formaldehyde, a probable carcinogen, a very toxic, hazardous air pollution. It is volatile. It escapes. Had they done what I consider to be their job, they would have found out, where are the sources? Where is that waste coming from that contains all that formaldehyde? And then go to those sources and find out what substitutions might be made or what processes could be added to the facilities that generate that waste that would reduce the amount of formaldehyde. That is what prevention is, to take a look at the problem, not wait until there is exact scientific evidence which, as Dr. Ozonoff and others have said, is often difficult.

Also, we know that prevention oftentimes saves all kinds of money. It is cost effective because there are many health effects, both in the workplace and in the environment that could be avoided, and that is a very good way to reduce health care costs, to improve the health of communities, the environmental health of communities, around this country.

Chair MILLER. Thank you, Dr. Cole. There is a college faculty joke that administrators don't like to have scientists on their university panels because they know where they stand. When the data changes, their opinions change. Dr. Broun.

POTENTIAL FIXES

Mr. BROUN. Thank you, Chair. I'll also start off to ask you all a question that I asked the first panel, and obviously you all have

pretty much answered that. If you were a dictator, what would you do differently to fix the problem, but let me ask Dr. Ozonoff, Doctor, if we could make a change to accomplish the purposes of which ATSDR is supposed to be doing, with what you are doing and other entities around the country are doing and even State agencies as I think you mentioned in your testimony are doing, if we enabled you or other entities, governmental or private, to be able to do these studies, wouldn't we be better off? Why? Why not? Just depending on how you answer the question.

Dr. OZONOFF. I am a scientist, so I am always going to say that research pays off and it is good to do research, and in fact, that is exactly what I am going to say. It is very difficult to know in advance what the benefit of any particular area of basic science research is going to be, except that we know that on average it pays off. At the risk of special pleading, let me just make an observation that lots of money was injected into the NIH and the recent stimulus package, but not all of NIH got money. The research program that provides the basic science for the Superfund program, underlying the basic science that we are talking about, got zero. CDC, except for bricks and mortar, got zero. NIOSH, which does the equivalent thing in the workplace, got zero. And part of the reason is is what Dr. Cole said. There is a vision here that is missing, and it is just not missing at ATSDR. You know, there is a wry adage among scientists, or at least cancer scientists, which is that no Senator championed an agency because his wife didn't get breast cancer or no Congresswoman championed an agency because her children were born healthy. When public health works, nothing happens, right? So therefore we don't have champions.

I think we are seeing some of the results of that. Public health agencies are not receiving the kind of moral support and vision, and they are not being invested from the top down with the kind of passion for public health that is required. That would make a huge difference, and of course, I am a scientist. I believe that research is important.

Mr. BROUN. Well, could we do that in the private sector if we just enable the private sector to do these things? Obviously there are strong pressures as Dr. Cole, in his testimony, talked about just from a liability perspective. Couldn't we do this better in the private sector instead of having one central governmental agency that is not undergoing peer review and not undergoing the types of investigative work and really is not charged or given the ability to do so, it seems to me?

Dr. OZONOFF. Well, I am in the private sector, and of course our research is conducted in the private sector with public monies, but I am very, as I said in my testimony, very strongly of the opinion that public health has the word public in it, that it is a public function, that it is a—it carries out a common purpose, all right, and that common purpose is very important. It needs to be supported. And ATSDR I think fulfills a role that just has to be fulfilled. Somebody has to be looking at these communities from the public health point of view, and that is what ATSDR was tasked with.

Mr. BROUN. Well, Dr. Cole, my time is about out so——

Dr. COLE. I think——

Mr. BROUN.—but you will have to answer quickly, please.

Dr. COLE.—you touch on something important which you said, can one agency carry out the mission? And remember, the mission not only talks about science and determinations of cause and effect, it also talks about prevention of harm. And I don't think we can forget that, and if you look at these communities, you will find that there are typically many, many health hazards in those communities. Diesel trucks, other plants besides the one that ATSDR or the landfill that they are investigating. There are multiple environmental stresses, particularly in so-called environmental justice communities, low-income communities. And these communities not only have many environmental stresses but economic stresses, nutritional stresses, and many other stresses which complicate the health effects. So the question is, what is the role of an agency like ATSDR in those kinds of situations? And this gets to your point that no one agency can do all of that. You know, there are economic concerns, there are energy concerns such as the need to weatherize homes and whatnot, there is lead in homes. Why not train local people to be a part of the solution to many of those problems? And there are examples of that. For example, in Trenton, New Jersey, community members have been trained to clean up the lead in people's homes. They get a job out of it. That has led to broader restoration efforts. So what can an agency like ATSDR do? Perhaps it can coordinate—go into a community, work with a community, find out what the needs are from the community, and then go to other agencies and the private sector. Maybe there is a plant that would contribute to taking care of something. Maybe they would clear a lot for a public park. Everyone can be part of that solution, but you can't slice and dice health. Health is a holistic concept. You have to look at the community and all of the things that are going on.

And I think the most unfortunate thing is the stove-piping of government. You have EPA over here, you have the Commerce Department here, you have ATSDR over here, CDC here, and really it takes, to deal with a community, it takes a village as someone said. Thanks for your forbearance there.

Mr. BROUN. Thank you, Chair.

Chair MILLER. Thank you, Dr. Broun. Dr. Ozonoff, do you have an opinion on whether Dr. Broun is a real scientist?

Dr. OZONOFF. As a physician, yes, I do. Yes, he is a real scientist.

Chair MILLER. I want to thank this panel as well, and we will take another quick break before our last panel. Thank you.

[Recess.]

Panel III:

Chair MILLER. Our final witness is Dr. Howard Frumkin, the Director of ATSDR and the National Center for Environmental Health. Dr. Frumkin, you will have five minutes to provide a spoken testimony, an oral testimony. Your full written testimony will be included in the record.

Again, it is the practice of this committee to take testimony under oath. Do you have any objection to taking an oath?

Dr. FRUMKIN. No, sir.

Chair MILLER. And you have a right to be represented by counsel. Do you have counsel here today?

Dr. FRUMKIN. No.

Chair MILLER. All right. If you would then stand and raise your right hand? Do you swear to tell the truth and nothing but the truth?

Dr. FRUMKIN. I do.

Chair MILLER. Thank you, Dr. Frumkin. You may begin.

STATEMENT OF DR. HOWARD FRUMKIN, DIRECTOR, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH AND AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (NCEH/ATSDR)

Dr. FRUMKIN. Chair Miller, Dr. Broun, Representative Broun, good morning. I am a physician and epidemiologist with 27 years of experience ranging from primary health care to research to environmental health practice. I have a long and public record to commitment to science, public health advocacy, and community service.

As a scientist, I am deeply committed to using the best science. As a public health advocate, I am passionate about promoting health and protecting the public from hazards. As a caregiver, I know that statistics are only proxies for real people and that when I serve those people, they deserve all of my skill, compassion, integrity, and courage, and as a public servant, I am accountable for achieving these results.

I am proud of my agency, of our excellent staff, and of the work we do in protecting public health. I testified before this subcommittee almost a year ago at a hearing that focused on our response to Hurricane Katrina, including our work specific to formaldehyde in temporary housing units. I testified at that time that in some respects we could and should have done better. I also noted that there were key lessons to be learned. During the past year, we have taken important steps to ensure that our current and future work builds on those lessons, the point to which I will return.

Committee staff prepared a lengthy report in advance of today's hearing. I respectfully disagree with many of the statements and conclusions in that report. I would welcome the opportunity to provide a different perspective at an appropriate time. In the meantime, in this brief oral statement, I want to make just three points.

First, protecting the public from toxic exposures is ATSDR's top priority, and we adhere scrupulously to good science in doing so. We work at several hundred sites each year. We identify public health hazards at a substantial proportion of sites. We offer recommendations to protect the public, and these recommendations have a strong track record of implementation by appropriate authorities. In some cases, even when exposures appear to be low, we recommend clean-up activities, adopting the preventive approach that Dr. Cole just described.

My written testimony includes examples of our successful work including instances in which we exercised independence and upheld scientific integrity despite considerable external pressure. Protecting the public on the basis of good science is ATSDR's top priority.

Second, we recognize challenges we face and limitations to some of our work. Some of this is intrinsic to our mission. While communities expect us to provide definitive answers about the links between exposure and illnesses, even the best science sometimes does not permit firm conclusions. An ailing patient visiting a doctor expects a definite diagnosis, but even the most thorough diagnostic workup cannot always yield an answer. At other times, the data needed to assess the health effects of an exposure simply have not been collected, as if a physician had to attempt a diagnosis without blood test results. In still other cases, we reach conclusions based on very sound science, but members of the public differ with our conclusions. These are all situations in which the communities we serve feel distressed and disappointed, and so do we.

Another challenge is this. Our staff has declined from about 500 in the early years of this decade to about 300 now. The implications are obvious.

Let me acknowledge that we are not perfect. As strong and science-based as our work is, there are things we could do better. In this morning's testimony, we heard a number of very sobering and disturbing perceptions. If we don't communicate well, if we are not accountable to communities, if we don't use available data fully, if we don't use the best possible monitoring techniques, if we don't correct misrepresentations of our work by other agencies or individuals, I don't believe these things happen regularly or often, but if they do, shame on us and we should do better.

I am firmly committed to representing opportunities for us to do better and to continuously improving our performance.

This leads to my third point. We are working vigorously to improve our work in four categories: overall mission, science administration, organizational management, and specific procedures.

With regard to overall mission, we are convening a national conversation to examine not only ATSDR's approaches to protecting public health, but how our work fits into the broader universe of agencies and organizations. We believe that some of our core practices now more than two decades old may be ready for renovation, a perception that some of this morning's witnesses echoed.

With regard to science administration, the Board of Scientific Counselors, an independent expert body, conducted a detailed review of our clearance and peer-review procedures at my request. While the Board found our procedure to be generally sound and effective, it identified several opportunities for improvement which we are implementing. For example, we have beefed up the staffing in our Office of Science, clarified clearance requirements to our staff, and aligned one division which had an independent peer-review process with the centrist peer-review procedures.

With regard to organizational management, CDC brought in an external firm, PriceWaterhouse, to review our center and to compare it to others at CDC. The focus was on human resource management. Overall, our center's management was comparable to that across CDC, a bit better in some respects, a bit worse in others. Several specific opportunities to improve emerged, and we have launched a detailed and aggressive management improvement initiative to address them. This includes innovative approaches to hiring new talent, management training, skill building in our staff,

improved issues tracking, and improved use of performance planning.

With regard to specific procedures, we continue to make improvements, refining the language we use to communicate our findings to the public, streamlining the updating of our toxicologic profiles, replacing the software that tracks our work at sites and more.

Mr. Chair, Dr. Broun, other Members of the Committee, on my own behalf and on behalf of enormously dedicated, hard-working staff, I affirm my commitment to good science, to good science administration, and to public service. In this, I fully agree with this committee. I am proud of the excellent work we do at hundreds of sites nationally. I recognize that even excellent work has room for improvement, and I pledge diligence in identifying and acting on opportunities to improve. I appreciate the constructive suggestions this Committee has provided to date, and I look forward to collaborating with this Committee as we move forward. Thank you.

[The prepared statement of Dr. Frumkin follows:]

PREPARED STATEMENT OF HOWARD FRUMKIN

Good morning Chairman Miller and other distinguished Members of the Subcommittee. Thank you for the opportunity to be here today. I am Dr. Howard Frumkin, Director of the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention's (CDC's) National Center for Environmental Health (NCEH).

I am a physician with 27 years of experience in environmental and occupational medicine and epidemiology. I have been Director of NCEH/ATSDR since September 2005. Previously, I served as Chairman of the Department of Environmental and Occupational Health at Emory University's Rollins School of Public Health and Professor of Medicine at Emory Medical School.

I am committed to the goal of serving the public by protecting the public's health, and bringing to bear the best science in doing so. As a public servant, I am accountable for achieving this goal. I am very proud of ATSDR's overall efforts to protect the public's health from chemical exposures.

I testified before this committee on April 1, 2008, at a hearing that focused on the work of ATSDR and NCEH in responding to Hurricane Katrina, including our work specific to formaldehyde in temporary housing trailers. I testified at that time that in some respects we could and should have done better. I also noted that there were key lessons to be learned. During the past year we have taken important steps to ensure that our current and future work builds on those lessons, which I will address later in this testimony.

Today's testimony will discuss more broadly ATSDR's scientific and programmatic activities, and will focus on three areas.

- First, I will provide background on ATSDR, including examples of work the Agency has conducted at specific sites in communities across the United States.
- Next, I will discuss some of the challenges faced by ATSDR.
- Finally, I will share a vision for ATSDR as we look toward the future, emphasizing our commitment to continuous improvement in four categories: overall mission, science administration, organizational management, and specific procedures.

The ATSDR Story

ATSDR is the principal non-regulatory federal public health agency responsible for addressing health effects associated with toxic exposures. The Agency's mission is to serve the public by using the best science, taking responsive public health actions, and providing trustworthy health information to prevent harmful exposures and disease related to exposures to toxic substances.

ATSDR was created by the *Comprehensive Environmental Response, Compensation, and Liability Act* (CERCLA) *of 1980,* more commonly known as the Superfund law, and came into existence several years later. CERCLA reflected Congressional and public concern with toxic chemicals, particularly hazardous waste, in the aftermath of such environmental disasters as Love Canal (New York) in the late 1970s.

ATSDR was charged with implementing the health-related provisions of CERCLA. The language in CERCLA, and in the subsequent *Superfund Amendments and Reauthorization Act of 1986*—or SARA—leaves room for interpretation, but in general terms, it assigns ATSDR four responsibilities, each of which is described in more detail below:

- Protecting the public's health
- Building the science base on toxic chemicals
- Providing information on toxic chemicals to health professionals and the public
- Establishing and maintaining registries.

ATSDR has pursued each of these responsibilities during the nearly quarter century since it came into being. Our work is very complex and it has not always been perfect, as I acknowledged to this committee last year, but overall I am proud of the wide range of achievements, and proud that we have constantly sought to improve our performance.

Protecting the Public's Health

A core function of ATSDR is assessing potential health hazards posed by hazardous waste sites and making recommendations for protecting public health. This is a mandated function in the case of Superfund sites, and discretionary in the case of other hazardous waste sites. Our site-specific work is presented in one of several forms: Public Health Assessments, Public Health Consultations, Exposure Investigations, and Technical Assists.

A Public Health Assessment, or PHA, is generally conducted when there are multiple contaminants and potential pathways of exposure. In a PHA, ATSDR examines past, present, and future exposure scenarios to evaluate whether people were, are, or may in the future be exposed to hazardous substances and, if so, whether that exposure is harmful, or potentially harmful, and in what ways. ATSDR scientists generally analyze existing environmental and health data—provided by EPA, other government agencies, businesses, and the public—and make recommendations. In some instances ATSDR scientists conduct their own health or exposure investigations. A Health Consultation is similar to a Public Health Assessment in that it evaluates environmental data and how people might be exposed, but focuses on a more specific health question and uses a more limited data set. The purpose of an Exposure Investigation is to fill environmental or biologic knowledge gaps with information needed for our public health work. A Technical Assist is a brief document that answers a specific, narrow question; because it does not require extensive background research and data analysis, it is generally completed more rapidly than the more detailed reports.

Recommendations for protecting health and preventing exposures are regular components of these documents. ATSDR is not a regulatory agency; our reports identify recommended actions that would be appropriate for EPA or other authorities to undertake, but do not compel these actions. Recommendations are directed to entities responsible for characterizing or mitigating exposures, including State and local government agencies. Our reports may also recommend that our agency conduct further work such as health studies, or health professional and community education. If there is an urgent health threat, ATSDR can issue a public health advisory warning people of the danger. ATSDR can also carry out health education or pilot studies of health effects, full-scale epidemiological studies, exposure or disease registries, disease and exposure surveillance activities, or research on specific hazardous substances.

In addition, ATSDR can help protect the public from chemical exposures in settings other than hazardous waste sites, circumstances that are collectively referred to as "releases." These releases may range from chemical plant explosions to a spill of coal combustion products. They can be those identified by government agencies or by individuals within the community through the petition process.

ATSDR responds to emergencies involving the release of chemicals, most often in collaboration with the Environmental Protection Agency. ATSDR personnel provide real-time public health guidance following acute releases of hazardous substances and health information to the public (for example, helping determine when people can safely reoccupy their homes and businesses after an evacuation).

Much of this public health protection work is carried out by State health departments, with funding and technical support from ATSDR. Our State cooperative agreement program functions in 29 states and one tribal government. In many cases, ATSDR funding provides the only support for these activities at the State level.

ATSDR's work in protecting public health has been highly productive. The Agency issues between 300 and 400 Health Assessments and Health Consultations, and provides more than 1,000 Technical Assists, each year. During the period 1995–2006, 73 percent of our recommendations were implemented by federal, State and local authorities.

Over the nearly quarter century of our work, we have made important contributions to the way community-based environmental public health is practiced. The required knowledge and skill were hard-won; in the early years growing pains were common, but over time ATSDR developed considerable expertise in community-based work. Our staff is committed to working closely with the communities we serve, to listening to and respecting community concerns, and to incorporating community input into our work plans. ATSDR's public communications recognize cultural, ethnic, and linguistic diversity. The Agency has helped advance the concept and practice of Environmental Justice, since many of the communities we serve are poor and/or members of racial and ethnic minorities.

ATSDR has a strong track record of sticking to the science and advancing public health, even in sometimes controversial, highly charged situations. Several examples are illustrative:

- **Montana:** Vermiculite mined by the W.R. Grace Company in Libby, Montana, was contaminated with tremolite asbestos. EPA and the Montana Congressional delegation requested that ATSDR evaluate human health concerns related to asbestos exposure in Libby. ATSDR has conducted a number of activities in the community, including: a screening program to identify people whose health may have been impacted by exposure to asbestos (revealing that 18 percent of those tested had abnormalities in the linings of their lungs, as compared to between 0.2 and 2.3 percent of people without asbestos exposure); a mortality review that compared asbestos-associated death rates for residents of the Libby area with those in Montana and the United States (finding that for the 20-year period examined, mortality from asbestosis was approximately 40 times higher than the rest of Montana and 60 times higher than the rest of the United States); and a Tremolite Asbestos Registry, a listing of individuals with asbestos-related disease or those at high risk of developing asbestos-related disease because of exposure to asbestos. ATSDR continues to be actively involved with the site and the community, joining recently with EPA to establish the Libby Health Risk Initiative, a program to add to the understanding of health effects of exposure to Libby amphibole.
- **Ohio:** The Brush-Wellman company, in Ottawa County, Ohio, is the major processor of beryllium in the United States. ATSDR completed a Health Consultation in 2002, and found that emissions at the time did not pose a risk. Past emissions were known to have exceeded applicable standards, but available data were not sufficient to permit assessment of the past hazard. Some local officials and the company strongly objected to follow-up activity, but ATSDR offered clinical testing for beryllium sensitization to local residents. All concerned individuals were tested; of 18 participants, none tested positive. Based on that finding, ATSDR did not recommend further testing. We followed up by educating local health care providers to help them identify and test for beryllium exposure and chronic beryllium disease.
- **Minnesota:** Excel Dairy is a large dairy farm in Marshall County, Minnesota. After neighbors complained of odors and respiratory and other symptoms, ATSDR worked with the Minnesota Department of Health (MDH) to sample for hydrogen sulfide (H_2S) at nearby homes. Data indicated that health based guidelines were frequently exceeded, often for hours at a time. In 2008 ATSDR recommended that Excel Dairy take immediate steps to protect health and safety, especially of children, such as by applying permanent covers to the manure lagoons. ATSDR also recommended that the Minnesota Pollution Control Agency continue to monitor air emissions of hydrogen sulfide, and that MDH work with local public health officials to provide people living at the Dairy with appropriate information to protect their health and safety. ATSDR also indicated that if measures to eliminate exceedances of the state's standards for H_2S were not effective, the Agency would consider further exposure monitoring in coordination with MDH. In 2008 ATSDR testified before a House Subcommittee on this matter. EPA is collecting hydrogen sulfide readings from the facility and will continue to conduct a follow-up assessment.
- **New Jersey:** The Kiddie Kollege Day Care Center in Franklin Township, New Jersey, was housed in a former thermometer factory, exposing children and staff to mercury. In 2007, ATSDR worked with New Jersey health and environmental officials and staff at the nearby Pediatric Environmental Health Specialty Unit,

a university-based effort funded partially by ATSDR, to assess the exposures. Initial findings included elevated levels in 31 percent of children and 33 percent of adults tested, with follow-up testing after exposure had stopped showing a reduction to low levels. New Jersey has since enacted legislation establishing stringent criteria before building permits can be issued for day care or educational institutions in environmentally high risk sites. ATSDR was directed to prepare a report on children's exposure to mercury, which was recently submitted to two Congressional committees.

- **North Carolina:** During the 1990s, residents of Randolph County, North Carolina, complained of respiratory symptoms that they associated with a nearby polyurethane foam manufacturing plant. ATSDR worked with State authorities to conduct blood testing and air monitoring. The findings prompted ATSDR to issue a public health advisory on October 20, 1997, advising local, State, and federal officials of potential adverse health impacts from hazardous air emissions. Concern focused on toluene diisocyanate, a known trigger of obstructive airway disorders. ATSDR also conducted an asthma investigation of children residing within a mile radius and found an elevated prevalence of this disease. During the last three years, ATSDR and the State health department went on to conduct a more comprehensive study of exposure and health in communities across North Carolina, despite strong industry opposition. Current plans include education for local physicians on the study results.
- **Ohio:** City View Center, a shopping center in Cuyahoga County, Ohio, was built on the site of a former landfill. In 2008, air monitors detected explosive levels of methane and other combustible gases. Based on the available information, ATSDR rapidly concluded that an urgent public health hazard was present, and recommended that immediate action be taken. ATSDR's finding provided the Ohio EPA, the Ohio Attorney General, and the U.S. EPA with further grounds for compelling the property owner to install an active vapor extraction system on the landfill to reduce the migration of gases into the shopping center.

