PREVENTING HARM – PROTECTING HEALTH: REFORMING CDC'S ENVIRONMENTAL PUBLIC HEALTH PRACTICES

HEARING

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

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PREVENTING HARM – PROTECTING HEALTH: REFORMING CDC'S ENVIRONMENTAL PUBLIC HEALTH PRACTICES

THURSDAY, MAY 20, 2010

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

The Subcommittee met, pursuant to call, at 9:03 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Brad Miller [Chairman of the Subcommittee] presiding.

Subcommittee on Investigations and Oversight

Hearing on

Preventing Harm – Protecting Health: Reforming CDC's Environmental Public Health Practices

Thursday, May 20, 2010
9 a.m. – 11:00 a.m.
2318 Rayburn House Office Building

Witness List:

Panel I

Ms. Cynthia A. Bascetta
Director
Public Health and Medical Services, Government Accountability Office (GAO)

Mr. Stephen Lester
Science Director
Center for Health, Environment & Justice (CHEJ)

Dr. John P. Wargo
Professor of Environmental Risk Analysis and Policy
Yale University

Dr. Marc Edwards
Charles P. Lunsford Professor
Department of Civil and Environmental Engineering, Virginia Polytechnic Institute and State University, Blacksburg, Virginia

Panel II

Dr. Robin M. Ikeda, MD, MPH
Deputy Director
Office of Noncommunicable Diseases, Injury and Environmental Health and Acting Director for the National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC)

HEARING CHARTER

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

Preventing Harm – Protecting Health: Reforming CDC's Environmental Public Health Practices

THURSDAY, MAY 20, 2010
9:00 A.M. TO 11:00 A.M.
2318 RAYBURN HOUSE OFFICE BUILDING

The Investigations and Oversight Subcommittee of the House Committee on Science and Technology will convene a hearing at 9:00 a.m. on Thursday, May 20, 2010, to examine the policies and procedures used by the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) of the Centers of Disease Control (CDC) to assess, validate and release public health documents and to detail specific instances where these offices have relied upon flawed science and incomplete data to draw critical public health conclusions. Resolving these policy and procedural issues within ATSDR and ensuring that the CDC's public health documents in general rely upon sound scientific data to reach public health conclusions is essential to ensuring the health and safety of the public. The purpose of this hearing is to help lay down a new road map for CDC in helping to reform its environmental public health practices, largely carried out by NCEH/ATSDR.

The Subcommittee plans to release two new reports at this hearing, one prepared by the Government Accountability Office (GAO) regarding ATSDR's clearance policies and procedures regarding release of its public health documents and a Subcommittee staff report on how the CDC responded to the District of Columbia's 2003/2004 lead-in-water crisis. This will be the Subcommittee's third hearing regarding ATSDR's public health practices in the past two years.[1] The hearing will also provide an opportunity for Members to question CDC regarding commitments made at the Subcommittee's last hearing to re-examine ATSDR's passed public health investigations on the island of Vieques in Puerto Rico, for instance, and to re-visit the agency's assessment of public health hazards in Midlothian, Texas.

GAO Review & Recommendations Regarding ATSDR Clearance Policies

Ms. Cynthia Bascetta, the Director of Health Care Issues at the GAO is responsible for leading reviews of programs designed to protect and enhance public health. She will provide testimony regarding the GAO's recent investigation of ATSDR's clearance policies. The GAO report based on her team's investigation concludes that the policies and procedures that ATSDR has established for preparing and releasing its public health documents lack "critical controls to provide reasonable assurance of product quality." Further, GAO finds that the roles and responsibilities of the agency's management regarding the development of ATSDR's products, their oversight and eventual clearance are not well defined. The agency also lacks a com-