Building the Science Base on Toxic Chemicals

In crafting CERCLA, Congress assigned an applied research role to ATSDR, which complements the biomedical research role of the National Institute for Environmental Health Sciences (NIEHS). The Agency has combined a program of original research with a longstanding commitment to assembling and making widely available the results of research across the scientific community.

ATSDR's applied research includes toxicologic research. In some cases this research is conducted in-house; for example, ATSDR scientists have developed innovative techniques of computational toxicology to help rapidly assess hazards of chemical releases. In other cases, ATSDR identifies critical toxicologic data needs and works with other federal agencies, as well as State agencies, universities, and volunteer organizations to fill those needs.

A key feature of ATSDR's scientific research is that it often grows out of site-specific public health activities. For example, as discussed earlier, ATSDR scientists have conducted a series of epidemiological studies in Libby, Montana, to assess the health effects of residents' long-term exposure to asbestos and related minerals.

Still other parts of ATSDR's research advance the science of exposure assessment. For example, in evaluating the health effects of past exposures to trichloroethylene in drinking water at Camp Lejeune, North Carolina, ATSDR scientists confronted a challenge: how to quantify people's past exposure to contaminants. Marines and their families had consumed water over a period of years from a variety of sources on the base that had varying levels of contamination. It became necessary to reconstruct past exposures based on available records—a complex process requiring historical analysis of contaminated drinking water using innovative ground water modeling and statistical techniques. ATSDR scientists developed and refined the necessary techniques with input from panels of experts and peer reviewers.

ATSDR scientists have compiled data and called attention to the problem of hydrogen sulfide exposure near construction and demolition landfills, a result of the degradation of gypsum wallboard; and described and quantified the problem of vapor intrusion, when volatile chemical contaminants in groundwater enter basements.

In addition to original research, ATSDR assembles existing data on toxic chemicals. ATSDR's *Toxicological Profiles* are thorough reviews of available toxicological and epidemiologic information on specific chemicals. They provide screening levels—called Minimal Risk Levels (MRLs)—that ATSDR health assessors and other responders use to identify contaminants and potential health effects that may be of

concern at hazardous waste sites. They are widely used references by scientists and members of the public.

Providing Information on Toxic Chemicals to Health Professionals and the Public

A third function of ATSDR is to provide health professional and community education through direct service at the community level, and through broader distribution of materials through the Internet and other mechanisms. For example, ATSDR's ToxFAQs is a series of summaries of information about hazardous substances. These are user-friendly documents excerpted from *Toxicological Profiles* and Public Health Statements. Each ToxFAQ serves as a quick and comprehensible guide, with answers to the most frequently asked questions about exposure to hazardous substances found around hazardous waste sites and the effects of exposure on human health.

ATSDR also develops and provides medical education to assist health professionals in diagnosing and treating conditions related to hazardous exposures. An example of this work is ATSDR's *Case Studies in Environmental Medicine*, a series of self-instructional modules that increase clinicians' knowledge of hazardous substances in the environment and aid in the evaluation of potentially exposed patients. ATSDR has developed other products for the medical community, including *Grand Rounds in Environmental Medicine* and *Patient Education and Care Instruction Sheets*. In addition, ATSDR and EPA established and support university-based Pediatric Environmental Health Specialty Units (PEHSUs) to provide education and consultation for health professionals, families and others about children's environmental health.

Establishing and Maintaining Registries

The fourth function assigned to ATSDR is registries—confidential databases designed to collect, analyze, and track information about groups of people who share defined exposures or illnesses. ATSDR also provides information to registrants about health services and other services available to them through other sources. Below are examples of registries in which ATSDR currently is actively involved:

- *Tremolite Asbestos Registry (TAR).* This is a registry of people exposed to tremolite asbestos originating in Libby, Montana. The TAR includes contact, demographic, exposure, and health outcome information for each registrant.
- *World Trade Center (WTC) Health Registry.* ATSDR has supported the New York City Health Department in developing the World Trade Center Health Registry. The WTC Health Registry is a comprehensive health survey of persons in the lower Manhattan area of New York City who were most directly exposed to the environmental effects of the events of 9/11/2001.

ATSDR Faces Challenges

While ATSDR has protected public health, advanced science, and provided science-based information since its inception, the Agency faces ongoing significant challenges. These are described below.

Science Cannot Answer All the Questions Posed at Sites

When communities are concerned about hazardous exposures, they want clear, definitive answers, much as an ailing patient wants a clear, definitive diagnosis. Communities often expect that an agency such as ATSDR will arrive on the scene, rapidly assess the situation, and reach unequivocal conclusions. Unfortunately, it is not always possible to reach such conclusions. Among the reasons:

- Accurate exposure data are often unavailable, especially for past exposures. Without accurate exposure data, it is impossible to correlate exposures with health outcomes.
- Accurate health data are often unavailable. While registries for certain diseases are sometimes available, such as cancer and birth defects, statistical information is not routinely collected for most health conditions. Without accurate health data, well matched to exposure data by time and place, it is impossible to correlate exposures with health outcomes.
- Some ailments, such as fatigue and headache, are difficult to measure objectively, and therefore difficult to characterize quantitatively.
- Complete information on the toxic effects of many chemicals is lacking, especially for such outcomes as neurobehavioral, developmental, and reproductive function, and especially following the types of long-term, low-dose exposures which occur in many communities.

- Toxicologic data usually refer to one chemical at a time, but in real life, people frequently are exposed to mixtures of chemicals. Scientific data on such mixed exposures are scanty.
- Many communities have relatively small populations, which are difficult to study for reasons of statistical power. It is for this reason that important health findings typically emerge from large studies. The Framingham Heart Study enrolled nearly 15,000 people over more than 50 years, and the National Children's Study plans to follow 100,000 children from before birth to age 21. In a community with a few hundred people, the opportunities for robust research are far more limited.

In summary, definitive answers sometimes do not exist, due to the inherent uncertainties of science, the limits of available data, the limits of small-area epidemiology, and the lack of appropriate public health tools.

Moreover, concerned citizens sometimes have honest disagreements with the results of ATSDR assessments. While ATSDR scientists use standardized methods to assure objective results, these sometimes yield conclusions that are not expected by or acceptable to community members. This is understandable. Community members, who are justifiably concerned about unwarranted exposures from hazardous wastes, may reject the concept of "levels of risk" when what they want is zero exposure. For example, in some situations, even where a source of toxic chemicals is identified, careful measurement may indicate that people absorb little or none of the toxic chemical. Such findings can be unwelcome to people who desire nothing less than complete elimination of the contaminant. In some cases, ATSDR and counterpart State agencies have repeated investigations several times, when negative conclusions were challenged, only to replicate the original findings—and consequently to face accusations of indifference or worse. Such situations are difficult and frustrating, both for dedicated ATSDR staff and for community residents who earnestly seek solutions to their problems.

Heavy Emphasis on Hazardous Waste Sites Relative to Other Exposure Routes

In the early 1980s, following the national attention generated by Love Canal, there was considerable focus on hazardous waste sites. CERCLA (including its public health component, ATSDR) reflected this focus. However, a variety of other sources, such as food, consumer products, water, and air, are well recognized, and for many Americans these, not hazardous waste sites, are the predominant pathways of exposure to chemicals.

Workload Challenges

With tens of thousands of hazardous waste sites around the Nation, and with countless other sources of chemical exposures, ATSDR faces a potential workload that exceeds its current staffing level. Though ATSDR's on-board FTE strength has fallen from 481 in FY 2002 to 306 in FY 2008, without a reduction in workload during that period, we continually strive to meet our mission through increased efficiencies and productivity and the efforts of our dedicated staff.

Limited Research Capacity Relative to Extensive Data Needs

ATSDR has a specific challenge with regard to its research capacity. ATSDR has carried out a limited program of targeted research, and has worked to identify data gaps and compile research from industry, academia, and other agencies. However, with the extensive data needs related to toxic exposures, this remains an ongoing challenge for the Agency.

Ongoing Efforts to Improve ATSDR

ATSDR is undertaking major efforts to improve its performance and to meet the challenges outlined above. These efforts range broadly, and can be described in four categories: review of the overall approach to carrying out our mission, review of science administration processes, review of management practices, and improvement of certain other procedures.

Review of the Overall Approach to Carrying Out Our Mission

Careful consideration of ATSDR's mission has revealed important challenges, as described above. After almost 25 years of operation with a relatively unchanged portfolio, these challenges justify re-examination of ATSDR's approach.

That re-examination is made more compelling by the many changes that have occurred in chemical science and technology during the quarter century of ATSDR's

existence. Together these changes have revolutionized the context within which ATSDR works to protect the public from chemical hazards.

- *Analytic chemistry* tools now permit measurement of unprecedented low levels of chemical exposures.
- *Biomonitoring*, the direct measurement of chemicals in people's body fluids, has advanced tremendously, enabling scientists to identify and quantify exposures.
- The *genetic revolution* and the emergence of the "omics" (genomics, proteomics, metabolomics) offer the potential to study gene-environment interactions, and to understand exposures and health effects at an individual level.
- *Toxicologic advances* such as computational and in vitro methods offer enormous opportunities for insight into chemical action, more rapidly and at less expense than ever before.
- *Green chemistry* represents an innovative approach that seeks to design and produce environmentally safe chemicals, avoiding the toxic effects on which ATSDR's work has focused.

Together, these considerations make clear that a re-evaluation of ATSDR's approach is timely and appropriate. Moreover, it is clear that ATSDR's responsibility—protecting the public from toxic chemicals—does not rest with ATSDR alone. Many other agencies share in this responsibility, and many other stakeholders—industry, environmental groups, community groups, professional associations—play essential roles.

In fact, review of the Nation's efforts to protect the public from chemical hazards over the last four decades—an effort that includes ATSDR but extends well beyond—yields compelling conclusions. As a nation we have achieved some notable successes, but we remain limited in our ability to assemble needed data, draw consistent conclusions, launch protective actions, and inform stakeholders. Various agencies and organizations—governmental and non-governmental, regulatory and non-regulatory—carry out public health functions related to chemical exposures. These functions include exposure and health surveillance, investigation of incidents and releases, emergency preparedness and response, regulation, research, and education. But improvements can always be made to increase coordination. Some key responsibilities are not carried out adequately, while others are needlessly redundant. ATSDR's mission and functions must be considered within this broader context.

In recognition of these realities, ATSDR and its companion Center at the CDC, the National Center for Environmental Health (NCEH), have initiated the *National Conversation on Public Health and Chemical Exposures*. This process will convene a wide range of stakeholders over one to two years, including community groups, industry, environmental groups, public health groups, and others. Early responses from various stakeholder groups has been highly supportive. We expect this effort to yield an action agenda for revitalizing the public health approach to chemical exposures. Part of this agenda will be direction for ATSDR as it moves into its second quarter century.

Review of Science Administration Processes

In 2008, this committee raised questions about the adequacy of existing procedures for internal clearance and external peer review of scientific documents at ATSDR. In response, NCEH/ATSDR asked the Board of Scientific Counselors (BSC), an external expert group charged with advising the Center on matters of science and science policy, to assess these procedures and to suggest any needed improvements. The BSC's overall conclusion was that the existing procedures generally function well to achieve quality-assurance goals. The BSC report identified and discussed several concerns and recommendations. A draft report was presented at the November 2008 meeting of the BSC and the BSC approved the final report in early March 2009. In the meantime, ATSDR has made specific improvements. For example, an independent peer review process maintained in one Division now is subject to additional oversight consistent with Center-wide procedures; the staff of the NCEH/ATSDR Office of Science has been enhanced through additional hiring, and review procedures have been reiterated to supervisors to help assure that all staff scientists are aware of them.

Review of Management Practices

In 2008, this committee also raised questions about management practices at ATSDR. In response, CDC commissioned an independent review of NCEH/ATSDR management practices. NCEH/ATSDR was compared to two other CDC Centers and to data from government-wide management-practice surveys, to permit conclusions about areas of particular need within NCEH/ATSDR.

In general, NCEH/ATSDR management practices were found to be comparable to those across CDC. Several opportunities for improvement were identified. Examples include: increasing management awareness of, engagement with, and accountability to the human capital strategy; improving the use of existing human capital systems including human resource data systems and processes, performance management, and recruitment strategies; and improving the Agency capability to constructively manage conflict and enable better program and scientific results. In addition, NCEH/ATSDR leadership, in consultation with those in supervisory positions at CDC's Coordinating Center for Environmental Health and Injury Prevention (that NCEH/ATSDR is a part of), identified other opportunities for management improvement. From these, NCEH/ATSDR developed a broad plan for management improvement, and began implementing that plan in late 2008. The plan has five areas of focus: (1) unifying and revitalizing our mission; (2) human capital strategy; (3) human capital practices; (4) employee relations; and (5) quality of work life. Below are some examples of steps being taken to improve management.

- Initiated strategic planning in each Division, as a step in engaging employees in efforts to achieve shared goals;
- Promote training of managers in team-building, leveraging diversity, complaint and conflict management, alternate dispute resolution, and conduct and disciplinary actions;
- Adopted Issues Management Tracking software in the NCEH/ATSDR Office of Policy, Planning, and Evaluation, to track issues and provide a mechanism for senior management to triage scientific issues to the appropriate office, and to maintain oversight until project completion;
- Initiated a system of job rotation within NCEH/ATSDR to allow staff to move to different positions for short periods (one to three months), to enhance staff skills, facilitate collaboration and innovative partnering within these entities, and improve morale;
- Initiated several activities to attract new public health professionals into entry-level positions, to ensure that the needs of the future will be met.

Improvement of Specific Procedures

Finally, NCEH/ATSDR continues to make a wide range of changes in specific procedures, in order to improve performance. Four examples, each specific to ATSDR and each taken from the last year, are illustrative.

- *The wording of Public Health Assessment conclusions:* ATSDR has for many years used five standard categories of conclusions in its Public Health Assessments: "Urgent Public Health Hazard," "Public Health Hazard," "Indeterminate Public Health Hazard," "No Apparent Public Health Hazard," and "No Public Health Hazard." Concerns were raised about this terminology. In particular, the "No Apparent Public Health Hazard" conclusion was seen by some communities as invalidating their concerns—an understandable reaction, since it was used in some cases of low but non-zero exposure, where a finding of zero risk would be hard to support scientifically. ATSDR reviewed these categories and developed a revised classification that more clearly communicates risk. The new conclusions replace telegraphic phrases with explanatory language, featuring specific information relative to the substance, the pathway, the time period, and the place. For example:

  "ATSDR concludes that touching, breathing, or accidentally eating zinc found in soil and dust at the XYZ site is not expected to harm people's health because zinc levels in soil are below levels of health concern."

  replaces

  "This site posed no apparent public health concern."

- *Process for updating Toxicologic Profiles.* Since its inception ATSDR has produced *Toxicologic Profiles* by reviewing the accumulated literature at a particular point in time, culminating in publication of a monograph that promptly commenced to go out of date. The *Profile* would be updated some years

later with a next edition, which would rather soon become stale. ATSDR is replacing this "book publication" model with a more contemporary model based on ongoing, web-based updates of relevant sections as new material becomes available.

- *Improved data management:* ATSDR requires a sophisticated data management system to track its large number of sites and activities. A custom-designed system, HazDat, was used for this purpose for years, but became obsolete. In response, ATSDR created Sequoia, a new database system, and launched it in February 2008. Sequoia is a scientific and administrative database developed to provide access to information on the release of hazardous substances from Superfund sites or from emergency events and to provide access to information on the effects of hazardous substances on the health of human populations. Sequoia assembles information on site characteristics; site activities; site events; contaminants found; contaminant media; basis for concentration levels, such as maximum, mean, or other descriptor; exposure pathways; impact on the population; ATSDR public health hazard categorization; ATSDR recommendations; interventions to be taken, as described in the public health action plan; and a record of intervention effectiveness. Sequoia should enable better tracking and attainment of performance measures, provide data to support Healthy People objectives, and provide accurate, comprehensive data to support the analysis and identification of site-related trends and the identification of appropriate public health interventions and studies.
- *Shift in product lines:* The standard ATSDR product over the years has been the Public Heath Assessment. These are thoroughly researched documents, based on extensive data reviews, and often require one to two years to complete—a delay that was unacceptable to some communities. However, community health concerns are often fairly specific. By using a more targeted approach such as a Health Consultation, Exposure Investigation, or Technical Assist to address those specific concerns, we can respond more rapidly, address public concerns more directly, and conserve scarce resources for instances when a full Public Health Assessment is necessary to address more complex exposure scenarios.

Conclusion

ATSDR is an agency with a relatively short history, but a history that spans much of this nation's response to health concerns resulting from hazardous environmental exposures.

Beginning with enactment of CERCLA legislation, ATSDR scientists have worked to define a new domain of Environmental Public Health at the community level, often working beyond the reach of the standard tools of public health. Some challenges were apparent initially: addressing questions for which there were no straightforward answers, working in charged settings, and working across cultural and institutional barriers. With time, other challenges have emerged: integration across multiple chemical exposure pathways; the rapid advance of science, leading to needed changes in Agency procedures; and allocating resources effectively.

While there have been setbacks along the way, ATSDR has worked diligently to address the needs and concerns of communities and the people in those communities. Few federal agencies have a stronger track record in working "on the ground" serving local communities. The Agency has developed innovative tools and skill sets in carrying out its mission. It has assembled a strong record of accomplishment—protecting health near hazardous waste sites, advancing science, and educating health professionals and the public.

Nevertheless I recognize the need for ongoing performance evaluation and constant improvement. This committee has pointed out several areas in which improvement may be needed. As described in this testimony, ATSDR is taking aggressive action to improve in four key domains: review of the overall approach to carrying out our mission, review of science administration processes, review of management practices, and improvement of specific procedures.

I am committed to ongoing improvement in every aspect of ATSDR's work, enabling us to achieve the goals assigned by Congress and deserved by the American public: protecting public health from dangerous chemical exposures.

BIOGRAPHY FOR HOWARD FRUMKIN

Howard Frumkin is Director of the National Center for Environmental Health at the U.S. Centers for Disease Control and Prevention, and the Agency for Toxic Sub-

stances and Disease Registry (NCEH/ATSDR). NCEH/ATSDR works to maintain and improve the health of the American people by promoting a healthy environment and by preventing premature death and avoidable illness and disability caused by toxic substances and other environmental hazards.

Dr. Frumkin is an internist, environmental and occupational medicine specialist, and epidemiologist. Before joining the CDC in September, 2005, he was Professor and Chair of the Department of Environmental and Occupational Health at Emory University's Rollins School of Public Health and Professor of Medicine at Emory Medical School. He founded and directed Emory's Environmental and Occupational Medicine Consultation Clinic and the Southeast Pediatric Environmental Health Specialty Unit.

Dr. Frumkin previously served on the Board of Directors of Physicians for Social Responsibility (PSR), where he co-chaired the Environment Committee; as president of the Association of Occupational and Environmental Clinics (AOEC); as chair of the Science Board of the American Public Health Association (APHA), and on the National Toxicology Program Board of Scientific Counselors. As a member of EPA's Children's Health Protection Advisory Committee, he chaired the Smart Growth and Climate Change work groups. He currently serves on the Institute of Medicine Roundtable on Environmental Health Sciences, Research, and Medicine. In Georgia, he was a member of the state's Hazardous Waste Management Authority, the Department of Agriculture Pesticide Advisory Committee, and the Pollution Prevention Assistance Division Partnership Program Advisory Committee, and is a graduate of the Institute for Georgia Environmental Leadership. In Georgia's Clean Air Campaign, he served on the Board and chaired the Health/Technical Committee. He was named Environmental Professional of the Year by the Georgia Environmental Council in 2004. His research interests include public health aspects of urban sprawl and the built environment; air pollution; metal and PCB toxicity; climate change; health benefits of contact with nature; and environmental and occupational health policy, especially regarding minority communities and developing nations. He is the author or co-author of over 160 scientific journal articles and chapters, and his books include *Urban Sprawl and Public Health* (Island Press, 2004, co-authored with Larry Frank and Dick Jackson; named a Top Ten Book of 2005 by Planetizen, the Planning and Development Network), Emerging Illness and Society (Johns Hopkins Press, 2004, co-edited with Randall Packard, Peter Brown, and Ruth Berkelman), *Environmental Health: From Global to Local* (Jossey-Bass, 2005; winner of the Association of American Publishers 2005 Award for Excellence in Professional and Scholarly Publishing in Allied/Health Sciences), *Safe and Healthy School Environments* (Oxford University Press, 2006, co-edited with Leslie Rubin and Robert Geller), and *Green Healthcare Institutions: Health, Environment, Economics* (National Academies Press, 2007, co-edited with Christine Coussens).

Dr. Frumkin received his A.B. from Brown University, his M.D. from the University of Pennsylvania, his M.P.H. and Dr.P.H. from Harvard, his Internal Medicine training at the Hospital of the University of Pennsylvania and Cambridge Hospital, and his Occupational Medicine training at Harvard. He is Board-certified in both Internal Medicine and Occupational Medicine, and is a Fellow of the American College of Physicians, the American College of Occupational and Environmental Medicine, and Collegium Ramazzini.

DISCUSSION

MORE ON ANIMALS AS SENTINELS OF HUMAN HEALTH

Chair MILLER. Thank you. Dr. Frumkin, you saw the photographs in Mr. Mier's testimony, and his testimony was that no one in Midlothian could get anyone at ATSDR to look at the dogs. There were a Ms. Markwardt's dogs, and there were several emails with ATSDR in which ATSDR on June 23 of this year, so just a few weeks ago—January 23. I don't know what I said. "Again, ATSDR is sympathetic to the plight of your animals but studies involving animals, even the sentinels for human health issues, are not activities engaged in or funded by our agency." Before that, ATSDR had sent an email or someone at ATSDR to Ms. Markwardt. "ATSDR is sympathetic to the plight of your animals. However, veterinarian animal issues are outside of our mandated

domain.'' Most recently, January 27, ATSDR wrote Ms. Markwardt and again said it was beyond the expertise or competence of the Agency and suggested that she talk to someone at Texas A&M. No one at Texas A&M has contacted her yet, and it is not clear they have the funding to pursue any kind of study on the animals.

You have heard the testimony from others about the value of animals as sentinels, as an indicator of something, some kind of exposure that may affect us humans as well, and I am sure you reviewed the report, our staff report, that shows several instances in which ATSDR did look to effect on animals as an indicator of effect on humans. Do you stand by those emails? Do you stand by the refusal to look at the dogs in Midlothian or other animals who have obvious health effects as not reliable or beyond the duties of your agency?

Dr. FRUMKIN. Mr. Chair, I think this goes back to a point that Dr. Ozonoff made. The range of expertise needed to serve communities in a comprehensive way is enormous, ranging from veterinary epidemiology to social science to meteorology and so on. We just don't have the expertise on board to do good veterinary epidemiology. Given that we have many more requests to do studies than we have resources to do them, one of the criteria we need to pay attention to is, do we have the expertise and capacity to do it well? In a case like this where it is a very, very heartbreaking situation, it certainly bears further looking into. We just don't have what it takes to look into it, and we believe we would serve the public better to be sure that in this case the pet owner is connected with competent veterinary epidemiologists than to try to take on something that is outside our lane.

Chair MILLER. But you wouldn't look at a dog to see if maybe that might tell you something about the effect there might be on humans?

Dr. FRUMKIN. It is a very worthwhile place to look. Animals, when they become sick, can very well be sentinels for environmental exposures. So I don't discount the importance of looking in that direction.

Chair MILLER. And you are familiar with the 1991 National Academies Report, Animals as Sentinels of Environmental Health Hazards?

Dr. FRUMKIN. Yes, as I just said, animals are very well-recognized valuable sentinels, but a small agency just doesn't have the capacity to do everything and that is a particular line of inquiry that just is outside our skill set.

MORE ON PEER REVIEW

Chair MILLER. Dr. Wilson, you hear the various suggestions that ATSDR simply does not do peer review or infrequently does, but Dr. Wilson said that there were fewer peer reviews of ATSDR's health assessment than most people had fingers and toes. Apparently Dr. Wilson is trying to protect the possibility he can return to being a country music disc jockey if need be. And everyone testified that ATSDR's default is not to seek peer review. It is an extraordinary circumstance when ATSDR does. Everyone seemed to think the default should be getting peer review.

Why is it that ATSDR does not fairly routinely have your health assessments, your methodology, your research, your conclusions peer reviewed?

Dr. FRUMKIN. Let me differentiate between two kinds of products. There are the scientific studies that we produce, and there are the site-specific reports. On our scientific studies, every one of them is externally peer reviewed. That is not only a matter of good practice but it is legislatively required, as I am sure your staff has alerted you.

On the site-specific activities, we are not required to get peer review, and so we have an algorithm that we turn to. It balances the need to get our products out quickly with the need to do rigorous science. The peer review is very worthwhile in terms of assuring the quality of science but does slow the process down somewhat. And so there is discretion on the part of our program managers to decide whether peer review is needed. Our Office of Science is involved in that decision, and when there is a site-specific report, that is either in the realm of uncertain science or is liable to be controversial or is in some other way appears to benefit from greater scrutiny, we do submit that to peer review.

Chair MILLER. The assessment by GAO panel, or the opinion of the GAO panel that site-specific studies should routinely be peer reviewed, you are familiar with that?

Dr. FRUMKIN. Yes, that was well before my time, but I am familiar with it.

Chair MILLER. Okay. And I assume that most people have 20 fingers and toes combined. Dr. Wilson's estimate that there were fewer than 20 that had been peer reviewed, is that correct?

Dr. FRUMKIN. I don't know what number of our products are peer reviewed. I would have to get back to you on that.

Chair MILLER. Well, in terms of the public feeling some confidence in an ATSDR study, wouldn't peer review add to their confidence?

Dr. FRUMKIN. I think peer review would be very helpful, and we are very, very open to discussing a more comprehensive program of peer review. We need to be mindful that we have to balance the need to be expeditious in releasing our products with the need to do the peer review. We heard the observation earlier that our products take too long to get out the door, and we have been very concerned about that and we have been working hard to accelerate the production of our reports. And so we would want to balance the two goods. But I think we are very open to looking further into more extensive and regular peer review.

Chair MILLER. My time has expired. Dr. Broun.

HINDRANCES TO ATSDR'S PERFORMANCE

Mr. BROUN. Dr. Frumkin, you sat here through this whole morning's testimony and heard all these charges against your agency and some against you personally, and kind of going along with what the Chair started out in the line of questioning, of these charges against you, how would you answer those—I know there have been a number of them but the most serious ones are mismanagement and not being scientifically based or honest. Would you please comment to that and since I just have five minutes, I

wanted to ask a second question. You can just probably spend the next few minutes doing those and my time will be up.

What are the greatest hindrances or stumbling blocks for you and your agency to perform the mission that you have been charged with?

Dr. FRUMKIN. Thank you, Dr. Broun. One challenge in carrying out our mission is that it is intrinsically very difficult mission. When communities expect us to come in and have firm answers and when those answers are in many cases elusive, either by their very nature or because the data we need aren't available, then we end up disappointing communities and our people are very disappointed in those situations as well.

So it may be that the very model of work that we use, the very kinds of services we deliver to communities need to be rethought, and our national conversation aims to do that.

We don't have the depth of expertise and breadth of expertise that an agency charged with our mission really ought to have. We need to have expertise in everything from meteorology to communication sciences to veterinary epidemiology, and we don't have that. We are a very small group, and in comparison to the thousands of hazardous waste sites that are out there, the countless thousands of additional chemical releases, our small agency really faces a huge challenge quantitatively.

I don't think that we face the challenge of disloyalty to science or unawareness of the best science or of lack of dedication. I think we have a very dedicated and caring workforce, but in the face of those challenges, the job is a tough job.

MORE ON POTENTIAL FIXES

Mr. BROUN. What would you do in the way of trying to overcome those stumbling blocks or hindrances to your being able to perform what the communities expect?

Dr. FRUMKIN. Well, I think the steps that I described earlier that we are now taking to improve our work very much respond to that question. So at the very large level of looking at our mission—there were some comments today about our work plan. Should we delegate more work to the states or less work to the states? Should we delegate more work to the private sector or less? Those are fair questions to ask, and we are asking questions at that large scale in our national conversation.

We do need to be very attentive to good science administration, and we need to look at issues like effective peer review and clearance and be sure that we are doing as well as we can. We have some suggestions already from this morning's testimony about more extensive peer review, and that is the kind of suggestion we need to take very seriously.

At the level of management within the Agency, we need very good management. We need skilled management with human resources issues and staff capacity building issues and so on attended to. We are taking a lot of steps in that direction, so I stand by what we are doing there. And then there are specific procedures that we could do better, and we are working hard to do better at them.

So I think that sort of thorough, open look, a willingness to identify places where we could do better and then to take advantage

of those opportunities really is what we need to have, and I am proud to say we have that.

Mr. BROUN. Can the private sector handle the functions of doing these studies and producing the scientific products that are necessary?

Dr. FRUMKIN. In some cases we do do that. We have private contractors who handle some of the preparation of our toxicologic profiles. In some cases when we conduct environmental sampling, we have private contractors who do that. So a certain amount of sharing of this responsibility is very appropriate.

I do believe that people expect their government to protect their health, and so I am proud that we have a core government role, and I think we ought to maintain that role, but I think shared arrangements between the public and private sectors are very, very practical and we have shown that they can work.

Mr. BROUN. So the answer to that is the State and private sector can perform these duties if we just enable them to do so?

Dr. FRUMKIN. I think so.

Mr. BROUN. Thank you very much. My time is out and I will yield back, Mr. Chair.

Chair MILLER. Thank you, Dr. Broun. Mr. Rothman has joined us. Do you have questions, Mr. Rothman?

Mr. ROTHMAN. I do indeed. Thank you, Mr. Chair.

Chair MILLER. You have five minutes.

MORE ON VIEQUES, PUERTO RICO

Mr. ROTHMAN. Thank you. Thank you, Doctor, for your testimony. I would like to discuss with you an example of what is a very disturbing conclusion that ATSDR has apparently rendered with regards to the public health of the community of Vieques, Puerto Rico. For over 60 years, roughly 200 days a year the U.S. Navy used the eastern end of Vieques to practice live ordinance training exercises. Numerous studies, both academic and scientific, have confirmed that levels of heavy metals, biotoxins, and carcinogens are sometimes up to 100,000 times higher than the safe levels in the local ecosystem, and the island suffers a drastically higher cancer rate than the rest of Puerto Rico.

I have got a lot of questions, Mr. Chair, which I will submit for the record. As many as I can get in, though, in my time I would be grateful to do.

In 2003 following four public health assessments, ATSDR published a summary of the Agency's work that included such observations that the residents of Vieques have not been exposed to harmful levels of chemicals resulting from Navy training exercises, that the bombing of the live impact area has not affected the drinking water, that levels of chemicals in Vieques' soil are not of public health concern, fish and shellfish are safe to eat every day from Vieques, and other conclusions that seem to be in conflict or contradiction to other independent studies that have found evidence of potential public health issues that ATSDR was unable to find.

Are you aware, Doctor, that the hair testing of the people of Vieques, for example, provided to the U.S. Navy showed extremely high levels of mercury disease, lead disease, cadmium disease, arsenic disease, and aluminum disease? Doctor?

Dr. FRUMKIN. Mr. Rothman, are you referring to disease or to the levels of exposure to those metals?

Mr. ROTHMAN. Level of exposure to those metals. Let us start there. If there is evidence of disease, I would like to know if you found that as well.

Dr. FRUMKIN. I am not familiar in detail with all of the data collected in Vieques over the years. Our agency's involvement in Vieques predated my arrival at the Agency. I do know that there has been sampling conducted by our people, and a lot of sampling conducted by others and can't fully explain the results or reconcile them.

Mr. ROTHMAN. Would you feel comfortable raising your family on Vieques today, Doctor?

Dr. FRUMKIN. I don't know enough about Vieques to be able to answer that question.

Mr. ROTHMAN. It is my understanding that the U.S. Navy has not been asked by ATSDR to provide the kind of relevant information that I think might clarify some of the conflict in conclusions. Would you have any objection to requesting from the Navy that kind of information?

Dr. FRUMKIN. No, sir. I am very happy to pledge to you moving out of this hearing to take a fresh look at the Vieques situation and to collect any data necessary to clarify the health situation for the people there.

Mr. ROTHMAN. That is very good news, Doctor. I understand that you don't have enough information. You have committed to getting more and being open to reexamining this whole issue anew, is that a fair summary of your statement?

Dr. FRUMKIN. Yes, sir.

Mr. ROTHMAN. Thank you very much, Doctor. No further questions, Mr. Chair.

Chair MILLER. Thank you. I do recognize myself for an additional round of questions. Dr. Frumkin, when I finished preparing my opening statement I felt bad. It is hard for a southerner to be that harsh. We say bless his heart, he means well, instead of the boy is just dumb as a fencepost. It is hard for us to be that critical. But the last second two panels made me feel much better about the tone of my opening statement.

CHANGES IN RESPONSE TO CRITICISM

You have heard a lot of criticisms today, you know of the GAO report that Dr. Ozonoff was part of, in 1992 there was a study called Inconclusive by Design that makes many of the same criticisms that we have heard today. I know that was before you joined ATSDR, and certainly the problems with ATSDR predates your joining the Agency, but can you identify anything that the Agency did in response to the GAO study or the study Inconclusive by Design that was scathing to respond to those criticisms? Any change the Agency made?

Dr. FRUMKIN. Mr. Chair, what I can speak to is efforts over the last three years, and that has been my time at the Agency. We have recognized the need for a thorough look at the way we do our business. We have recognized the need to do better in many ways. Many of the criticisms that were leveled in those reports 20 years

ago are still leveled now, so we need to take those seriously. That is exactly the motivator for this national conversation that we are launching. It is meant to be a multi-stakeholder effort, a very serious and probing effort, to ask over the last 20 years of our work, what is going well, what hasn't gone well, and what do we need to do to do much better moving into the future.

Chair MILLER. Not just still but within the last two hours within this Committee room. You have said that there are constraints of budget which I am sure is always true of any Federal Government agency, and that is some of the reasons that the science isn't better than it is or that it is not peer reviewed, that you don't look at all the documents, you don't go look at the dogs. But you have also heard all the testimony today about the importance of a community being able to trust ATSDR's assessment that if there is not something for them to worry about, they need to be able to know that that ATSDR assessment is something that they can rely upon. And you have heard that communities can't rely upon that. Have you considered whether it would be better to do fewer reports but do them well? Get them peer reviewed, have something the communities can rely upon but that an assessment that is not reliable, is not credible, is worse than no assessment at all.

Dr. FRUMKIN. One of the very important possible solutions for us is to take on fewer projects and to put more resources and time into each project and do them in more depth, and I think that is something we need to consider very seriously as we move forward with our planning. It is also the case that sometimes we do quite good work, very good work, but our results are simply not welcome by the community which has other expectations than what we can deliver, and that is not a matter of malfeasance or inability on the part of our people. It is a matter that some of the questions that communities very understandably need to have answered just can't be answered. And so we need to be very careful about acknowledging and when we need to do better in order to win the trust of the community when we simply need to communicate better and be more accountable, even when we have unwelcome news to deliver.

Chair MILLER. I yield back the balance of my time. Dr. Broun, do you wish to have a second round of questions?

Mr. BROUN. Mr. Chair, thank you. I have a number of questions that I am going to submit to the witness, and I appreciate your offer and I am glad to give you forbearance on time, so we will work together I think very well.

CLOSING

Chair MILLER. Mr. Rothman has left us. We are now at the end of our hearing. Thank you, Dr. Frumkin. Under the rules of the Committee, the record will remain open for two weeks for additional statements from any Member. I think I neglected to mention that one of the witnesses, Dr. Cole I think, had—we will admit into the record letters that Dr. Cole made part of his—appended to his testimony, and there can be submissions of follow-up questions from the Committee for any witnesses. And all witnesses are now excused, and the hearing is now adjourned.

[Whereupon, at 12:56 p.m., the Subcommittee was adjourned.]

Appendix:

Answers to Post-Hearing Questions

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ANSWERS TO POST-HEARING QUESTIONS

Responses by Salvador Mier, Local Resident, Midlothian, Texas; Former Director of Prevention, Centers for Disease Control

I thank you for the opportunity to respond to the following questions and offer my perception.

As a prelude to my responses, I want to emphasize—**public health desperately needs the mission that gave birth to the ATSDR to be carried out.** This mission has never been truly respected or realized. A culture of passive resistance by internal and external forces was instituted at its inception to keep ATSDR from completing its mission. This well-engrained culture of passive resistance is still very much alive and pervasive today.

Although disgraceful, the FEMA trailer fiasco was no different than the egregious 1991 ATSDR political move at reducing pollution control and cleanup costs for industry by minimizing and denying the public health hazard of dioxin. ATSDR denied the science then—and contrary to scientific evidence—trivialized dioxin's proven and potential impact on public health and attempted to get other agencies to jump on their bandwagon. The same pattern of trivialization and denial is pervasive in the majority of ATSDR public health assessments and consultations and in their Toxicological Profiles upon which their findings are based. The problems identified by this Subcommittee are only the tip of the iceberg.

One only needs to track forward the culture instilled by Dr. Vernon N. Houk, former Director, Center for Environmental Health, CDC. In so doing it should be obvious that in order to evoke the critically needed changes within ATSDR, all direct or indirect proteges of Dr. Houk currently in leadership above and within ATSDR should be replaced—starting with at a minimum the Director, Coordinating Center for Environmental Health and Injury Prevention (CCEHIP), down through at a minimum ATSDR Director, Deputy Director and Director, Division of Health Assessments and Consultations. Merely tossing a new frog into the swamp as Director is insufficient to bring about the desired consequences.

Questions submitted by Representative Paul C. Broun

Q1. Can the private sector or State agencies perform some or all functions of ATSDR? Would this be appropriate? What conflict of interests could arise? How could you protect against this?

A1. Functions inherent to ATSDR's mission should be the responsibility of a public agency—and the public rightfully expects this to be a responsibility of a federal agency. A federal agency such as ATSDR is (or should be) further removed from the internal State pressures that impair and compromise a state's ability to make unbiased assessments. Private and State agencies could perform some functions of ATSDR but there are serious conflict of interest issues (especially for State agencies) that compromise their ability to conduct fair and objective assessments.

Possible Conflict of Interest—State Agencies

In a statement attached to my written testimony, Dr. Al Armendariz, School of Engineering at Southern Methodist University (SMU) in Dallas, Texas, made the following observations to which I concur.

> "There is an obvious potential for a conflict of interest when the ATSDR contracts with State regulatory agencies to perform health assessments or to conduct follow-up environmental sampling. [Example] In Texas, the TCEQ is the State agency that grants permission to facilities in the form of "permits" to emit pollutants to the atmosphere. In the permit writing process, the State agency is making a legal statement that a facility will not adversely impact public health. There is a very obvious potential conflict of interest when the same agency later goes into the community to do follow-up sampling in response to an ATSDR investigation. A State agency is essentially examining whether the facilities to *which it granted permission to emit pollutants at an earlier date* are now in fact causing an adverse public health impact. If ATSDR is going to work with other organizations to conduct assessments or do follow-up sampling, ATSDR should work with independent third parties with no obvious conflict of interest, such as State universities or schools of public health, a Federal Government contractor, the American Lung Association, etc."

Possible Conflict of Interest Private Sector

Many universities, schools of public health and other health-based organizations often depend on grants from private industries to fund many of their research projects. The threat of losing a grant becomes very real if an organization engages in activities that may not be advantageous for a contributing entity and presents a conflict of interest.

It is crucial to build in safeguards that prevent participation if a potential for conflict of interest exists whether it be a State government or an independent third party.

Problems With State Cooperative Agreements

The degree to which public health issues conflict with industrial prosperity concerns varies greatly from state to state. As an example, in Texas there is considerable political and industry influence (some subliminal and some strongly overt) on the State environmental agency. This tone of supporting industry at the cost of public health has been clearly set by the State administration and is vigorously advocated and promoted by industry lobbyists and generally has been supported by the State legislature. It would be irresponsible to pretend this is an exaggerated issue. It is a pervasive observation expressed by diverse groups of stakeholders and should not be dismissed. In many states the ability for State agencies to make an objective assessment of the impact of toxic exposure on the communities' public health is greatly compromised. *This is why most communities turn to ATSDR—because it is perceived to be more distant from local political pressures.*

Currently, where there is a State cooperative agreement between ATSDR and the state, ATSDR abdicates the investigative and decision-making responsibility back to the state—the same institutions that previously failed the community. **This is a costly "no value realized" process—an egregious waste of taxpayer's money.**

It would be naïve to think that ATSDR can do all of the necessary work independent of the state but ATSDR should assume greater responsibility for many of the required tasks. Public Health Assessments/Consultations performed under State Cooperative Agreements should be severely limited—particularly when all avenues within the state have already been exhausted and a community turns to ATSDR as the last resort. **Resources wasted under these cooperative agreements should be re-channeled to improve ATSDR's methodologies used to identify suspected environmental exposures to hazardous chemicals, conducting their own assessments/consultation, improving quality control and having their work peer reviewed by external experts.**

Q2. To what extent do you attribute the ATSDR's problems to leadership?

A2. See my opening statement. There appears to be an entrenched institutionalized culture that has weakened ATSDR's commitment to objectively temper and counter external pressures and has created internal weaknesses that dissuade the Agency from fulfilling its mission. **Changes in this entrenched institutionalized leadership that go deeper and higher than that of the Director's position are critical if this culture is to change.**

Q3. Do you believe ATSDR attempts to include revolutionary scientific methods and techniques in their work?

a. If not, how would you propose they better integrate cutting edge science?

b. Is there any risk to getting too far ahead of a technology or method and coming to conclusions that are ultimately proven unfounded?

c. How would you set up policies or procedures to appropriately manage and unitize these innovations?

A3. I believe that there are internal barriers to and deficiencies in easily accessible scientific data. This make it difficult for ATSDR public health assessors to readily access and incorporate the evolving science into their decision-making processes.

It appears ATSDR assessors are almost exclusively dependent on summary statements and obsolete ATSDR toxicology profiles. Based on language and references reflected in their findings, it appears ATSDR assessors do not have access to evolving science or are not allowed to work "out of the box established by the ATSDR *Toxicological Profiles*." Language in these *Profiles* appears to be the basis for most arrived conclusions in the assessments/consultations.

In his written testimony to Congress Dr. Howard Frumkin states "Since its inception ATSDR has produced *Toxicologic Profiles* by reviewing the accumulated literature at a particular point in time [not at the cutting edge], culminating in a publication of a monograph that promptly commenced to go out of date. The *Profile*

would be updated some years later with a next edition, which would rather soon become stale."