[1] In April 2008, the Subcommittee held a hearing on a flawed public health consultation written by ATSDR for the Federal Emergency Management Agency (FEMA) that addressed human health issues regarding exposures to formaldehyde in toxic trailers that were provided to victims of Hurricanes Katrina and Rita. That hearing also examined retaliation by ATSDR's leadership against Dr. Chris De Rosa, then the agency's chief toxicologist, for concerns he raised with both the quality of this report and public health concerns he had with these trailers. Links to witness statements and other material from this hearing are available here: *http://www.science.house.gov/publications/hearings_markups_details.aspx?NewsID=2133*. Last year the Subcommittee held another hearing on specific investigations by ATSDR that were criticized by outside scientists and local communities they affected as being woefully inadequate, based upon faulty scientific data or omitting critical information. Links to this hearing's material are available here: *http://science.house.gov/publications/hearings_markups_details.aspx?NewsID=2376*.

prehensive risk assessment process for evaluating priorities regarding its development, review and release of public health documents.

The lack of policies and procedures guarantees that ATSDR's products will be of variable quality. Further, problems with the clearance and review of critical public health documents has been exacerbated since 2007 when ATSDR took its database tracking system called the Hazardous Substance Release and Health Effects Database or HazDat off line. According to ATSDR, the database "contained scientific and administrative information on the release of hazardous substances from Superfund sites or from emergency events and on the effects of hazardous substances on the health of human populations."[2] To replace the HazDat database ATSDR designed a database called Sequoia intended to track requests, exposure data, work flow for site-specific products, and to improve the flow of information about newly initiated work between management and staff. But ATSDR officials told GAO that it is still unclear if the agency will need additional database systems to provide them with all the information they need to effectively manage the agency's activities.[3] In addition, the Sequoia database is not yet fully operational.

The result of having unclear policies and procedures combined with the lack of an information infrastructure that can help assess critical toxic exposure data, track specific public health investigations, or coordinate and synchronize management and staff assessments of potential human health hazards due to toxic exposures is a haphazard, ad hoc review of the agency's public health reports prior to their release. In fact, critical determinations regarding whether or not an ATSDR public health assessment or health consultation should be submitted for external peer review, the GAO found, are left largely to the discretion of the agency's management and staff. In addition, ATSDR's leadership has repeatedly argued that the vast bulk of the agency's products, including public health consultations and public health assessments are exempt from peer review.

The 1986 Superfund Amendments and Reauthorization Act (SARA), which amended the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), *did* exempt ATSDR's public health assessments from mandatory peer review.[4] Congress has never revised that exemption and this language has repeatedly been cited by ATSDR leaders as the reason they do not subject their public health assessments to a scientifically credible and rigorous peer review process. The SARA amendment, however, never forbid or banned ATSDR from conducting peer review of its public health assessments. The agency simply chooses not to submit the vast majority of its public health documents for any sort of external peer review.

ATSDR does claim that its scientific "studies" are subjected to peer review.[5] However, the agency argues that public health consultations—the main product coming out of the agency—are not scientific studies and therefore not required to go through the peer review process. As a result of these attitudes by management, GAO found a vanishing small number of ATSDR products in 2008 underwent peer review. GAO's review shows that only 2 of the 282 public health assessments and health consultations ATSDR published in FY2008 underwent external peer review. In 1991, nearly twenty years ago, GAO recommended that at least a sample of future ATSDR public health assessments undergo external peer review. However, GAO's most recent review in 2010 found that "ATSDR does not currently have such a policy and instead relies on management and staff discretion to determine which public health assessments should be submitted for external peer review." According to GAO, 80-percent of non-management ATSDR staff believe that external peer review would be beneficial in ensuring the quality of ATSDR public health products.

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[2] "Hazardous Substance Release and Health Effects Database," Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, available here: *www.atsdr.cdc.gov/hazdat.html*.

[3] "Agency for Toxic Substances and Disease Registry: Policies and Procedures for Public Health Product Preparation Should Be Strengthened," Government Accountability Office, GAO–10–449, April (ck) 2010.