Dr. Frumkin stated that ATSDR will be replacing the "book publication" model of the *Toxicological Profiles* with a more contemporary model based on ongoing, web-based updates of relevant sections as new material becomes available. How cutting edge the science will be depends on the time lapses between the availability of the data and the update. **ATSDR assessors should have immediate easy access to all cutting edge scientific studies data bases and should be mandated to incorporate the findings into their conclusions.**

It appears extensive data needs for the Agency have not been met. In his testimony, Dr. Frumkin acknowledges, "ATSDR has a limited research capacity relative to extensive data needs. Although ATSDR has carried out a limited program of targeted research and has worked to identify data gaps—with the extensive data needs related to toxic exposures, this remains an ongoing challenge for the Agency."

Keeping up with science appears to be a greater problem than "getting ahead of science." Hence, the question, "Is there any risk to getting too far ahead of a technology or method and coming to conclusions that are ultimately proven unfounded?" is frustrating.

Let us pretend for a moment that ATSDR indeed accesses the cutting edge science and this science presents validated information that warns us of the need to incorporate measures to mitigate harm. **What is the greater risk—taking preventative measures or ignoring emerging science? Protections that mitigate suspected risks can be relaxed if further scientific findings emerge that more robustly support an alternative explanation—but damage to human health cannot be retroactively mitigated and many illnesses and death cannot be undone.**

Resources dedicated to establishing a more proficient science data base and a mandate to incorporate cutting edge science into the public health assessments is critical.

Q4. How did your experiences with State and local health officials differ from that of ATSDR?

a. Were they better or worse?

b. Do you believe there was enough coordination, too little, or too much?

c. Did you view ATSDR's work as simply "rubber-stamping" the state's work, or did they provide value?

A4. Shortly after ATSDR changed Midlothian's health assessment to a consultation, ATSDR made it clear that they were abdicating all of their responsibilities for making decisions back to the state. ATSDR was to sign off on it. This basically made it clear that they would simply be "rubber-stamping" the state's work.

We had very little interaction with ATSDR—unless we pursued it and the bulk of the interaction was via e-mail communication. Up until about six to seven months ago we had frequent communication (both via telephone and e-mail) with several of the State public health agency staff. We have had almost zero communication (either that we have initiated or they have initiated) since. This July it will be four years since we petitioned the ATSDR for a Public Health Assessment.

You ask, "Was the state better or worse than ATSDR. For at least 20 years the community went to the State agencies asking them for a health assessment because they were experiencing increasing public health problems. The community found themselves on a merry-go-round. The health department consistently told them that the environmental agency says that the toxins to which they and their animals were exposed was not supposed to make them sick so there was no point in discussing or looking at their health issues.

In desperation for trusted health information, the community turned to ATSDR. ATSDR catapulted them right back on the same merry-go-round. The community ended up back in the same arena—receiving more of the same. Was there a difference? No.

Q5. What was your impression of ATSDR's coordination with other federal agencies like EPA?

A5. **Since ATSDR was not actively involved with the process, there was no opportunity to form an impression of ATSDR's coordination with other federal agencies.**

Q6. How does ATSDR's level of competence compare to other federal and State entities charged with protecting public health?

a. Would you characterize the work ATSDR does as a specialized niche?

b. Do any other agencies perform this same work?

c. Can you identify any areas of duplication?

A6. Would I characterize the work ATSDR does as a specialized niche? Yes. ATSDR's Public Health Assessments/Consultations **should be a special niche—** operating independent of external influences.

Assessing the impact of toxic exposure on public health is dramatically different from most other public health challenges. First, the science of environmental health is still evolving and the challenge of attempting to associate environmental toxins to illness and disease is apparently extremely difficult. Competency or lack of competency is difficult to compare because ATSDR (and other agencies working in the environmental health arena) appear to have a strong lack of will, interest or courage to attempt to associate illness and disease that might be associated to industrial toxins. *Thus, in my opinion, it is not so much competency that sets ATSDR and other similar agencies apart from other public health entities but rather the mindset in approaching the public health challenges is drastically different.*

Efforts to link epidemiological data to toxic emissions from industry evoke a drastically different set of dynamics and resistance as compared to linking epidemiological data with a bacteria or virus as sources. This is especially true when the emissions are from industries that are active and remain an integral economic part of the community. These are very real dynamics that science confronts in this arena and are extremely difficult to deal with and cannot be dismissed. To dismiss them is to be naïve and irresponsible. ATSDR has a tendency to trivialize and deny the existence of epidemiological data.

Agencies involved in assessing the public health impact of industrial toxins must make more serious efforts to utilize epidemiology. Although epidemiology is a common public health tool the utilization of this instrument is almost non-existent in communities impacted by industrial toxins. Time and time again we have been told by both ATSDR and the State Public Health agency that epidemiology is too expensive, too labor intensive and too difficult in the application to environmental health issues.

"Do any other agencies perform the same work?" Yes, some local and State health departments have environmental health components that can perform some of this work but the level of expertise and competency varies significantly and with some it is questionable. Also, see previous comments regarding potential conflict of interest.

Are there areas of duplication? This is a good question. There may be some that involve ATSDR, the National Center for Environmental Health (CDC and under the same Director) and the National Institute for Environmental Health Sciences. This should be explored.

Q7. How does ATSDR compare with similar entities in other countries?

a. Do international public heal agencies have similar problems?

b. What do you attribute this to?

A7. I have not studied similar entities outside the U.S. therefore do not feel qualified to answer any part of this question.

However, note the testimony from Dr. Randall Parrish, University of Leicester (UK). Using a readily available tool, Dr. Parrish was able to pick up where ATSDR left off and identify depleted uranium in people exposed at Colonie, NY. In this situation I attribute this more to **lack of will** by ATSDR.

Q8. ATSDR does not do large-scale environmental sampling, and relics upon the EPA and states to conduct this work.

Q8a. Do you believe ATSDR should also be doing this work?

A8a. **ATSDR has the responsibility for scientifically evaluating the adequacy, effectiveness and appropriateness of all data upon which they will base their decisions—**including environmental sampling and monitoring (conducted by a State agency or other entity). This is an important fist step in any analyses they perform. If based on science and logic ATSDR deems there are gaps and flaws with the adequacy of this data, then EPA, an EPA contractor or the private sector could assume this responsibility. EPA is the logical federal agency for this responsibility because of their expertise. I would assume that EPA also has the budget capacity to consider undertaking some of these sampling activities (since frankly this is part of their mission).

Although most State environmental agencies have this capacity they are too often in a compromising and/or conflict of interest position because they issue permits to industries and legally certify that those industries will not adversely impact the

public health of the communities in which they operate. See prior statement regarding potential conflict of interest.

Q8b. How would you suggest we pay for this work?

A8b. Adequate data necessary to arrive at a scientific conclusion is not a luxury item and should not be considered optional. The primary question should not be how the work should be financially supported but rather how scientific conclusions can be made without it. *We pay for this work regardless of whether it is done by ATSDR or another entity.* The question should be, "How can we get the most reliable data?" ATSDR resources misdirected towards State Cooperative Agreements could be redirected to pay for this work.

When determining cost you must also factor the increased cost of health care that would ensue addressing illnesses that stem from our failure to take adequate preventative measures to protect public health.

Q8c. Would this be worth limiting the number of other studies, assessments, or consultations the Agency initiated?

A8c. ATSDR has already instituted a "shift in product lines" downgrading to Health Consultations, Exposure Investigation, or Technical Assists to as they put it—"respond more rapidly, and address public concerns more directly—and conserve scarce resources to address more complex exposure scenarios." **Perhaps a closer look at this shift in product lines is necessary to determine whether there was a value added or lost.** Take Midlothian, Texas as an example.

Midlothian, located within the DFW eight-hour Ozone Non-attainment Area, is a complex scenario with the largest *concentration* of cement kilns and one of the largest steel mills in the U.S. These processes alone emit a large volume of chemical and heavy metal toxins. The circumstances are further confounded because these cement kilns are classified as waste recyclers permitted to burn refuse such as tires, petroleum coke, asphalt roofing, etc. For 20 years the community has been exposed to hazardous waste incineration—some even before trial testing was completed. TXI currently is permitted to burn hazardous waste in four outdated wet kilns not designed to burn hazardous waste. These cement kilns are not required to meet the more stringent MACT standards required for commercial hazardous waste incinerators. Animal and human health issues have been surfacing for almost 20 years. This is a complex scenario rife with aggregate toxic chemical exposures and multiple confounding circumstances which logic would tell you would demand a public health assessment.

Instead of performing a public health assessment ATSDR instituted this "shift in product lines" and downgraded the assessment to a "consultation." And as far as being able to "respond more rapidly,"—almost four years later it is still not finalized. And as far as "address public concerns more directly"—the document, and the comments by the six scientists who reviewed the draft do not support that the public's concerns were addressed.

The question to ask is, "To what extent has this "shift in product lines" already taken place—**and has it improved the process and conserved resources?"**

Q9. Please describe the process that you (or your community) went through in petitioning for ATSDR's help.

Q9a. Was your review ever downgraded to a health assessment or health consultation?

Q9b. Were you consulted in this decision, or were you simply informed by the Agency?

Q9c. Did you have any ability to appeal this decision?

A9a,b,c. The responses to these questions are all in my written and oral testimony.

Q9d. How did this affect your overall impression of the services ATSDR provided?

A9d. My impression was that Midlothian would not be getting a true unbiased public health assessment that would withstand the scrutiny of unbiased scientists. I knew that Midlothian's public health assessment would not be subjected to an internal or external peer review. Therefore out of desperation, I appealed to the science community for help in reviewing the draft consultation published for public comment. Six scientists responded. Their comments will give you insight and answers to many of the questions you ask herein.

Q10. Please describe your level of communication with ATSDR.

a. Do you feel this was adequate?

b. What do you think they should have done differently?

A10. Once the ATSDR abdicated their responsibility for assessing Midlothian's public health to the state, the bulk of our communication was with the State agency staff. Basically, we feel ATSDR should have retained the responsibility for making this assessment.

Q11. Do you believe ATSDR products accurately communicate agency findings?

a. What are some of the problems you have identified in their reports?

b. How can the Agency be more effective in communicating risks?

A11. It is the weakness of and the omissions in their findings more so than ATSDR's inability to accurately communicate these findings that creates the problem. **Communicating a concept or conclusion that does not have a solid scientific basis and ignores "community concerns" will always remain difficult.**

Dr. Frumkin's statement that communities expect that ATSDR reach **unequivocal** conclusions does not accurately represent what communities expect.

Giving reasons such as "accurate exposure data are often unavailable"—"accurate health data are often unavailable"—"complete information on toxic effects of many chemicals is lacking, especially for such outcomes as neurobehavioral, development, reproductive function, and especially following the types of long-term, low-dose exposures which occur in many communities"—"scientific data on mixtures to chemicals is scanty," Dr. Frumkin further states, "Unfortunately, it is not always possible to reach such **[unequivocal]** conclusions.

Yet in an effort to force conclusions into neat little boxes labeled "No Apparent Public Health Hazard" or "Indeterminate Public Health" ATSDR reaches **"unequivocal"** conclusions—**ignoring all alleged unknowns as if the lack of data equated to no harm.** Communities expect trusted health information based on sound science. It is the "monkey sees no evil" game that ATSDR plays that communities find frustrating. These unknowns should be acknowledged and be part of their conclusions.

The proposed sample wording/rewording, *"ATSDR concludes that touching, breathing, or accidentally eating zinc found in soil and dust at the XYZ site is not expected to harm people's health because zinc levels in soil are below levels of health concern,"* given in Dr. Frumkin's testimony, as is just an example of an extension of gobbledegook. This exampled phraseology is lacking explanatory information that the public needs and to a large degree is condescending and insults the community's intelligence. It is barren of the scientific basis (expressed in layman's terms) upon which conclusions are based that the public seeks and would just exacerbate frustrations that currently exists.

Consider how lead is addressed as an example and suggested clarification when less than a Public Health Hazard is issued.

Even though the preponderance of evidence shows that there is no safe blood-lead level, ATSDR consistently uses—**as a refuge to not assess public health impact at lower levels—**the statement (cut and pasted from their *Toxicological Profiles*), *"CDC has determined that a blood lead level at or above 10 micrograms per deciliter (μg/dL) in children indicates excessive lead absorption and is grounds for intervention"*—**essentially condoning 10 μg/dL blood-lead level as an acceptable health risk.**

If ATSDR continues to refuses to incorporate accumulated blood-lead levels lower than 10 μg/dL as a health risk, at a minimum, communities seeking trusted health information deserve this type of explanation:

> All scientific research shows **there is no known safe level of lead.**
>
> Shortly after lead gets into your body, it travels in the blood to the "soft tissues" and organs (such as the liver, kidneys, lungs, brain, spleen, muscles, and heart). After several weeks, most of the lead moves into your bones and teeth. In adults, about 94 percent of the total amount of lead in the body is contained in the bones and teeth. About 73 percent of the lead in children's bodies is stored in their bones. Some of the lead can stay in your bones for decades; however, some lead can leave your bones and re-enter your blood and organs under certain circumstances (e.g., during pregnancy and periods of breast feeding, after a bone is broken, and during advancing age).
>
> Lead (from mother's current exposures, and that leaching from the mothers bones) interferes with neural development in children and developing fetuses even at extremely low levels. Even at very low levels, lead is associated with

negative outcomes in children, including impaired cognitive, motor, behavioral, and physical abilities. Fetal lead exposure can cause delay in the embryonic development of multiple organ systems, including retardation of cognitive development in early childhood.

Recent science associates very low blood-lead levels in adults with cognitive deficiencies, increased deaths from heart disease and stroke and miscarriages.

Deleterious human health effects at blood-lead levels 10 times lower that 10 μg/dL have been observed. **CDC recommends a blood-lead level at 10 μg/dL as a point of intervention (not as an acceptable level of poisoning or as an acceptable health risk)** because successful chelating treatments below this level have not been identified; therefore, prevention of exposure is essential. *(Statements should be foot-noted with applicable studies/references.)*

Q12. Are you aware of ATSDR's recent efforts to improve its processes and management?

a. Do you believe they will adequately address your concerns?

b. How would you improve tile Agency's processes and management (or even culture)?

A12. I have read some of the Agency's proposed efforts. These efforts to date have not been reflected in the quality of the end products—Public Health Assessments/Consultations.

I have a major concern about the proposed "National Conversation" to determine the "public health approach to chemical exposures." It appears to be another form of "passive resistance" to proactively addressing the issues that are before ATSDR. Just like public health assessments and consultations are drawn out for years—keeping the public silenced and at bay, thinking that their guardian agencies are taking health-protective actions—this "National Conversation" will serve as an infinite diversion—a refuge for inaction.

ATSDR already knows what they have to do and they have the science to back needed action. Although it is good to keep dialogue open and consistently seek improvement, ATSDR just simply needs to start fulfilling its mission.

Agency processes and management practices are fairly simple to correct and modify. Agency mindset and culture appear to be well engrained and institutionalized over a long period. Effecting a change in mindset and culture requires concerted proactive action.

Senior leaders who have maintained their positions in this current environment are most culpable in setting the existing mindset and culture. To effect desired changes within the Agency, they need to be replaced. In my opinion, at a minimum, the Director, Coordinating Center for Environmental Health and Injury Prevention (CDC), the Director of ATSDR, the Deputy Director and the Director of the Division of Health Assessments and Consultations must be replaced. There may be a need to make other personnel changes in this agency but that would require a review by an outside entity to determine this need.

The new CDC Director must clearly understand the ATSDR mission and the desired mindset and culture necessary in order that ATSDR can carry out its mission. This understanding is critical to assure that the appropriate replacement staff is appointed and in turn, the new mindset mandate is translated to the Agency staff.

Q13. How can ATSDR do a better job characterizing past exposures given the complexity of the task? Do you have any specific recommendations?

A13. ATSDR needs to scientifically validate the merits of environmental data available. If the system collecting data is suspect, then the data produced are also suspect and should not be used as a basis for ascertaining exposure either past or present.

ATSDR should review empirical evidence and determine whether this empirical evidence could be related to exposure. Empirical evidence such as birth defect and cancer clusters, animal and dog birth defects and other health issues are sometimes much better monitors of exposure than any mechanical devices. These are red flags that should warn that something could be awry and further investigation is needed.

If cumulative body burden and past exposures are material to predicted outcomes of current exposure assessments, ATSDR should not proceed as if they are not material. **Lack of data should not be interpreted by ATSDR as an absence of a negative public health impact.**

If past exposures are material to locating people that were in harms way and needing possible additional medical attention or to assess long-term effect on people in similar situations, then ATSDR needs to ensure the best tools are used to assess

these past exposures. See Dr. Randall Parrish's testimony regarding ATSDR's failure to use available tools to assess depleted uranium at Colonie, NY.

In some cases, ATSDR should consider implementing CDC's biomonitoring activities to determine past exposure. This should be given strong consideration in communities where the environmental monitoring system is weak and thus the data generated cannot be used as a basis to accurately characterize past exposure. This activity is under the auspices of the National Center for Environmental Health at CDC and is under the management of the ATSDR Director.

Q14. What roles should ATSDR play in exposure routes not associated with hazardous waste (such as food, consumer products, water, and air)?

a. How should the Agency address these issues?

b. Would there be any overlap with other agencies?

c. What should the Agency do when there is a duplication of effort?

d. Do you believe ATSDR's current mission is appropriate?

A14. **ATSDR is the principal federal public health agency charged with the responsibility of evaluating the human health effects of exposure to hazardous substances in air, water, and soil and the food chain.** Other federal agencies already have responsibility for assuring the safety, efficacy, and security of food, drugs and other consumer products. Although their paths may sometimes cross, the roles and scope of their activities are very different. ATSDR needs to do a better job with its current responsibilities and not even contemplate the expansion of their role.

Dr. Frumkin's expression in his testimony of concern about **heavy emphasis on hazardous waste sites** is puzzling since this encompasses the bulk of ATSDR's responsibilities. **The statement,** *"However, a variety of other sources, such as food, consumer products, water, and air are well recognized, and for many Americans these, not hazardous waste sites, are the predominant pathways of exposure to chemicals,"* **is worrisome.** Determining whether the toxins/chemicals from the hazardous waste sites are contaminating the food, water and air to **is within** ATSDR's scope of responsibility. Furthermore for many Americans living in, near or on hazardous waste sites—**what impacts their health is not an either or situation. Exposure to chemicals and toxins from these hazardous waste sites is a confounding factor on top of the normal body burden of toxins experienced by the many Americans.**

ATSDR's current mission is extremely appropriate and critical to the public health of this nation—it just needs to be carried out.

Continued failure to properly assess the impact from toxic exposures or to be clear about potential health impacts will continue to imperil the Nation's public health. It will be a signal to industries and the environmental agencies that the edge has not yet been reached and activities that produce further increases in toxic emissions may be possible or that further preventative measures are not necessary.

Those opposed to the success of ATSDR's mandated mission would realize a great victory should ATSDR maintain the status quo or be abolished.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Randall R. Parrish, Head, Natural Environmental Research Council (NERC) Isotope Geosciences Laboratory, British Geological Survey

Answers to questions will refer to the question numbers 1 to 14; several of the questions refer broadly to interactions witnesses have had with ATSDR; in my particular situation these are not relevant since I have never had any direct or indirect contact with ATSDR. ATSDR has not contacted me with regards to my work at any time. I have not attempted to contact ATSDR either. My contribution has mainly been in evaluating the ATSDR Health Consultation done at Colonie, NY.

Questions submitted by Representative Paul C. Broun

Q1. Can the private sector or State agencies perform some or all of the functions of ATSDR?

a. Could they do it better?

b. Would this be appropriate?

c. What conflict of interests could arise?

d. How could you protect against this?

A1. As I live in the UK I do not feel I have sufficient knowledge of either State agencies or private sector organizations to address this question.

Q2. To what extent do you attribute the ATSDR's problems to leadership?

A2. I express my personal view here: I do feel this is in part a leadership issue. In large organizations leadership sets the tone and agenda. I listened to the response of the Director of ATSDR during testimony and generally felt that his comments indicated to me that he had failed to set a clear agenda of priorities for the Agency, and that he was probably out of his depth, regardless of how good an academic scientist he is or was in his previous role. Weak leadership has undoubtedly contributed to the acute difficulties the Agency is in now. Poor judgment near or at the top has led to some of the imprudent actions—especially the formaldehyde issue.

Q3. Do you believe ATSDR attempts to include revolutionary scientific methods and techniques in their work?

a. If not, how would you propose they better integrate cutting edge science?

b. Is there any risk to getting too far ahead of a technology or method and coming to conclusions that are ultimately proven unfounded?

c. How would you set up policies or procedures to appropriately manage and utilize these innovations?

A3. In my experience at Colonie, NY, there is little doubt that the Agency failed to take account of and incorporate advances in methods of toxic exposure detection. The Agency should ask the broad questions—for example—what levels of exposure might have occurred and can these be documented; can modeling be used to estimate better what inhalation of toxic uranium oxide might have occurred? These types of questions can be addressed. In my opinion the Agency need not have full expertise within its own staff to answer all possible technological questions, but they should have an outward-facing comprehensive knowledge of where to find the experts and how to engage them as consultants, advisors, or as analysts. If they embraced this type of ethos, they could retain the capability of using the best methods and best science while not being compelled to find this top notch expertise always within house. I suspect the Agency has the worst of both worlds—neither the experts in house nor the interest to seek outside expertise. This would lead to a highly insular organization that would, over time, become more and more inadequate given its remit. I do not have sufficient current knowledge of the organization to comment much further except to say that what I am suggesting is not rocket science—just pretty much down to Earth common sense. If they want to get to the bottom of an issue, you need to seek the best experts and use the most appropriate tools. I would also say that if the Agency always requires the use of routine methods that are common and well established, and if they require any method to be formally accredited in a lab, then they will miss major opportunities because the common methods may not be appropriate for unusual requirements.

Q4. How did your experiences with State and local health officials differ from that of ATSDR?

a. Were they better or worse?

b. Do you believe there was enough coordination, too little, or too much?

c. Did you view ATSDR's work as simply "rubber-stamping" the state's work, or did they provide value?