[4] "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*. The new law also set an arbitrary deadline of December 1988 for the poorly funded and poorly staffed agency to conduct public health assessments at an astounding 951 Superfund sites. In order to accomplish a quantitative victory by conducting these assessments at so many sites in so little time the quality of the reports, exempted from peer review, suffered as a result.

[5] See Appendix C, "ATSDR Peer Review Policy," Revised: March 1, 1996, on pages 22–27 in: "Public Health Response Plan: Midlothian, Texas, Public Comment Release, January 21, 2010, prepared by The Agency for Toxic Substances and Disease Registry and the Texas Department of State Health Services, available here: *www.atsdr.cdc.gov/sites/midlothian/docs/Midlothian_Public_Comment%201_25_10.pdf*.

The Subcommittee DC/CDC Lead Staff Report

These sorts of systemic failures that fail to appropriately design public health studies, fail to adequately validate public health data, or fail to sufficiently examine public health conclusions can result in flawed, incomplete or scientifically unsound public health recommendations and conclusions that may result in serious public health consequences. A key example of the impact these systemic problems can have is documented in a Subcommittee staff report on the investigation into how the CDC responded to the Washington, D.C. lead-in-water crisis in 2004.

On Saturday, January 31, 2004, *The Washington Post* published a story that informed the public for the first time that water tests conducted the previous summer by the D.C. Water and Sewer Authority (WASA) showed that thousands of DC homes, two-thirds of those tested, had elevated lead levels in their tap water above the Environmental Protection Agency's (EPA) limit of 15 parts-per-billion (ppb).[6]

In mid-February 2004 the CDC responded to a request from the District of Columbia government to help evaluate potential human health affects of elevated lead levels in the city's drinking water. This assistance resulted in the publication of a CDC "Morbidity and Mortality Weekly Report" (MMWR) article, published on an "emergency basis" on March 30, 2004 that concluded: "The findings in this report indicate that although lead in tap water contributed to a small increase in BLLs [blood lead levels] in DC, no children were identified with BLLs >10μg/dL [10 micrograms of lead per deciliter of blood], even in homes with the highest water lead levels. In addition, the longitudinal surveillance data indicate a continued decline in the percentage of BLLs >10μg/dL."[7] The paper, and talking points prepared by the CDC's primary author of the MMWR, to respond to the public, press, congressional and other inquiries regarding the MMWR article reassured the public that there was no evidence of human health harm due to elevated lead levels in DC's water.

The MMWR included two distinct studies. One looked at 84,929 historical blood lead level (BLL) test results provided to the District of Columbia's Department of Health (DCDOH) between January 1998 and December 2003, primarily from commercial laboratories that conducted these tests for physicians' offices, health clinics and hospitals. According to the MMWR this longitudinal analysis showed that between 1998 and 2000 the percentage of children with elevated BLLs decreased substantially, but that the decline for those living in homes with lead service pipes declined less dramatically from 2000 to 2003. This leveling off of the decline came just after WASA added chloramines to the drinking water supply.[8]

The Subcommittee's investigation, however, found that the number of children in the District of Columbia who had elevated blood lead levels (BLLs) in 2002 and 2003 is more than *three times* higher than the CDC reported either at the time of the crisis or since. Today, the CDC maintains that 315 DC children suffered from elevated blood lead levels in 2002 and 2003, yet the laboratories that conducted these tests informed the Subcommittee that in reality at least 949 DC children had elevated blood lead levels at the time. The DC government's own database now show that 963 children suffered from elevated blood lead levels in 2002 and 2003. By early 2004, the CDC was aware of critical data integrity issues regarding public health surveillance data it had on DC blood lead tests yet it failed to clearly address or thoroughly investigate these issues even as they relied on that data to construct the MMWR article.

The table below shows the break out of children with elevated lead levels as reported by the CDC, the District and through the Subcommittee's own efforts to work with health labs that analyzed District blood tests in 2002 and 2003.

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[6] 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.