A4. I felt that the quality of the ATSDR health consultation at Colonie, NY was fair at best, but to be fair, that of the NY agencies were no better. Neither agency seemed to feel the need to do any proper study of the situation. Both appeared to act not in a proactive precautionary way, but almost entirely in a response to public pressure. In neither case was protecting public health at the top of the agenda. Neither agencies appeared to satisfy the concerns of the public in any substantial way and this I consider to be a failure of will.

Q5. What was your impression of ATSDR's coordination with other federal agencies like EPA?

A5. No comment, not enough knowledge.

Q6. How does ATSDR's level of competence compare to other federal and State entities charged with protecting public health?

a. Would you characterize the work ATSDR does as a specialized niche?

b. Do any other agencies perform this same work?

c. Can you identify any areas of duplication?

A6. No comment, not enough knowledge.

Q7. How does ATSDR compare with similar entities in other countries?

a. Do international public health agencies have similar problems?

b. What do you attribute this to?

A7. Hard to answer. In the UK we have the Health Protection Agency and quite rigorous standards on brownfield or toxic substance sites and there is a much stronger linkage between governmental levels dealing with these sort of things, unlike the diffuse jurisdictions in the U.S.; of course the UK is much smaller and the situation is different. I get the impression that there is more proactive precautionary work done in the UK than the U.S. given like for like situations. The U.S. has a long history of companies with long standing links to the U.S. military and U.S. DOE being allowed to pollute badly and get away with it, at taxpayers' expense. In the UK there is a 'polluter pays' default policy, which requires costs to be borne primarily by those that do the polluting. For example in the Colonie, NY area, the DOE-contracted National Lead Industries did all the polluting and paid for none of the cleanup, with the government willingly picking up the tab for the mess ($190M) and still with no agency seemingly interested in evaluating the public health implications of it all. National Lead has had a habit of abandoning sites and moving on. The ethos that allows this to continue should be changed—this is long overdue but unfortunately an entrenched pattern.

Q8. ATSDR does not do large scale environmental sampling, and relies upon the EPA and states to conduct this work.

a. Do you believe ATSDR should also be doing this work?

b. How would you suggest we pay for this work?

c. Would this be worth limiting the number of other studies, assessments, or consultations the Agency initiated?

A8. I think the most effective advice I could give ATSDR is to prioritize its many projects and for those they commit to, to do them well, rather than cover all of them poorly. This again, is just common sense. They need to re-establish their credibility and they have to do excellent and thorough work to achieve this. If their resources are insufficient to do this at all sites, then they either need additional resources, or need to do fewer of them. All of this is based on the assumption that they also need to root out systemic problems within the Agency that prevent them from being efficient and doing the best science.

Q9. Please describe the process that you (or your community) went through in petitioning for ATSDR's help.

a. Was your review ever downgraded to a health assessment or health consultation?

b. Were you consulted in this decision, or were you simply informed by the Agency?

c. Did you have any ability to appeal this decision?

d. How did this affect your overall impression of the services ATSDR provided?

A9. See the preface; I have had no contact either way with the Agency—they have not contacted me nor have I contacted them. They clearly had something to gain from contacting me, but on the basis of their report, I felt that it was sufficiently superficial and in part ill-informed that I was unlikely to gain any new knowledge of the Colonie Site by contacting them.

Q10. Please describe your level of communication with ATSDR.

a. Do you feel this was adequate?

b. What do you think they should have done differently?

A10. See the preface; I have had no contact either way with the Agency—they have not contacted me nor have I contacted them. They clearly had something to gain from contacting me, but on the basis of their report, I felt that it was sufficiently superficial and in part ill-informed that I was unlikely to gain any new knowledge of the Colonie Site by contacting them.

Q11. Do you believe ATSDR products accurately communicate agency findings?

a. What are some of the problems you have identified in their reports?

b. How can the Agency be more effective in communicating risks?

A11. I detailed what I felt were failings in the Colonie Health Consultation in some detail in my original testimony, which is available; I refer the Committee to this.

Q12. Are you aware of ATSDR's recent efforts to improve its processes and management?

a. Do you believe they will adequately address your concerns?

b. How would you improve the Agency's processes and management (or even culture)?

A12. No, I am not really aware of what if any progress has been made. Little or none of this was evident during the Committee hearing of 12 March, nor was it convincingly made clear in the written testimony materials. I would not be surprised if any 'progress' was instead relatively superficial. My personal opinion here is that the Agency is unlikely to recover to an acceptable state without major leadership change through the fabric of the whole senior leadership layer at ATSDR, but again, I do not have detailed knowledge.

Q13. How can ATSDR do a better job characterizing past exposures given complexity of the task?

a. Do you have any specific recommendations?

A13. This is a very important question and gets at the heart of the public health issue of sites that have historic rather than active pollution signatures. Many toxic substances produce health impacts many years after exposure and it is therefore ESSENTIAL that the best and most innovative methods be used to attempt to assess and detect such exposures and try to quantify them, so that health outcomes might be evaluated against the exposure data in order test linkages. The Colonie, NY example is a perfect illustration of the need for ATSDR to do better. If as occurred, the Agency assesses the current information and concludes there was a major health risk, but then says it can do nothing because it happened 20 years earlier, well that just isn't good enough. Our group as you know come along right afterwards and did the work that the ATSDR should have realized could be done. Neither ATSDR nor the NY agencies seemed the least inclined to pursue the issue and instead they appeared to fail to even appreciate that health consequences may persist. In my opinion (as detailed in my written testimony) they badly misunderstood many aspects of this problem and largely missed the point—a demonstration of inadequate knowledge of the science and issues. If they need to know what the past exposure might have been, the Agency could commission the best labs (private or public sector) to develop such tests when such tests (with their high sensitivity requirements) are unavailable via routine methods. This is what the UK did in order to satisfy Gulf War veterans who had persistent concerns about exposure to depleted uranium munitions. If the methods don't exist to detect a substance retained in the body from an historic exposure, then talk to the experts and commission new methods to be developed.

Q14. What role should ATSDR play in exposure routes not associated with hazardous waste (such as food, consumer products, water, and air)

a. How should the Agency address these issues?
b. Would there be any overlap with other agencies?
c. What should the Agency do when there is duplication of effort?
d. Do you believe ATSDR's current mission is appropriate?

A14. I do not have sufficient knowledge to answer this question.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Jeffrey C. Camplin, President, Camplin Environmental Services, Inc.

Questions submitted by Representative Paul C. Broun

Q1. Can the private sector or State agencies perform some or all of the functions of ATSDR?

A1. A major problem with ATSDR research and studies is that private sector and State agencies perform much of their work in an unsupervised manner. I have identified many reports performed in the Chicago area regarding asbestos where ATSDR has allowed State agencies to perform incredibly faulty Public Health Assessments. ATSDR then "rubber stamps" these reports without reviewing their accuracy. In another case, ATSDR funded a study by the University of Illinois at Chicago School of Public Health that also contained flaws. When I complained to ATSDR about the poor quality of the study they funded I was told by ATSDR leadership that it was not their report and they could not require any changes. When I told them that all ATSDR funded studies must follow their quality guidelines ATSDR stood silent. To summarize, ATSDR needs to focus on "accountability" of their own staff and those partners they delegate work to. Without accountability the flawed studies will continue.

Q2. To what extent to you attribute the ATSDR's problems to Leadership?

A2. Again, the leadership fails to hold their agency accountable for their work products. When I challenged the flawed studies by State agencies "rubber stamped" by ATSDR in Illinois, my challenges were not addressed. I wrote specifically to ATSDR, CDC, and HHS leadership and was responded to with form letters that ignored my challenges. In one case I filed an ethics complaint against ATSDR staff that disturbed asbestos contaminated sand during an exposure study while families were on the beach. The ATSDR staff had personal protective equipment on while they exposed families to asbestos fibers. I was told by ATSDR leadership that their staff was ethical and only perform work in a professional manner. Yet I had video and photos of the egregious behavior that ATSDR refused to comment on. The leadership is arrogant and complacent. ATSDR will continue to generate flawed work products as long as the leadership is complacent and does not hold their staff or partners accountable for their flawed work.

Q3. Do you believe ATSDR attempts to include revolutionary scientific methods and techniques in their work?

A3. It is the exact opposite: ATSDR uses outdated, flawed, and unscientifically modified methods to perform their work. All of their asbestos studies contain numerous modifications and limitations which skew and downplay the toxicological findings of their studies. All of their asbestos pubic health assessments and consultations use a risk model that they admit is inaccurate and outdated. Yet instead of using more accurate risk models, ATSDR clings to the outdated model. ATSDR simply adds disclaimers to their report that state the risk from asbestos is significantly underestimated. This is unacceptable. However, ATSDR leadership refuses to acknowledge the use of better scientific methods. They won't even run a side by side comparison of the outdated risk models to more current scientific methods and techniques in their work. This is unacceptable and a major scientific flaw in ATSDR studies.

Q4. How did your experience with State and local health officials differ from that of ATSDR?

A4. State and local agency reports were definitely "rubber stamped" by ATSDR. This is a problem when State and local agencies also participated in studies run by ATSDR staff. ATSDR, State, and local agencies play off each other when their reports are challenged. ATSDR will say that the state had control, while the state might say the local agency actually made key decisions, while the local agencies point the fingers back at the state and ATSDR. Draft documents and e-mail are not subject to FOIA so it is impossible for the public to determine who actually made any decisions on studies. ATSDR generally fights all FOIA's. It would be helpful if this agency was more transparent. Also, when State or local agencies will not respond to FOIA's I generally requested the information from ATSDR. ATSDR would state that they would not give me information from their files from other agencies and that I would have to get any documents from those agencies. Again, ATSDR

promotes an atmosphere of secrecy to impede any accountability of responsible parties; particularly of their own staff.

Q5. What was your impression of ATSDR's coordination with other federal agencies like EPA?

A5. ATSDR and EPA play games with consultations and Public Health Assessments. For instance, EPA performed an asbestos study at Illinois Beach State Park in 2007. ATSDR helped them develop the study, they were present at the site when the study was performed, and they even participated in the study by disturbing beach sand and wearing air monitoring equipment. ATSDR Region 5 staff did all of this. The same staffer from ATSDR Region 5 also helped review the study. Then EPA asked ATSDR to review the study as though it was the first time ATSDR had seen the report. Region 5 ATSDR then asked the EPA's TRW asbestos group to review their risk assessment. However, Region 5 ATSDR staffer who participated in the testing and who was preparing the risk assessment was also a member of the EPA's TRW asbestos group. In the final risk assessment opinion the ATSDR Region 5 staffer documented the process as though he had no involvement other than being the risk assessor. In reality he had been involved in the entire process from design to final report to peer review (of his own work). The EPA needed a study that said the asbestos risks were low because of their involvement with bungling an asbestos Superfund site that created the contamination. ATSDR played along with EPA the entire way to make sure the testing was rigged and the risk models were flawed. The ATSDR staff also made sure he was involved in the peer review so his work product would not be challenged. This is not transparency or "independent" peer review. This is rigging a study with the EPA to cover-up the mistakes of their past flawed work product.

Q6. How does ATSDR's level of competence compare to other federal and State entities charged with protecting public health?

A6. I believe that ATSDR has the potential to generate very competent work. However, the leadership of ATSDR has developed a culture where their work supports preconceived conclusions by rigging studies and the data. ATSDR is very competent in arrogantly generating flawed work products. They know that there are not too many others who have the knowledge to challenge them. When someone does challenge them they arrogantly hide behind the integrity of the Agency and their many credentials. They cannot handle the truth. ATSDR leadership and staff are very smart. Unfortunately they do not use their knowledge to promote public health. They use their expertise to cover-up for errors made by other agencies.

Q7. How does ATSDR compare with entities in other countries?

A7. I am working with the Italian government to write a paper on how asbestos contaminated shorelines have been addressed by the U.S. vs. Italy. The Italian government errs on the side of caution when risks from asbestos are unknown. The Italian government was shocked to hear how ATSDR was estimating risk from asbestos contamination along the Illinois Lake Michigan shoreline. I have been asked by the Italian government to participate on their scientific review panel when they host the World Asbestos Conference later this year in Italy. Many other nations will be presenting at this conference. Most countries look to the U.S. for leadership on pubic health and toxicological studies. However, they have become just as disappointed as I have been with the quality of their work. ATSDR does not act in a precautionary manner unlike most European countries. ATSDR is sliding backwards as the rest of the world passes them by.

Q8. ATSDR does not do large scale environmental sampling and relies upon the EPA and states to conduct this work. Do you believe ATSDR should do this work?

A8. ATSDR actually did some asbestos testing in Illinois. I video taped some of the testing where ATSDR staff from Region 5 and the Atlanta office exposed the public during their testing. I filed an ethics complaint against them. ATSDR concluded their work did not pose a risk to human health. However, when they asked Region 5 EPA to provide comments, EPA found "extremely high exposures" that ATSDR downplayed. ATSDR published their flawed report anyway stating it was their report and EPA had no jurisdiction. ATSDR should not be doing testing!

Yet there is also a problem with others doing the testing. ATSDR generally takes the data from their "partners" study at face value. There is no validity or accuracy checks done on the data. I have found significant problems with data used by ATSDR in their studies. ATSDR never. seems to review or reject ANY data. They just take the numbers and plug them into their outdated risk models and conclude

everything is just fine. The solution is to hold ATSDR accountable for verifying the integrity of data that they use in their studies. ATSDR must be the Agency that independently verifies that data used in their risk assessments is accurate. Right now they do not do this, at least with asbestos studies.

Q9. Please describe the process that you (or your community) went through in petitioning for ATSDR's help.

a. Was your review ever downgraded to a health assessment or health consultation?

b. Were you consulted in this decision, or were you simply informed by the Agency?

c. Did you have any ability to appeal this decision?

d. How did this affect your overall impression of the services ATSDR provided?

A9. WE DID NOT PETITION FOR ATSDR's HELP. WE CHALLENGED THEIR FLAWED DATA AND ASKED FOR BETTER STUDIES AND MORE ACCURATE RISK ASSESSMENTS. ATSDR REFUSED TO ACKNOWLEDGE THEIR PAST ERRORS AND FLAWS IN THEIR STUDIES. ATSDR CONTINUED TO GENERATE NEW TESTING FOR THE SOLE PURPOSE OF COVERING UP THEIR FLAWED STUDIES, NOT TO IMPROVE UPON THEIR FLAWED WORK.

Q10. Please describe your level of communication with ATSDR.

A10. I have challenged their flawed work through their information quality guidelines to no avail. I also appealed their decisions without having my concerns addressed in their responses. All I have ever asked for is ANSWERS to the questions I posed to them about the quality of their reports and studies. ATSDR (from the top down) ignores any challenges and provides responses that avoid the actual challenge. There should be an independent review of ATSDR's responses to information quality challenges. Right now there is no accountability for their non-responses to legitimate challenges and concerns.

Q11. Do you believe ATSDR products accurately communicate agency findings?

A11. NO! ATSDR loads up their studies with all kinds of limitations and qualifiers that significantly impact the accuracy of their findings. Then ATSDR portrays their findings (with great confidence) that everything is fine. Yet buried in the report are these significant limitation and qualifiers that indicate how flawed the study actually is. ATSDR needs to communicate just how unreliable their information actually is. Better yet, they should just do more accurate testing. ATSDR serves the polluter by generating "gray area" studies that don't really say one way or the other if a hazard exists. This is another way ATSDR performs studies that harm public health.

Q12. Are you aware of ATSDR's recent efforts to improve its processes and management?

A12. There are no improvements. ATSDR already has good policies and structure. The leadership is the problem. Since the leadership has not changed I find it hard to believe anything has improved. What evidence exists that anything has improved? I know in 1991 ATSDR said they were going to improve and they didn't. Actions speak louder than words. What has really changed and what is the evidence that has been verified by an independent agency. I don't believe Dr. Frumkin's empty words that things are changing. According to Dr. Frumkin's arrogant testimony before the Subcommittee, "I am proud of the excellent work we do at hundreds of sites nationally. I recognize that even excellent work has room for improvement" (line 2229). I do not think that ATSDR was ridiculed back in 1991 or by this subcommittee for improving upon their "excellent" work. ATSDR continually generates flawed work products that harm public health. Major changes need to take place. Leadership of ATSDR must be held accountable. If ATSDR leadership is not held accountable, their complacency will continue.

Q13. How can ATSDR do a better job characterizing past exposures given the complexity of the task?

A13. ATSDR needs to use accurate risk models. For asbestos, ATSDR knowingly uses outdated risk models to calculate risk. ATSDR needs to make great improvements with how they assess exposures to asbestos.

Q14. What role should ATSDR play in exposure routes not associated with hazardous waste (such as food, consumer products, water, and air)?

A14. ATSDR needs to take a more holistic approach to public health assessments. Most times they put blinders on and only look at risks from the perspective of a certain hazardous waste in a certain location. In reality, the public has multiple exposures from a variety of sources. The risk from one specific site might not be enough to declare a significant risk. However, when that risk is added to similar risks in nearby areas or through other pathways the risk rises to a level of concern.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Ronnie D. Wilson, Associate Professor, Central Michigan University; Former Ombudsman, Agency for Toxic Substances and Disease Registry

Questions submitted by Representative Paul C. Broun

Q1. Prior to the establishment of ATSDR, how was public health protected?

a. What role did academia play?

b. What role does academia play now?

c. What role does the private sector play?

d. How does this compare to now?

e. Has the role of protecting public health simply shifted from the private sector to the public sector?

A1. Prior to the creation of ATSDR, little was known about the health effects of toxic waste exposures. Some research had been conducted by academia (often funded by or in conjunction with the private sector) and some by EPA. There was a huge gap in knowledge and there was no regulatory or legislative mandate to fill the void. Other than academia, little work in the private sector has transpired to protect public health from environmental exposures.

Although academia does play a role, ATSDR has provided funding and oversight for much of the academic research. ATSDR has also conducted important studies on the health effects of environmental exposures.

With no regulatory or legislative mandate, outside academia little research has been conducted by the private sector.

Q2. To what extent do you attribute the ATSDR's problem to leadership?

A2. Many, both within and outside the Agency, feel that the present leadership is a major portion of the problem with and within ATSDR. To be fair however, conducting research in environmental health and promoting public health is sometimes difficult and involves a high degree of complexity. Mistakes can be made with the best intentions. However, no matter the intent, mistakes have occurred and leadership has known about ATSDR's deficiencies and has failed to take corrective action.

Further, ATSDR leadership has become a poster child for micro-management, even to the point of making determinations regarding the exact words are to be used in health assessments, studies and consultations. While ATSDR's leadership may be talented, they are not, and will never be experts in everything, yet no matter what the issue or the science involved, leadership can, and will, mandate their opinion over that of those who are indeed experts—often with a bit of world renown. A perfect example is the Katrina Trailers in which management refused to recognize the dangers and sought to cover up the issue and ultimately forced the removal of a senior scientist at great expense to the taxpayers.

Q3. Can the private sector or State agencies perform some or all of the functions of ATSDR?

a. Could they do it better?

b. Would this be appropriate?

c. What conflicts of interests could arise?

d. How could you protect against this?

A3. ATSDR partners with academia and State government to conduct research and health assessments. Other than academia, the private sector cannot, and will not do this work to protect public health. If the private sector conducts research at all, they will do it to protect their interests. ATSDR also does cutting edge research (e.g., groundwater contaminant fate and transport modeling as is being done at Camp Lejeune; B-cell work in conjunction with the CDC National Center for Environmental Health lab; polycythemia vera cluster investigation in conjunction with academia and State government; and the Brick Twp, NJ Autism Cluster investigation, started in 1998 by ATSDR in conjunction with CDC's Developmental Disabilities division, which provided the first, clinical estimate of autism prevalence in a U.S. community since the late 1980s and established that autism was sharply increasing.

The key problem with ATSDR is the poor quality of many of the health assessments and health consults. This could be changed by requiring independent peer review and by encouraging ATSDR to involve the community at the planning and

scoping stage of the health assessment/consult as well as the conduction of the health assessment/consult.

ATSDR has helped build capacity of State governments. Funding by ATSDR to several states in the late 1980s was crucial in establishing birth defect registries in these states as well as crucial to the use of these registries to investigate the health effects of environmental exposures. ATSDR funded the Woburn study of childhood leukemia that was conducted by the MADPH. ATSDR funded, provided oversight, and conducted the water and air modeling for the Dover Twp/Toms River, NJ childhood cancer study that was conducted by the NJDOH.

ATSDR is a leader in epidemiological research on the health effects of exposures to toxic waste chemical contaminants in drinking water, having either conducted or funded the major studies in this field (e.g., four NJ studies, Woburn, Camp Lejeune, Tucson). ATSDR also funded studies in two states that first documented that exposures to disinfection byproducts (e.g., Trihalomethanes) in drinking water was associated with adverse birth outcomes (low birth weight and specific birth defects).

Q4. Are community complaints about the work of ATSDR new?

A4. Community concerns were the basis for enactment of CERCLA. Therefore, from the beginning of ATSDR, communities have rightfully looked to "their agency" to solve health concerns. However, such concerns have often strained at the limits of environmental science. Working more closely with communities will help, but will not solve all the communities concerns.

Q4a. Why does this seem to be a perennial problem?

A4a. Although ATSDR is second only to CDC's STD/HIV in the involvement of communities in its activities, this is not saying much because, other than STD/HIV, the rest of CDC has a poor record on this as well! It is a problem because ATSDR still is not fully committed to involving communities at the ground floor of the planning and scoping of its activities and the conduction of its activities. There are some exceptions, such as the CAPs that have been formed at a few sites.

ATSDR needs to create a mechanism for full community involvement at each site. Community involvement should be from the moment a site is discovered (or where a hazardous condition becomes know) until the site clean-up is complete. This may require a community action group or it may be handled in a simpler fashion. But some mechanism should be mandated, established, and employed.

The issue continues to arise because of a form of "ivory tower syndrome," in which the staff, most often in an assessment or consultation role, does not seek community input because, ". . . we are the scientist, what do they know." In such instances, the failure to include the community not only generates resistance but also serves to restrict the information flow from the community and to the community.

Q5. Do you believe ATSDR products accurately communicate agency findings?

a. What are some of the problems you have identified in their reports?

b. How can the Agency be more effective in communicating risks?

A5. Toxicological profiles and health assessments are often not reader-friendly. The health assessments often answer questions that are not of interest to the community and fail to address adequately questions that are of interest. There is too much "boiler-plate" material that is unnecessary. Public health assessments (PHAs) need to be tailored to the particular site and the concerns at that site. In addition, PHAs are uneven in their quality. As for risk communication, holding large "availability sessions" and public meetings is not usually the best way to communicate risks! (See answer to #4 on the need for community participation mechanisms).

Profiles, by law, must present the most up-to-date toxicological information. According to some scientific journals, they are the most often cited toxicological resources. ATSDR has provided a public health statement in the front of each toxicological profile that is intended to be understandable to the lay audience, e.g., community groups. More recently, the profiles have added material that is intended to be helpful to a medical readership. However, if the documents are not meeting the specific needs of an audience, perhaps the Agency could use focus or other similar groups as a sounding board for improvement of the final products.

ATSDR should work closely with the concerned community members (e.g., the activists), State and local health agencies and health providers to ensure better health communications. ATSDR must seek to make sure the questions of concern are addressed, to establish trust, to be fully transparent, to obtain community buy-in to the approach being undertaken, to make sure the community understands the limitations of the agreed-upon approach, and to establish the best way to communicate the information/risks.

PHAs would possess far greater value if mid-level to lower-upper level management was not so concerned with political correctness and "softening" the information. Certain words, like "carcinogenic" cannot be used because the public might become "alarmed." Yet, the community is asking for the accurate information.

Q6. Are you aware of ATSDR's recent efforts to improve its processes and management?

a. Do you believe they will adequately address your concerns?

b. How would you improve the Agency's processes and management (or even culture)?

A6. I see no evidence of any improvement. The initial planning for the so-called "conversation" developed with hardly any staff input. So staff feel the new process is designed protect (shield) our leadership from Congressional attacks.

Morale is at an all time low throughout CDC as well as ATSDR, primarily because leadership does not respect staff and does not seek staff input at the ground floor of the planning stage of new initiatives or reorganization, etc. ATSDR and National Center for Environmental Health (NCEH) staff are not collaborating as they should—a failure of the leadership. There is too much concern about "turf" within and between ATSDR and NCEH, and there is insufficient commitment to community involvement at ATSDR and NCEH.

Either the existing leadership needs to seriously address these problems or they need to be replaced with leadership that will address these problems. Likewise, Congress should mandate a formal merger, or separation, of ATSDR and NCEH, so the staff and the public will have an understanding of to whom they need to speak and who is responsible for assigned functions.

Q7. What was your impression of ATSDR's coordination with other federal agencies like EPA?

A7. It is my experience that ATSDR often does try hard to coordinate and work with other agencies but gets little response and cooperation from these agencies. However, one could also assume that some of the failure of other agencies to be cooperative is in part the self infliction of wounds. I have hear high level officials from four Regions of the EPA indicate that while ATSDR could do good work, they took so long to do so that others ways of dealing with problems without including ATSDR had become the norm.

Q8. How does ATSDR's level of confidence compare to other federal and State entities charged with protecting public health?

A8. I am not sufficiently versed in all the efforts of other agencies, but in general both federal and State entities have been hamstrung by lack of funding/staff and the policies. However, I have never seen confidence or talent as a problem at ATSDR. Rather, I have seen restrictions on the staff by management to "word smith" documents (assessments and consultation) to avoid "alarmist" issues is more the problem.

Q9. How does ATSDR compare with similar entities in other countries?

a. Do international public health agencies have similar problems?

b. What do you attribute this?

A9. I have no knowledge of any agency in any other country that is similar to ATSDR.

Internationally, the Agency is respected, often by countries that have no such public health entity. Having products from ATSDR, like toxicological profiles, serves to assist other countries.

Q10. ATSDR does not do large scale environmental sampling, and relies upon the EP and states to conduct this work.

a. Do you believe ATSDR should do this work?

b. How would you suggest we pay for the work?

c. Would this be worth limiting the number of other studies, assessments or consultation the Agency initiated?

A10. Large scale sampling probably should continue to be performed by EPA and the states, although it would be helpful to involve ATSDR at the ground floor of the planning, scoping and conduction of sampling at each site. ATSDR should work more closely with other federal agencies/groups, e.g., the U.S.G.S., in order to gather current environmental data.

Sampling should be paid for by the polluters, and most often times is paid via the cost recovery efforts of EPA.

During the early days of ATSDR's existence, there was a serious problem with the number of health assessments that the Agency was required to perform in a short period of time. This is no longer a major problem. Instead, the major problems for the PHAs and consults are unevenness and lack of consistency across the PHAs/consults, failure to address the concerns of the community, and poor scientific quality. Much of this could be resolved by requiring peer review of PHAs and health consults.

Additionally, the ATSDR Board of Scientific Counselors should monitor the quality of PHAs and set up a task force (within ATSDR or independent of ATSDR) to deliberate and develop a consensus concerning the risks of specific, controversial hazardous substances (e.g., TCE, PCE, dioxin, PCBs, perchlorate, and emerging threats) that would guide ATSDR's health assessments Finally, full community participation is vital to the success of ATSDR's work.

Q11. Do you believe ATSDR attempts to include revolutionary methods and techniques in their work?

a. If not, how would you propose they better integrate cutting edge science?

b. Is there any risk to getting too far ahead of a technology or method and coming to conclusions that are ultimately proven unfounded?

c. How would you set up policies or procedures to appropriately manage and utilize these innovations?

A11. ATSDR is at the forefront in historical exposure reconstruction modeling for drinking water. In its effort at Camp Lejeune (working with expert researchers at GA Tech and expert consultants), it is breaking new ground in the modeling of the historical groundwater migration of contaminants in order to provide the epidemiological studies at the base with monthly estimates of contamination levels at the tap decades before testing of the tap water quality were performed (i.e., actual testing for contamination did not begin until 1982 but the water modeling effort was able to provide scientifically sound estimates of contaminant levels back to the beginning of the water plant's operation in the early 1950s).

No other epidemiological study of drinking water contamination has conducted such an extensive, and cutting-edge, modeling effort. ATSDR also is in the forefront of disease cluster investigation methods, e.g., its use of molecular testing to confirm polycythemia vera cases in PA, its use of clinical testing to confirm autism cases at Brick Township, and its use of water modeling and air modeling at Toms River.

ATSDR's use of immune function tests in communities in proximity to several toxic waste sites identified a pattern of blood cells in certain individuals that resembled a pattern seen in chronic lymphocytic leukemia although these individuals did not have leukemia. This was the first time this phenomenon was observed. In collaboration with the NCEH lab, ATSDR conducted the first of its kind study to follow-up these individuals with this pattern of blood cells and found that these individuals were at increased risk of eventually having leukemia and that this pattern of blood cells was associated with living in proximity to hazardous waste sites.

ATSDR also provided funding and oversight to academic researchers who conducted research focusing on the health effects of exposures to PCBs in the Great Lakes region and at Anniston AL.

ATSDR has state-of-the-art GIS technology and an expert staff on GIS mapping and analysis methods.

ATSDR does attempt to include novel, innovative methods in its research. In addition, the protocols of all ATSDR epidemiological studies must undergo peer review and IRB review before the study is conducted. After the study is conducted, the report of the findings (either a journal article draft or a draft report) must undergo peer review as well as agency clearance. Even with these reviews, it is possible for the quality of the study to be substandard scientifically. Therefore, the Board of Scientific Counselors should set up a task force that monitors the quality of the epidemiological research at ATSDR. These review mechanisms should ensure that the findings and conclusions are not "unfounded."

Q12. How can ATSDR do a better job characterizing past experiences given the complexity of the task?

a. Do you have any specific recommendations?

A12. Historical exposure reconstruction is the best way to do this, but it is expensive, time-consuming, and cannot be done at most sites because of lack of sufficient data. But often the problem is that the public health assessment (PHA) is not focused enough on past exposures. Of course, it is understandable and appropriate for

a PHA to focus on present exposures if they are occurring. But a strong commitment to evaluate, as best one can, past exposures is needed as well. Often, this is one of the major concerns a community has. The PHA should go the extra mile to uncover any information that would help it to characterize past exposures.

Q13. What role should ATSDR play in exposure routes not associated with hazardous waste (such as food, consumer products, water and air)?

a. How should the Agency address these issues?

b. Would there be any overlap with other agencies?

c. What should the Agency do when these is duplication of effort?

d. Do you believe ATSDR's current mission is appropriate?

A13. ATSDR's current mission is appropriate. If there are gaps (e.g., disinfection byproducts in drinking water, other exposures not related to toxic waste substances), then ATSDR should work with NCEH to make sure these gaps are filled. ATSDR should conduct epidemiological research on the health effects of exposures to disinfection byproducts and other non-microbial contaminants (CDC focuses on microbial contaminants) in drinking water, and become the leader in this research, but the Agency has not moved strongly in this direction. ATSDR may require more staff and resources, it does have the expertise for water and air modeling and it has access to the NCEH lab.

Any overlap with EPA could be resolved (e.g., by collaboration!), but in most instances there really is not overlap with EPA (or any other agency) in the research effort. ATSDR really does fill an important gap in the research on the health effects of environmental exposures.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Henry S. Cole, President, Henry S. Cole & Associates, Inc., Upper Marlboro, Maryland

This report is written in response to a series of questions by Congressman Broun and is based on my experience with ATSDR and a number of affected to communities where ATSDR provided health assessments or consultations. It is also based on my experience in dozens of communities impacted by hazardous waste sites, power plants, factory pollution, etc., where State regulatory agencies were involved. I have not answered several questions, e.g., those involving past exposure methodologies, and cutting edge technologies. Please use other sources of information for these issues.

Questions submitted by Representative Paul C. Broun

Q1. Big picture: Does ATSDR contribute to the health of environmentally stressed communities?

A1. In working with environmentally stressed communities, ATSDR has focused largely on determining whether a particular source(s) have the potential to expose and adversely affect the health of residents. This function is clearly embedded in the Agency's mission statement:

> *ATSDR's mission is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related exposures to toxic substances.*

However, this statement also requires ATSDR to take "responsive public health actions" and to *provide* information in a way that would actually prevent harmful exposures and improve community health. In my judgment, ATSDR's efforts toward these objectives are lacking.

The communities in greatest need of help are most often impacted by a multitude of environmental stresses: e.g., a waste management facility, factory pollution, highly toxic diesel emissions, and unhealthful levels of inhalable particulates and/or ground level ozone. Perhaps there are sewerage related problems. There are other stresses as well—such as unemployment, no access to health care, aging populations, lack of adequate housing, etc. Although there is clearly a need to study the health impacts of various sources and chemicals, studies alone will not bring real help to communities.

A holistic approach

Needs vary from one community to another; i.e., the local health clinic may need expertise to deal with environmental exposures, perhaps a local credit union or pension fund could invest in restoring homes to livability, or perhaps the need is set up volunteers to visit the homes of elderly neighbors on a continuing basis. Such efforts will require a different vision and much greater coordination between programs and agencies. However, there are examples of community-based approaches which attempt to solve problems holistically. For example, in Trenton, a non-profit organization, Isles, Inc. has set up programs to remove lead from home environments and has trained residents to address these problems and to restore dilapidated buildings. These programs have led to employment and entrepreneurial opportunities. Trenton has the potential to bring in up to $2.4 million for green collar jobs and career development activities, many of them connected to restoration and improved environmental health. See *http://www.isles.org/*

This program is by no means unique. In fact, President Obama's economic stimulus package contains funding for community-based training and employment in areas such as weatherization and renewable energy. (See also, *The Green Collar Economy* by Van Jones and Ariane Conrad, 2008 for many examples of community-based initiatives aimed to bring environmental health and economic progress to communities.)

Multi-Agency Approach

Of course, no one agency is equipped to deliver the multi-faceted assistance that many environmentally stressed communities need for improved health. Given that the Administration is looking for ways to make government funding work more effectively, Congress and the Administration should consider creating an agency in the Department of Health and Human Services with a broader mission than ATSDR. The new agency would focus on the problems and needs of environmentally

stressed communities. This agency would work closely with communities and local governments to assess and meet the broad needs of public health. ATSDR would be replaced by (or "morphed" into) a branch that provides scientific assistance to the new agency. The new agency would marshal the resources of a broad range of government entities including EPA, the National Institutes of Environmental Health, Housing and Urban Affairs, the Department of Agriculture, Commerce Department, etc., to deliver the most needed targeted services (e.g., medical, nutritional, community restoration, educational) etc. The Agency would also attempt to work with local authorities and industries to seek creative solutions (e.g., a program to retrofit truck fleets with particulate filters and catalytic converters to curb highly toxic diesel fumes).

Q2. The role of the private sector.

A2. A number of Congressman Broun's questions focus on the potential role of the private sector in protecting public health. I have separated private sector into several components:

- Regarding industries (e.g., manufacturing, energy, agribusiness, pharmaceuticals, etc.)—in general they have failed to protect public health (communities and workers) without strong regulation and enforcement by government. A good example is mountain top mining (MTM)—coal companies blast the tops of mountains to get at coal and dump the overburden into the headwaters of streams. The Bush Administration removed regulatory obstacles to MTM despite extensive damage to ecosystems and communities in Appalachia.
- Industrial research institutes that address environmental health, in my judgment, often tilt their scientific findings to protect the financial interests of their corporate members. For example, research funded by the chlorinated plastic industry attempts to downplay the dangers associated with the life cycle impacts of vinyl plastics. One exception is the insurance industry, especially those that insure health and environmental damages. Such insurers have a stake in preventing illness and environmental problems such as toxic spills and climate change (potential for increased frequency and intensity of storms and related damage).
- Private research institutes and institutes of higher education have brought about an enormous increase in our understanding of the relationship between toxic chemicals and health effects.
- The work of consulting firms often depends on the interests of the client. For example, consulting firms working for potentially responsible parties at Superfund sites may conduct field studies and risk assessments that understate the extent of the problem requiring remediation. As a result clients have lower cleanup costs. However, this is not to say that all consulting firms do biased research; to the contrary many firms have produced excellent studies for government, non-governmental organizations, etc.

Q3. The role of State agencies.

A3. In my experiences, State regulatory agencies and State departments of health have been weak in their protection of community health. In some cases this has to do with insufficient resources. For example, such agencies rely on the regulated industries for information (e.g., stack testing). In other cases there is an extremely close relationship between agency officials and corporate officials. In many cases, economics, combined with political influence, trumps environmental health. For example, in the Ohio EPA has permitted an energy company to build a large coke oven battery in Middletown, OH despite the impacts on the local airshed (already a non-compliance zone with regard to ozone and PM2.5); this facility will be located about 0.7 miles upwind of an elementary school.

Q4. ATSDR's Leadership Problem.

A4. ATSDR's mission statement is as follows:

> *ATSDR's mission is to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related exposures to toxic substances.*

The Agency's conduct with regard to formaldehyde exposure in FEMA trailers alone requires that the Agency's top leadership be replaced. There were at least three serious problems: (1) bad science (2) failure to protect the health of families living in the trailers and (3) communicating reassurance rather than accurate information on risk to trailer occupants. The Oversight Subcommittee report (date) dem-

onstrates that the behavior of top ATSDR officials, including its Administrator, not only failed to carry out the Agency's mission but destroyed its credibility beyond repair.

In addition, the Agency under current leadership lacks both the vision and creativity that is needed to restore the health of environmentally stressed communities.

Q5. Community Complaints.

A5. As I have stated in my testimony, a large number of communities are frustrated and angered by ATSDR's work in their communities. For example, a national organization with a large grassroots following has warned in its publications that communities may opt to boycott ATSDR (and cooperating State health departments) unless the Agency negotiates with the community in good faith regarding study protocols and related issues of public concern.[1]

Witness statements at the March 12, 2009 hearing provide further evidence that the problems at ATSDR are widespread. Secondly, two Congressmen testified at the hearing about the problems with the Agency's investigations of the naval bombing range in Vieques, Puerto Rico. These problems described include: studies that are shallow and predictably inconclusive from the start, flawed methodologies, over reliance on company or federal agency data (e.g., DOD, DOE), failure to use all available sources of information, failure to effectively involve communities in the design of studies, and a failure to obtain peer review, especially in controversial cases. Finally, ATSDR's response to uncertainty is too often to find an "inconclusive hazard" without recommendations for further study or preventive measures. Rather than err on the side of precaution, ATSDR often issues "no evidence" findings that are quickly translated by sources and enforcement agencies to mean "no problem." While there are dedicated scientists and other professionals at ATSDR, the prevailing leadership has failed to take advantage of a large store of expertise and desire to help communities. *Moreover, the Agency has done little to provide actual relief from or prevention of harm in environmentally stressed communities.*

Risk communication:

The quality of risk communication depends upon several factors: (1) the quality of information used as inputs to the assessments (2) the inclusion of all applicable exposure pathways and routes (3) the confidence that community members have in those conducting the assessment and reporting the findings. One way to ensure that all of these conditions are met is to involve the community and their technical advisors from the outset. Programs that give community organizations access to environmental and public health scientists should be expanded. Independent peer review should be provided when concerned parties request on.

Trends: are the complaints new?

Current efforts: The complaints outlined above are certainly not new. The Agency got off to a very bad start by conducting a large number of congressionally-mandated health assessments at sites on the Superfund National Priorities List (NPL). These were cursory reports based on EPA and industry data. Residents had little or no opportunity to provide input or comments. Residents in many "Superfund Communities" felt that the reports understated their impact and need for protection. Spurred by widespread and growing criticism in the late 1980's and early 90's then Administrator Dr. Barry Johnson sponsored a series of large meetings that included grassroots organizations and ATSDR staff. These meetings led to the formation of an ongoing Community and Tribal Committee and a Community Involvement Branch (CIB) at the Agency. CIB has formed ongoing community advisory panels (CAPs) to obtain input and promote dialogue between officials and residents; upfront and continued work of CAPs have helped to improve the responsiveness of ATSDR to community concerns and the Agency's trust level. In addition, Dr. Johnson directed the Agency to take decisive action at a number of sites. I believe that these efforts paid off in terms of what ATSDR was able to deliver and its trust among affected communities. In my judgment the Agency has lost focus following Dr. Johnson's retirement (1998). Dr. Henry Falk had good intentions but lacked the strong leadership skills needed to guide an Agency with a difficult mission.

As stated above, the Agency has suffered irreparable harm under Dr. Frumkin. His recent efforts to establish a national dialogue are simply "too little and too late" to make the kind of changes that are needed.

Q6. ATSDR Products.

[1] Stephen Lester, Center for Health Environment & Justice, *Assessing Health Problems in Local Communities.* Updated April 2007.

A6. One critical problem with risk communication in ATSDR products is that the Agency fails to effectively involve communities in the design of studies and in the wording of reports. In my written testimony (March 12, 2009), I stated that community members should (and their experts) be given an effective opportunities to provide input on protocols for all investigations and on drafts of all reports (including health consultations) before they are finalized. Community advisory panels that work with ATSDR over extended periods have been effective in a number of cases; these help to build confidence in the final ATSDR product.

Moreover, ATSDR products are almost never peer reviewed. ATSDR should provide a peer review process whenever interested parties (e.g., community members) request one. Affected communities often have a legitimate need for concern and help; community members are likely to be highly suspicious where ATSDR comes up with "no-evidence or no-impact" finding—unless they have been involved from the outset in a meaningful way that develops a strong level of trust.

Q7. ATSDR coordination with other agencies.

A7. ATSDR works very closely with U.S. EPA's Superfund Office. The coordination takes place largely at the regional level, with ATSDR regional officials often headquartered in EPA regional offices. ATSDR also uses data generated by EPA or by parties liable for cleanups including industries in the private sector and federal facilities (especially Department of Defense and Department of Energy facilities). In my judgment, ATSDR often allows these agencies to control the flow of information, the extent of testing, and even the outcome of studies. Federal agencies including EPA, DOD, and DOE must often address issues involving cost. For example, given the absence of the Superfund feedstock tax, EPA has little money to fund cleanups; thus they are dependent on the industries liable for the cleanup to conduct the remedial work. Negotiations do not always center on protection of health and environment, but on the costs to the company and the agreed upon cleanup may be less than protective of health and the environment. ATSDR officials who work in close coordination with EPA officials may in some cases be unwilling to "rock the boat." I would recommend that agencies conducting health studies be *given greater resources to obtain their own data* and greater independence from EPA and potentially liable parties including federal facilities. Potentially responsible parties (PRPs) should reimburse health-based agencies for the costs of investigations.

ATSDR also has cooperative agreements with State Departments of Health (DOHs). The DOHs often conduct public health assessments under cooperative agreement for ATSDR. The DOHs operate under similar restraints with regard to obtaining information.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Howard Frumkin, Director, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry (NCEH/ATSDR)

Questions submitted by Representative Paul C. Broun

Q1. Please explain the difference between a Health Assessment, a Health Consultation, an Exposure Investigation, and a Technical Assist.

A1. A **public health assessment** is defined as a comprehensive site evaluation of data and information on the release of hazardous substances into the environment in order to assess any past, current, or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects (42 Code of Federal Regulations, Part 90, published in 55 *Federal Register* 5136, February 13, 1990).

A **public health consultation** is a response to a specific public health issue or question which requires the analysis of site-specific data, health outcome data or chemical-specific data. A public health consultation can also serve as a written record of a verbal response provided when immediate public health input is needed. Often site-specific data is provided to ATSDR as it becomes available and in order to provide timely input on public health issues ATSDR will develop multiple public health consultations. Public health consultations are therefore more limited in the range of issues addressed. For instance, a public health consultation often includes the review and analysis of information on a single pathway of exposure whereas a public health assessment includes the review and analysis of multiple pathways of exposure.

Public health assessments differ from public health consultations in that they may consider all pathways at a site, and are released for public comment and include a response to comments.

In an **exposure investigation,** ATSDR collects and analyzes site-specific information and biological tests (when appropriate) to determine whether people have been exposed to hazardous substances. Exposure investigations support a site evaluation by conducting targeted sampling to evaluate exposures within a community. ATSDR documents the findings and analysis of its exposure investigations in the public health consultation format.

A **technical assist** is a response to external requests for environmental public health technical and/or educational information. Such requests may be received via phone calls, letters, and/or e-mails from external requestors. In general, the technical assist will be used by the requestor to make a more informed decision. Unlike other ATSDR documents, technical assists do not include a public health hazard category. If a data or information package is submitted for evaluation or a public health hazard category will be determined, a public health consultation or public health assessment is the appropriate format to document the analysis and decision process.

Q1a. How does ATSDR determine which products to provide?

A1a. A preliminary assessment is made of the exposure pathways, the environmental media data, and community concerns to decide what product or products would provide the most appropriate and timely public health response. In most cases ATSDR will coordinate with the person requesting our services to discuss the request and the products and services that are most likely to meet their needs.

Q1b. Does ATSDR consult with the petitioner when it chooses which product to provide?

A1b. When ATSDR receives a petition, a team of environmental scientists, physicians, toxicologists, and other staff members evaluates all site information and decides whether ATSDR will perform a Public Health Assessment or if some other action—such as a Public Health Advisory, Health Consultation, or community environmental health education—would better meet the community's needs, or if no ATSDR involvement is needed. As noted above, in most cases ATSDR coordinates with the petitioner to discuss the request. Petitioners are informed in writing of ATSDR's decision and the reasons for it. Throughout the Public Health Assessment process, ATSDR is in regular communication with the petitioner and the community.

Q1c. Does the petitioner have any recourse to appeal ATSDR's decision?

A1c. The petitioner may request a change in the type of ATSDR product at any time. However, as a practical matter, few ever do as the ATSDR proposed product

is tailored to produce the most timely and relevant public health response. Public health assessments are designed for more complex sites to address multiple human exposure pathways and many contaminated media whereas health consultations focus on a single human exposure pathway and media.

Q2. Approximately what percentage of work done by ATSDR is self-initiated, mandated by law, or the result of an outside petition?

A2. Very little of ATSDR's work at sites is strictly self-initiated. Approximately 35–45 percent of our current work results from citizen petitions and National Priorities List (NPL)-mandated work. The majority of the remaining work comes from federal and State agencies, primarily requests from EPA and State environmental agencies.

Q2a. How many petitions for assistance does ATSDR receive in a year?

A2a. ATSDR has received more than 750 petitions since the Agency first began accepting them in 1987. The average number of petitions each year is approximately 35. (ATSDR received 34 petitions in 2008.)

Q2b. What percentage of petitions are you able to actually assist on?

A2b. While all petition requests are carefully reviewed, approximately 60 percent have been accepted resulting in the development of a Public Health Assessment or Health Consultation.

Q2c. How do you prioritize such petitions?

A2c. Petition requests are prioritized using available data based on the likely severity of the environmental and physical hazards, an understanding of the potential pathways of exposure and the affected population, the availability of data needed to carry out an assessment, and evidence or suggestions of adverse health outcomes in the community.

Q3. What options does ATSDR have if sampling data is limited for a particular review?

A3. ATSDR routinely deals with incomplete exposure information. ATSDR's ability to draw public health conclusions is sometimes limited by the quantity and/or quality of the exposure information. It is critical that the exposure information used to evaluate the risk for adverse health effects be complete and accurate. Often situations exist in which either no—or insufficient—data are available or we cannot answer the questions posed by the community due to limitations in science, even when data are available. However, we do have options for responding to situations in which there is limited sampling data, as we discuss below.

If exposure data are limited, we can

- search for and retrieve existing data (ATSDR has pioneered methods, and is very experienced at this task),
- measure past exposures using new and innovative methods (however, even when we can measure levels in the environment, it is difficult to know if people have actually been exposed),
- model past exposures,
- use biomonitoring techniques (such as those developed by the National Center for Environmental Health laboratory) when appropriate,
- report that there are limitations when we cannot quantify exposures and say so, communicating well, or
- recommend that needed sampling be done by agencies such as EPA and State agencies that are equipped to perform the sampling.

If health outcome data are limited, we can

- use existing health outcome databases (although the United States does not systematically collect data on many health outcomes, such as asthma, neurodevelopmental disorders, or immune function disorders) or
- collect data by performing epidemiological studies (such studies are expensive and time-consuming, and therefore only rarely feasible).

Q3a. Is caveating the limitations in the report your only option?

A3a. No. We have many options, as described above.

In addition, ATSDR works closely with CDC's National Center for Environmental Health Environmental Public Health Tracking Program. The Tracking Program

brings together data on environmental hazards, exposure to environmental hazards, and health effects potentially related to exposure to environmental hazards.

As a final note, we need to emphasize that caveats are important. The public needs to know if data is missing and how that may limit what we can do.

Q3b. How challenging is this in terms of communicating results?

A3b. This creates frustration for some members of the public, who expect definitive answers. For example, at Colonie, New York, we considered an epidemiologic study of workers exposed to metals. We requested health data for the former workers but were not able to obtain the data. This important and missing piece of information, combined with the lack of environmental data for the years of peak activity at the plant, left a research gap for investigators and frustrated members of the community.

However, we do have options for responding to situations in which there is limited sampling data, as we discussed above.

Q3c. How do you propose ATSDR address this issue?

A3c. We address the issue of not having enough data by using the best available data, recommending how data gaps can be filled, and communicating the limitations of that data to the communities we serve.

ATSDR is striving to expand the use of state-of-the-art exposure assessment strategies, and also to combine the use of sampling and modeling results. For example, to accurately estimate park visitor exposures to asbestos at the Illinois Beach State Park site, ATSDR employed activity-based-sampling and used the most current methods for asbestos analysis, developed by the International Organization for Standardization.

We also recognize that we must redouble our effort to be clear about the limitations of the data and to work with communities from the beginning of the public health assessment process, and throughout the process, to ensure that—to the extent possible—expectations are realistic. ATSDR has launched initiatives so that concerned citizens better understand the complex nature of environmental exposures and will be able to make informed decisions about the exposure to toxic substances and their health.

Q4. In the case of formaldehyde levels in FEMA trailers, EPA conducted sampling after limited consultation with ATSDR. That sampling was deemed to be insufficient to characterize long-term exposure. How does the Agency now ensure that it receives appropriate samples to adequately characterize exposure and risk?

A4. In the case of the initial work with the FEMA trailer data, ATSDR's role was as a technical assist that primarily involved reviewing EPA sampling data.

In its initial review, ATSDR staff did not consider the implications of chronic exposures. That has been corrected. We corrected the Health Consultation and published a revised document providing background information on exposure to formaldehyde and health effects (including those of long-term exposure), and clarifying the limitations of the data analysis.

Following the initial assessment, and recognizing that the ATSDR health consultation was not designed to reflect actual conditions of those living in trailers, CDC's National Center for Environmental Health undertook—and is continuing to conduct—extensive activities to assess health risks related to temporary housing units used after Hurricane Katrina. These activities include: a structural study to analyze emissions from individual components of trailers and mobiles homes used as temporary housing, and a study of occupied housing to evaluate levels of formaldehyde under actual living conditions. This effort led to recommendations regarding the use of the trailers as temporary housing and resulted in FEMA removing people from units with unsafe levels of formaldehyde. NCEH also is undertaking a comprehensive long-term study of children's health related to Hurricane Katrina. Recognizing that this is a broader problem, NCEH and ATSDR convened a group of agencies to address broadly the health challenges of manufactured structures. The results of this effort are expected during the coming year.

ATSDR routinely confers with other agencies on sampling methodology. Recent examples include the coal fly ash spill in Tennessee and concerns over the use of Chinese drywall in homes. ATSDR brings unique value by adding public health expertise to EPA's sampling expertise, allowing the methods to consider the ways that people are actually exposed.

Q5. How can ATSDR do a better job characterizing past exposures given the complexity of the task? Do you have any specific recommendations?

A5. Reconstructing past exposures is a core challenge in the environmental health field. ATSDR routinely deals with incomplete exposure information. ATSDR has several options for investigating exposures and potential health effects.

We can search for and retrieve existing data. ATSDR scientists are skilled at locating data sources and obtaining available data.

ATSDR is utilizing new ways to measure past exposures. Using innovative methods, ATSDR scientists are able to measure levels of environmental contaminants in ways previously unavailable; however, even when we can measure levels in the environment, it is often difficult to know if people have actually been exposed.

ATSDR also has developed methods to model past exposures. The Agency uses exposure-dose reconstruction as an approach that incorporates computational models and other approximation techniques to estimate cumulative amounts of hazardous substances internalized by individuals presumed to be or who are actually at risk from contact with substances associated with hazardous waste sites. For example, ATSDR developed techniques for modeling complex water distribution systems to investigate past exposures to TCE and PCE at Camp Lejeune in North Carolina. ATSDR's water modeling activities support the Agency's current epidemiologic study of childhood birth defects and cancer possibly related to past exposure to contaminated drinking water at the base. We are also exploring the use of modeling in conjunction with sampling data.

In addition, we are increasingly using biomonitoring techniques to measure the level of contaminants that are actually in people's bodies. However, this is only appropriate for past exposures when the chemical persists in the body. Some are quickly metabolized or expelled and, therefore, do not yield usable biomonitoring results.

Advancing science in the three areas discussed above—1) measuring past exposures, 2) modeling, and 3) biomonitoring—would further improve the characterization of past exposures.

Q6. How does ATSDR decide when to partner with State health departments?

A6. ATSDR works closely with State and local health departments whenever possible. In more than half the states, this work is carried out through our cooperative agreement program using federal funds. Funding is based on a competitive process to ensure states are qualified to conduct this work. In all the states, we provide technical assistance as requested by the states.

Q6a. Do these partnerships end up providing states with additional resources from the Federal Government?

A6a. Yes. The cooperative agreement program allows states to build capacity in environmental health. Even though resources are limited, in many cases the only capacity within the state to deal with health impacts of hazardous waste sites comes from money ATSDR provides.

Q6b. Is this an appropriate function of the Federal Government, or should states be funding work with their own resources?

A6b. There is a role for both the Federal Government and the State governments in environmental health. How these roles are balanced is a policy decision.

The *Comprehensive Environmental Response, Compensation and Liability Act* (CERCLA), as amended by the *Superfund Amendments and Reauthorization Act* (SARA), provides that "The activities of the Administrator of ATSDR described in this subsection and section 9611 (c)(4) of this title shall be carried out by the Administrator of ATSDR, either directly or through cooperative agreements with States (or political subdivisions thereof) which the Administrator of ATSDR determines are capable of carrying out such activities. Such activities shall include provision of consultations on health information, the conduct of health assessments, including those required under section 3019(b) of the *Solid Waste Disposal Act* [42 U.S.C. 6939a (b)], health studies, registries, and health surveillance." See 42 U.S.C. 9604(i)(15).

Q6c. How does ATSDR ensure that conflicts of interest do not arise, or that ATSDR's work is simply seen as a "rubber stamp?"

A6c. In general, conflicts do not arise in our work activities with State health departments. Our goal is mutual—we want to provide the best public health information for the communities potentially impacted by a toxic exposure. ATSDR interacts with State Health Departments on a routine basis, in the context of technical assistance; and ATSDR has a more formalized process, the State Cooperative Agreement Program. There is an inherent sensitivity in working collaboratively with our State Partners. The states are closer to their community concerns. On the other hand, federal agencies can provide additional resources or certain types of specialized exper-

tise. ATSDR prides itself on strong working relationships with State Health Departments. In rare cases-say, when the state owns the site of concern—there may be an appearance of or the potential for a conflict of interest, however, ATSDR minimizes any potential impact and ensures that these sites are addressed with the best public health approach available. In all cases, ATSDR insists that good science be used in all products produced by the state with our support. Protecting public health is our first priority.

ATSDR routinely receives requests from State Health Departments for technical assistance. For example, when a coal burning power plant had an accidental release of fly ash in a Tennessee community, the Tennessee Health Department immediately requested ATSDR technical assistance in responding to community health concerns. In providing technical assistance ATSDR provides independent review based on its expertise and experience, and does not simply "rubber-stamp" conclusions or products. In this circumstance, the Tennessee Health Department prepared a fact sheet to distribute to the local community members to provide information on their health and this fly ash release. ATSDR reviewed the fact sheet and noted that the statement related to health concerns was too reassuring to the community, since it did not consider the longer-term exposure to the fly ash in the sediment. The Tennessee Health Department agreed with ATSDR to change the fact sheet language. The revised fact sheet in now on their web site and being used for all additional public health meetings.

Q7. How has the Agency evolved in terms of the services it provides?

A7. Initially, most of ATSDR's work was mandated at Superfund sites, listed on EPA's National Priorities List. Over the years, the amount of that work has declined, as fewer Superfund sites have been proposed. Technical requests from other agencies and from State and local health departments have emerged as an increasing force for ATSDR's environmental health response work. The role of ATSDR is an important one and despite the modest resources (approximately $74 million), we make positive contributions to health and safety in many communities.

Q7a. Has the number of health assessment and consultation petitions increased recently?

A7a. Petitions have remained relatively stable through the years, averaging approximately 35 per year. From 1987–2007, ATSDR received more than 750 petitions. Approximately 60 percent of these were accepted and addressed by ATSDR and its cooperative agreement partners.

Q7b. Has the Agency begun to investigate additional pathways of exposure?

A7b. Although Love Canal and other hazardous waste sites were the focus when CERCLA was enacted and ATSDR created, ATSDR authority under CERCLA is not limited to hazardous waste sites—it extends to hazardous substance "releases." This can include multiple ways people are exposed to chemicals. Examples of the breadth of ATSDR's work include our emergency response program and our work with air releases from power plants and industrial facilities, such as those at the Mirant and Rubbertown sites.

Enormous progress has been made in addressing threats from hazardous waste sites. In addition, emerging science has provided greater insights into how people are exposed to chemicals and what chemicals are in people's bodies. It is clear that many human exposures to chemicals are not from waste sites. As a result, we recognize the importance of investigating sources and pathways of exposure beyond hazardous waste sites.

In evaluating the health impacts of chemical exposures from a broader range of sources, we are cognizant of the possibility of duplication of effort with other agencies. This is part of the motivation for our National Conversation on Public Health and Chemical Exposures. Over a year into planning, this process involves a broad cross-section of stakeholders, including environmental groups, communities, professional groups, public health groups, industry, and other agencies, to assess our work to date, in the broader context of cross-government efforts to address chemical hazards and to make recommendations for involvement. These may involve substantial changes in how ATSDR does its work. This effort will identify gaps in, and emerging priorities for, the public health approach to chemical exposures and identify solutions that strengthen public health.

Q7c. How has this impacted the Agency?

A7c. ATSDR has done limited work with exposures to hazardous substances not related to hazardous waste sites, such as naturally-occurring asbestos, air emissions from power plants and industrial facilities, and uranium in water. The National

Conversation on Public Health and Chemical exposures will help inform development of approaches to addressing potential health impacts of other sources and pathways of exposure.

Q7d. How has the Agency adapted its communications strategy to meet these changes?

A7d. We have and will continue to communicate effectively with the communities we serve. Through openness, cultural competency, and careful needs assessment, we actively engage communities through our site work. Our Community Involvement Branch includes communication specialists, health educators, and other professionals with extensive experience in this area. These professionals, like others at the Agency, stay abreast of developments in the field and incorporate them into our work.

Q8. The ability to determine causation is complex and analysis of health risk levels vary based on numerous factors.

A8. Communities often expect that an agency such as ATSDR will arrive on the scene, rapidly assess the situation, and reach unequivocal conclusions. Unfortunately, it is not always possible to reach such conclusions. Definitive answers sometimes do not exist, due to the inherent uncertainties of science. Available data—both environmental and health outcome data—are often limited. Small area epidemiology lacks the statistical power to draw definitive conclusions. Finally, the public health field often lacks the appropriate tools to allow us to establish causation.

Despite limitations, ATSDR has identified a public health hazard in approximately 30 percent of cases. In approximately 40 percent of cases, available data suggest little or no risk, and, in approximately 30 percent of cases, available data do not permit a conclusion. In addition, our documents include specific recommendations and follow-up actions to be taken by agencies with appropriate jurisdiction. More than 70 percent of these are implemented.

It is possible to draw certain negative conclusions with confidence. For example, with sufficient information we may positively conclude that contamination from an identified source is not reaching a community. However, positive conclusions are harder to reach. For example, even when we identify a complete pathway and document exposure, we cannot always establish a causal link between the exposure and disease in the community. In many cases, it is impossible to draw firm conclusions.

Q8a. How does the Agency communicate the limitation of their products and findings?

A8a. ATSDR communicates these limits both in person and in writing. For example, Community Involvement and Health Education Specialists, through public meetings, public availability/poster sessions and other community meeting formats, communicate with stakeholders throughout the process. Through early and ongoing communication, ATSDR provides information on public health implications, risk, and limitations of our work in qualitative terms. The information includes how we will be:

- reviewing environmental data (to include environmental or health data limitations and data gaps),
- gathering community concerns,
- identifying ways people might come in contact with chemicals,
- determining if people are being exposed,
- determining how that exposure might affect public health,
- providing conclusions and recommendations,
- preparing a public health action plan, and
- communicating community involvement activities.

In summary, we want communities to know what to expect, including the difficulty in coming up with a causal link between exposure and disease. For example, we communicate "risks" instead of "cause."

In addition, ATSDR has recently revised its public health hazard conclusion categories to more clearly describe, using plain language, the potential risks from eating, touching and breathing unsafe chemicals. Our revised hazard conclusion categories will be placed at the front our documents so that the community is immediately aware of our public health messages and other issues about the site.

Q8b. To what extent do you attribute criticism of agency products to poor communication?

A8b. We attempt to minimize the potential for poor communication. Communicating information is fundamental to ATSDR's Public Health Assessment process, and we work very hard at it. ATSDR has extensive experience and great expertise in communicating with the public. However, we recognize that there are always opportunities to do better.

Sometimes, however, community members, who are justifiably concerned about exposures to hazardous substances, may reject the concept of "levels of risk" when what they want is zero exposure. Despite our early and active engagement with communities and our scientific attempts to address their concerns, there will always be expectations which we cannot meet. In the case of Illinois Beach State Park, several individuals remain convinced that dangerous exposures are occurring, despite four rounds of extensive air sampling over the last decade using highly reliable methods that reached the opposite conclusion. In stressful situations, research shows that many people have difficulty processing information and give greater weight to negative information. By pulling from this research, we can better guide our communication efforts.

Q8c. Do you have any suggestions on how to better communicate the limitations?

A8c. As I said in my testimony, even excellent people and organizations can always improve. ATSDR is continuing to take steps to improve our ability to communicate complex scientific information to communities, including:

- Continue fine-tuning our community involvement process; focusing our site teams on the skills needed to effectively interact with communities, including preparing and presenting information to stakeholders, and including them in the decision-making processes.
- Continue initiating contact before the health assessment process begins and listen to community concerns, obtain critical information, and assess needs, and increasing our on-site community-level environmental health literacy education efforts.
- Continue incorporating community outreach activities as a standard component of the ATSDR Public Health Assessment and Health Studies activities.
- Continue developing and incorporating community health education activities along with our community outreach activities.
- Implement the new language and format of our public health hazard conclusion categories so that our health messages are clearer and easier to understand.
- Continue to use PHCs, LPHCs, and TAs to respond to stakeholder environmental health concerns in a timely manner.

Our goal is to include the community in the public health activities at the beginning and during the health assessment to ensure they are provided current, ongoing, and relevant information throughout the process and have the opportunity to provide input.

Q9. Do you believe ATSDR attempts to include revolutionary scientific methods and techniques in their work?

A9. ATSDR pays close attention to emerging scientific methods, and uses them when appropriate. We recognize the need to balance the use of new methods with the use of validated and widely accepted techniques. For example, when we investigated polycythemia vera (PV) in Pennsylvania, as public health scientists, we knew that most cluster investigations do not identify environmental causes, and are cautious and deliberate about such investigations. ATSDR focused initially on verifying and quantifying the excess cases of disease, sought outside hematologic expertise, and remained open minded about a possible environmental etiology. The hematology expert had identified a genetic mutation called JAK2 found to occur in most PV patients. This revolutionary discovery has now led scientists to search for the cause of the JAK2 mutation in hopes that this knowledge will help them find the cause of PV. Using this genetic marker, ATSDR scientists confirmed 38 cases of PV. ATSDR will further evaluate the spatial distribution of cases and review available environmental data. ATSDR plans to conduct further scientific research to determine the cause of the PV.

Ultimately, the decision of when to use new methods is a scientific judgment and a decision best made in consultation with a broad range of scientific experts. Through expert panels and peer review, ATSDR engages independent scientists and scientists from other agencies and institutions in its decision-making process.

When ATSDR develops new methods, we report those methods through peer-reviewed, scientific journals.

Q9a. How can the Agency better integrate cutting-edge science?

A9a. The methods ATSDR uses to integrate new technologies with existing science work very well. For example, we have re-trained scientists to apply new methods. We have a dedicated GIS unit and a dose reconstruction lab. ATSDR scientists have developed innovative techniques of computational toxicology to help rapidly assess hazards of chemical releases. ATSDR also provides training to State and local partners to assist them in incorporating new methods into their health assessment work.

In addition, ATSDR scientists continuously monitor scientific literature and attend professional meetings to increase their awareness of new techniques and how to apply them to their work at sites. We use peer review to ensure that these methods are the best available for assessing exposures and protecting public health.

ATSDR's external Board of Scientific Counselors evaluated our site assessment and our peer review procedures. While providing us with a number of constructive recommendations, their report highlights the soundness of our approach in incorporating both public and expert scientific input.

ATSDR also works closely with NIH and other science-based agencies and organizations to keep abreast of new and innovative technologies, methods, and techniques.

Q9b. Is there any risk to getting too far ahead of a technology or method and coming to conclusions that are ultimately proven to be unfounded?

A9b. There is a risk to getting too far ahead of a technology or method. However, we do not shy away from using cutting-edge science. Before cutting-edge techniques or methods are applied to a public health problem, those approaches are peer-reviewed as are the developed products (be they Public Health Assessments, health studies, toxicological profiles, etc.). Our primary objective is to protect public health and we maintain that objective throughout the health assessment process.

Q9c. How would you set up policies or procedures to appropriately manage and utilize these innovations?

A9c. The decision to use new methods requires scientific judgment. These decisions are best made in consultation with scientific experts, both internally and externally. Through the use of expert panels and peer reviews, ATSDR calls upon the expertise of independent scientists and scientists from other agencies to inform our decision-making process.

When ATSDR develops new methods, we report those methods through peer-reviewed, scientific journals.

We clearly identify limitations in methods, data analyses, and conclusions in our products, as is standard in scientific documents. We have peer review policies and procedures in place to triage documents when new or controversial science is applied. Additionally, our Board of Scientific Counselors has reviewed clearance procedures and receives programmatic reviews and updates and provides guidance on our scientific approaches and programs.

Q10. How does ATSDR compare with similar entities in other countries?

A10. Most countries do not have any agency similar to ATSDR, nor do they have programs as comprehensive as those administered by the Environmental Protection Agency (EPA) to regulate and remediate chemical releases. Each year ATSDR receives requests from the governments of other countries to send their scientists, physicians, epidemiologists, and engineers to Atlanta for special training on conducting public health assessments. For example, the French government does not have an agency comparable to ATSDR;, they have sought ATSDR staff to teach in French public health agencies, and have sent public health scientists to train with ATSDR. In addition, the Pan American Health Organization (PAHO) has translated our public health assessment manual into Spanish for use by public health officials in Latin America.

Q10a. Do international public health agencies have similar problems?

A10a. The World Health Organization (WHO) has limited capabilities in the core areas of ATSDR's work. Addressing health issues related to environmental exposures to hazardous substances often is left to the independent countries to address. The Basel Convention addressed the trans-boundary shipment of hazardous waste, but did not include any health-related discussion.

ATSDR is seen as the world leader in addressing public health concerns related to exposures to hazardous waste.

Q10b. What do you attribute this to?

A10b. Even though hazardous wastes have been a concern for many years, the investment of resources to address public health issues resulting from these exposures has been limited. More investment must be made to improve the science and the methods that public health officials use to evaluate exposures and to educate and assist communities with environmental health concerns.

Q11. ATSDR does not do large scale environmental sampling, and relies upon the EPA and states to conduct this work.

Q11a. Do you believe ATSDR should also be doing this work?

A11a. Many times, environmental data already exist, based on regulatory requirements. However, to answer important exposure questions, ATSDR scientists often need data that do not exist. These are needed to fill gaps between existing sets of data or to provide site-specific information related to exposures and health.

In limited cases, ATSDR does conduct environmental or biological sampling, although these efforts can be tremendously expensive and time-consuming. ATSDR can only conduct a few large-scale sampling projects each year. This leaves ATSDR with the difficult trade-off between conducting more extensive sampling at fewer sites, and responding to concerns at a greater number of sites.

To make the best use of limited resources, ATSDR generally works in partnership with other agencies when large scale environmental sampling is needed. These agencies often have the regulatory authority to conduct environmental monitoring and sampling, as well as the technical expertise and resources. As noted earlier, ATSDR often is called on to provide technical assistance in development of sampling plans to ensure sampling is conducted in a way that maximizes the usefulness of data for assessing exposures. And, ATSDR often assists in evaluating data, applying its expertise in the health effects of potential exposures.

There are also creative solutions to this dilemma. For example, environmental sampling is useful, but, in some cases, it can be replaced by biomonitoring. In the case of 1,4 Dioxane, ATSDR used existing NCEH biomonitoring data to determine that there were no detectable levels in the people sampled. This was an economical solution that allowed us to use our resources to respond to other exposures.

Q11b. How would you suggest we pay for this work?

A11b. ATSDR does not have the resources to conduct large-scale research—either to develop environmental or biological sampling data to assess exposures or to investigate the toxicological properties of a hazardous substance. The Agency identifies data needs, seeks out existing data to fill those needs, and works in partnership with other agencies, at the federal, State, and local levels, as well as with academic institutions and private entities, to develop data to meet needs where sufficient data do not currently exist.

Q11c. Would this be worth limiting the number of other studies, assessments, or consultations the Agency initiated?

A11c. Limiting the number of sites in order to free up resources to conduct original sampling would diminish ATSDR's capacity for responding to community concerns and frustrate communities seeking answers to important health concerns. Already ATSDR does only a small number of health studies, which are far more resource intensive than other approaches.

Sites under consideration for Public Health Assessments, Health Consultations, Exposure Investigations and Technical Assists come to ATSDR through the Superfund process, from direct requests from other federal agencies (EPA, DOE, DOD, etc.), and from requests from concerned community members. ATSDR reviews each site and prioritizes according to need and available resources; however, we strongly believe that it is important to remain responsive to communities, to work with them to address health concerns, and to engage at sites as needed.

Q12. What role should ATSDR play in exposure routes not associated with hazardous wastes (such as food, consumer products, water, and air)?

a. How does the Agency intend to address these issues?

b. Is there any overlap with other agencies?

c. What does the Agency do when there is duplication of effort?

A12. ATSDR helps protect the public from exposures to hazardous substances from releases at hazardous waste sites and at a variety of other settings. These releases may range from chemical plant explosions to a spill of coal combustion products. They can be those identified by government agencies or by individuals within the community through the petition process.

A series of environmental laws in the 1970s and 1980s defined the U.S. approach to chemical exposure risks. A mosaic of agencies and organizations, governmental and nongovernmental, regulatory and non-regulatory, carry out various public health functions. As a result, some key responsibilities may not be carried out adequately, and others may be redundant. ATSDR's mission and functions must be considered within this broader context.

In recognition of these realities, ATSDR and its companion Center at the CDC, the National Center for Environmental Health (NCEH), have initiated the *National Conversation on Public Health and Chemical Exposures*. This process is designed to identify gaps in, and emerging priorities for, the public health approach to chemical exposures and identify science-based solutions that strengthen public health. This will build on ATSDR's strong working relationships with a broad range of stakeholders, and further help us to use resources responsibly, avoid redundancy, and eliminate gaps in public health coverage.

Public health functions related to chemical exposures include exposure and health surveillance, investigation of incidents and releases, emergency preparedness and response, regulation, research, and education. When our efforts overlap, we work closely with other agencies by sharing data and expertise to recognize and mitigate community exposures and protect public health. For example, ATSDR responds to emergencies involving the release of chemicals, most often in collaboration with the Environmental Protection Agency. ATSDR personnel provide real-time public health guidance following acute releases of hazardous substances and health information to the public (for example, helping determine when people can safely reoccupy their homes and businesses after an evacuation).

ATSDR also works with other partner agencies to provide advice and guidance on topics such as exposure routes, toxicology, data sampling, data collection, epidemiology, and data analysis. We collaborate with the Food and Drug Administration and U.S. Department of Agriculture on issues pertaining to food, with the Environmental Protection Agency and U.S. Geological Survey on air and water concerns, and with the Consumer Product Safety Commission when product safety is in question. We may evaluate data collected by these other agencies for health implications, while our partner agencies may examine other aspects, such as environmental or regulatory implications.

Q13. How does ATSDR's level of competence compare to other federal and State entities charged with protecting public health?

A13. ATSDR is a non-regulatory environmental public health agency. We are community-oriented, working to respond to local concerns. We operate by bridging the work of other agencies, and between federal agencies and states. We are a specialized agency, and, in the areas in which we specialize, we are very good.

However, we are a small agency, lacking the depth and breadth in some areas that would enable us to more fully fulfill our mission. With only 300 employees, we lack adequate capacity in certain important fields, such as veterinary epidemiology, industrial hygiene, and air quality modeling. To address these challenges, we work closely with other federal and State agencies. To help devise a long-term solution, we have initiated our National Conversation to identify gaps in, and emerging priorities for, the public health approach to chemical exposures, and to identify science-based solutions that strengthen public health.

Q13a. Would you characterize the work ATSDR does as a specialized niche?

A13a. Several agencies (including NIH's National Institute of Environmental Health Sciences and EPA, in addition to ATSDR) share responsibility for assessing the human health effects from exposure to environmental contaminants. ATSDR does have a specialized niche in assessing exposures to hazardous waste. CERCLA specifically established ATSDR for this purpose. ATSDR has pioneered the public availability session and remains an authority on public interaction with communities potentially impacted by hazardous waste sites. ATSDR is a world leader in providing toxicological profiles of specific toxic substances. ATSDR's toxicological profiles are frequently used and held in very high regard, domestically as well as internationally.

Q13b. Do any other agencies perform this same work?

A13b. ATSDR's work complements that of NIEHS, EPA, the National Toxicology Program (NTP), NIOSH, OSHA, FDA, and Consumer Product Safety Commission (CPSC). These agencies, along with other agencies and organizations, governmental and non-governmental, regulatory and nonregulatory, carry out various public health functions related to chemical exposures. These functions include exposure and health surveillance, investigation of incidents and releases, emergency pre-

paredness and response, research, and education. NCEH/ATSDR plays a significant role in carrying out several of these key public health functions.

Q14. In your testimony, you describe one of the problems ATSDR faces is the difficulty ATSDR sometimes faces when a community refuses to believe your conclusions. Specifically, you mention that ATSDR and counterpart site agencies have had to repeat investigations several times at the same location which end up yielding the same conclusions as the original investigation. This does not seem like the most efficient use of resources. What can be done to ensure that communities who have genuine problems have access to the resources ATSDR can provide?

A14. ATSDR does, from time to time, revisit a site. In some instances this may be considered inefficient, but we consider it to be prudent, as our work is a mixture of community service and the best science. If new data are available, new scientific methods emerge, or community concerns persist, this may justify returning to conduct additional work at a site.

For example, in the case of Illinois Beach State Park, continuing questions illustrated a need for additional information. New sampling techniques provided a greater level of confidence in the results. Even there, a small number of community members were not convinced. However, through the cooperation with other federal and State agencies, we provided the community with scientifically rigorous health guidance. On the other hand, after careful review of new research related to the Colonie, New York, site, since the hazard has long ago been removed, among other reasons, ATSDR concluded that a community study would be unlikely to have scientific yield or public health benefit.

Q15. In your written statement, you mention the challenges related to the research capacity at ATSDR. Given the workload and the statutory authorities given to ATSDR, would you consider research to be a primary goal for this organization? Would it not make more sense that you identify gaps in scientific knowledge through your public health assessments and leave it to another, more-equipped agency or organization to undertake the research required to fill those holes?

A15. ATSDR is charged under CERCLA with expanding the knowledge base about health effects from exposure to hazardous substances.

Research on the human health effects of environmental exposure to hazardous substances is conducted by a number of federal agencies, including the NIEHS, NCEH, EPA, and ATSDR. ATSDR carries out its research responsibilities through a number of mechanisms. The Agency takes steps to initiate needed research. For example, ATSDR identifies important data gaps and takes steps to fill those gaps, such as through petitions to the National Toxicology Program to conduct research on particular exposures (i.e., naturally occurring asbestos). ATSDR also funds a longstanding program through the Association of Minority Health Professions Schools (AMHPS) to conduct needed research, while supporting the training of minority professionals in toxicology.

ATSDR has a distinct role in applied public health research, arising from the Agency's site-specific work. Examples of ATSDR's work in applied public health research include the development of innovative modeling techniques at Camp Lejeune in North Carolina, investigation of community exposures to TDI (toluene diisocyanate) in North Carolina, research on a possible environmental component of polycythemia vera in Pennsylvania, and research into beryllium disease in community settings in Ohio.

This research flows from our field work. We definitely have a research role, but we need to be strategic. In some cases, it is better for us to leave research to others; in other cases, it is important that ATSDR do the research, based on the unique expertise and experience of its workforce.

Questions submitted by Representative Steve Rothman

Q1. ATSDR seems to say to the people of Vieques Island, "Nevermind. Nothing to worry about here."

A1. This is not an accurate characterization of ATSDR's approach to the people of Vieques. Over the last decade ATSDR's work in Vieques has been extensive, careful, and responsive. This work included:

- A series of Public Health Assessments (PHAs) to investigate environmental contamination on the island and possible pathways by which people might be exposed to those contaminants.

- Training and materials for health care providers and educators so that accurate environmental health information was available to the community.
- Extensive consultation with the community, before, during, and after its investigations, to hear public concerns and to incorporate them into its work.

ATSDR's work on the island included four PHAs, each investigating a different potential pathway of exposure to dangerous chemicals: groundwater and drinking water (2001), soil (2003), fish and shellfish (2003), and air (2003). In addition, we convened two expert panels, one to evaluate the accuracy and reliability of hair testing, and one to assess environmental risk factors for heart disease.

Throughout the course of our work in Vieques, we encouraged community participation, provided educational material, and held meetings to explain both our findings and the methods used to reach our conclusions. We solicited public comments on each of our Public Health Assessments and addressed those comments in our final documents. We met with members of the community, both individually and in public forums, to discuss the findings. We worked through health care providers and educators on the island to make educational material available to residents. This is a record of Agency action that reflects sincere concern for, and accountability to, the people we serve.

ATSDR continues to be dedicated to the health of the people of Vieques. We have committed to re-engaging in Vieques, to assessing new or persistent health concerns, to analyzing any new data, and to reassessing our conclusions as appropriate.

Q1a. Why is it that independent scientists can find troubling evidence of potential public health issues that ATSDR is unable to find?

A1a. ATSDR is not aware of any published peer-reviewed scientific studies that have documented human exposure to hazardous chemicals on Vieques at levels of health concern.

There is evidence of environmental contamination on Vieques. We are aware of some credible, though unpublished, measurements of chemicals in grass, in non-edible plant species near the live impact area (LIA) at the eastern end of the island, and in non-edible animals, as well as studies of how plants may take up metals. These data suggest that some plants near the LIA and some non-edible marine species contain contaminants—results that correspond to ATSDR's own findings. However, this contamination was some miles from where people live on the island. Moreover, detailed assessment did not identify specific pathways—say, eating, drinking, or breathing—by which people might absorb these contaminants. At the time of our assessments, neither the food people were eating, nor the water they were drinking, nor the air they were breathing, nor the soil they were touching, contained contaminants at levels associated with health problems. Even if contaminants are present in the environment, if they do not reach people's bodies, then human health effects are not expected.

The Environmental Protection Agency (EPA), National Oceanic and Atmospheric Administration (NOAA) and others continue to characterize the nature and extent of the contamination associated with past Department of Defense (DOD) activities on the island. Based on this work, we are currently considering whether new data warrant additional activities to assess potential exposures that might impact the health of the people of Vieques.

Q2. Are you aware of the scientific studies done on the island of Vieques questioning the ATSDR's public health assessments?

A2. Through media reports, we are aware of several studies of environmental contamination and health on Vieques. ATSDR has requested the environmental studies for review, but was informed that they had not been published and were unavailable. ATSDR also followed up on reports of a study of cancer mortality on Vieques; however, this report has also not yet been published. ATSDR is assessing the quality and availability of cancer registry data in Puerto Rico, including Vieques—previously unsatisfactory but now said to be much improved—to determine if the registry can be used to study cancer rates on Vieques.

Q3. Are you aware of the hair testing of the people of Vieques themselves, provided to the U.S. Navy, showing extremely high levels of mercury, lead, cadmium, arsenic and aluminum?

A3. ATSDR is aware of the human hair analysis, which indicated elevated levels of mercury (and antimony in one individual). Hair analysis is a controversial method in environmental health, and one that can be subject to variability and inaccuracy. To assess the Vieques findings, ATSDR convened an independent expert panel to evaluate the science of hair analysis. This is an example of ATSDR's willingness

to carefully evaluate whether emerging or novel scientific methods might assist in our assessments. In this case the expert panel concluded that the hair analysis was likely to be unreliable. ATSDR offered to follow up with a broader, biological exposure investigation, of which human hair analysis would be a part, in addition to other specimens; however, the community opted not to participate at that time.

ATSDR was also made aware of results of animal hair testing from the Puerto Rico Department of Agriculture in cooperation with the Farmers Association of Puerto Rico. These groups concluded that agricultural products from Vieques were suitable for consumption and did not contain toxic levels of these contaminants.

Q4. How do you evaluate the public health exposures of dangerous contaminants at specific sites?

A4. We assess whether chemicals released into the environment are reaching people by empirically evaluating the specific pathways that might operate: eating, drinking, touching, or inhaling the chemicals. If there is a "completed pathway"—evidence that chemicals are reaching people—we then determine quantitatively whether the exposure levels are associated with adverse health effects, by turning to toxicological, epidemiological, and medical studies in the literature.

Q4a. How do you know what to test for?

A4a. Two main sources guided our sampling efforts: in-house expertise related to chemicals present in explosive residue; and Department of Defense (DOD) data regarding the composition of the bombs. The Environmental Protection Agency (EPA) has an oversight role in working with DOD to determine adequate characterization of the nature and extent of contaminants. In addition to reviewing sampling data from other agencies, ATSDR sampled for bomb-related metals and explosive residues.

Q4b. Did the U.S. Navy provide ATSDR with a list of all the chemicals used at its Roosevelt Roads Naval Station on Vieques or found in its munitions which have leached chemicals onto the island and into the sea as a result of ordnance exercises at the Vieques Naval Training Range for over 69 years?

A4b. Yes, the Navy provided ATSDR with a list of chemicals found in its munitions; however, we cannot know with certainty whether the list of chemicals provided by the Navy was complete.

Q4c. Did the U.S. Navy provide information to ATSDR about the amount of depleted uranium, or napalm or Agent Orange or dioxins or other potentially toxic chemicals it used on Vieques?

A4c. The Navy provided ATSDR with this information. The information the Navy provided indicated that:

- Two Marine aircraft fired 263 rounds of ammunition armed with depleted uranium (DU) penetrator projectiles on the LIA in February 1999.
- The Nuclear Regulatory Commission (NRC) conducted an environmental survey on Vieques in June 2000.
- More than 70 percent of the DU rounds have been located and the locations have been marked.
- NRC reported that a recent survey found no additional depleted uranium.

Q4d. Wouldn't you agree that the party who is in the best position to know exactly what toxics and chemicals were used on Vieques is the U.S. Navy? If so, did ATSDR ever demand the kind of relevant information I've mentioned here, so that the people of Vieques and those of us who are concerned about their health might know what they have really been facing in terms of harmful exposure to all these toxic chemicals?

A4d. The Navy has extensive information on environmental contaminants in Vieques, and ATSDR must rely on the Navy data in its assessments. This not unusual; we often have to rely on data from others. In the case of Vieques, ATSDR asked for and received data from the Navy. ATSDR has also received information from NRC on depleted uranium, from the U.S. Fish and Wildlife Service (FWS) and NOAA on aquatic life, and from EPA on various environmental media.

Q5. Do you stand by your agency's assessment that Vieques is a perfectly safe environment?

A5. No ATSDR document says that the environmental is perfectly safe. However, each of our Public Health Assessments on specific pathways is based on solid analysis and we stand by these documents. According to the data we have reviewed, as

long as people do not enter restricted areas, including the LIA and nearby waters, they are safe from contaminant exposure and from the physical injury risk associated with unexploded ordnance.

Q6. Would you feel comfortable raising your family in a similar environment?

A6. The data we have reviewed have revealed nothing that would prevent me from raising my family on Vieques. However, I would keep my family out of the restricted, unremediated areas in the LIA.

Q7. What do you think ATSDR could have done differently to improve the public health assessments performed on Vieques?

A7. Vieques is one of ATSDR's most comprehensive investigations. It included four Public Health Assessments, in addition to other work. The Vieques investigation included assessments of the air pathway, soil pathway, water pathway, seafood pathway, hazards associated with vibrations, and numerous review panels to evaluate unpublished data collected by others. ATSDR provided numerous health education, physician education, and school-based environmental health education resources and training to help the community gain the knowledge to identify hazards, protect themselves from the hazards, and notify authorities about the hazards.

EPA and other agencies are engaged in an environmental clean up and additional sampling, and ATSDR remains available to review their data as necessary.

As discussed above, ATSDR's focus was on assessing exposures rather than health outcomes. Some may suggest that we should have done a health outcome study during our work on Vieques. Typically, ATSDR does not investigate health outcomes unless exposures are documented. This is to focus ATSDR's limited resources in communities where exposures are found.

ATSDR was—and is—interested in learning more about health statistics on Vieques, especially if there is strong local support for such an inquiry. At the time of our work on Vieques, cancer registry data were not considered adequate to support rigorous analysis. Since ATSDR's work, the Puerto Rico cancer registry has made significant progress. We may consider using these data to address the concern about the cancer rate on Vieques.

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