[7] "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water—District of Columbia, 2004," *Morbidity and Mortality Weekly Report (MMWR)*, MMWR Dispatch, Vol. 53, March 30, 2004, available here: *http://www.cdc.gov/mmwr/pdf/wk/mm53d330.pdf.*

[8] "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water—District of Columbia, 2004," *Morbidity and Mortality Weekly Report (MMWR)*, MMWR Dispatch, Vol. 53, March 30, 2004, available here: *http://www.cdc.gov/mmwr/pdf/wk/mm53d330.pdf.*

- Table 1 -
Number of Individual DC Children Under Six Years Old with Elevated Blood Lead Levels in 2002 and 2003

YEAR	CDC[9]	DC DOH[10]	I&O Subcommittee[11]
2002	122	637	457
2003	193	326	492
TOTAL	315	963	949

[9] Cities and states that have cooperative agreements with the CDC and obtain CDC grant funds for their lead programs are required to provide CDC with their raw public health surveillance data regarding lead screening tests each year. Since 1992, the District of Columbia has received nearly $12 million in CDC lead grant funding. Once the CDC receives this raw surveillance data, which is supposed to include *all* blood lead tests performed that year, then CDC publishes a separate list based upon the number of children tested, not the number of tests conducted, on the CDC lead branch web-site. The incomplete raw surveillance data CDC received from DC regarding the city's 2003 blood lead tests in early 2004 were provided to the CDC for use in the March 2004 MMWR report. The numbers posted by CDC on its web-site in March 2005 regarding the number of individual children who had elevated blood lead tests in DC in 2003 was based on this incomplete and flawed data and remain there today, available here: *www.cdc.gov/nceh/lead/data/State_Confirmed_byYear_1997_to_2006.xls*.

[10] The District of Columbia government's numbers in this chart are based upon records provided by the DC government to the Subcommittee in summary forms called LeadTrax Management Reports. The DC government switched from a CDC developed database that tracked blood lead level test results called STELLAR in 2004. This database had many technical problems and management issues in the DC lead office contributed to a tremendous backlog of test data being entered into STELLAR. As a result the 2003 blood lead test data in STELLAR was woefully incomplete. When the DC government switched from STELLAR to a new database tracking system called LeadTrax that replaced STELLAR in April 2004 the DC lead program re-obtained 2002 and 2003 blood lead test data from the laboratories and re-loaded it into the new LeadTrax database. As a result, DC had much better, more complete and accurate 'historic' blood lead test data entered into LeadTrax by 2005. Somehow, either through miscommunication or misunderstandings between the DC lead branch and the CDC lead branch CDC never seems to have realized this critical fact and never attempted to obtain this new data to revise the original findings of the 2004 MMWR article.

[11] The Subcommittee obtained summary data of the number of individual children five years old or younger who had elevated blood lead levels above the CDC "level of concern" of >10µg/dL [10 micrograms of lead per deciliter of blood] in 2002 and 2003 that were reported to the DC Department of Health. The Subcommittee wrote to all seven laboratories providing blood lead test data to DC back in 2002 and 2003, so that we could compare the data CDC posted on its website with the data the labs reported to DC. Under the CDC's lead grants to the District, copies of the raw public health surveillance data regarding blood lead tests provided to the DC government from these laboratories was supposed to be provided to the CDC.

The MMWR report also included a separate study known as the "Cross-Sectional Study" that specifically targeted homes in DC with extraordinarily high water lead levels of 300-parts-per-billion (ppb) or above, and attempted to correlate those high levels of lead in water to the incidence of elevated BLLs among residents in those homes. The MMWR found that even in 98 DC homes with the highest levels of lead in their drinking water none of the 201 residents from these homes had elevated BLLs above the CDC's level of concern.

The Subcommittee found that many of the study participants did not drink the tap water at all therefore eliminating any potential health risks resulting from elevated blood lead levels. In fact, the majority of the participants in this study reported drinking bottled water, according to a spreadsheet containing raw data for this study. But this was never mentioned in the MMWR article. In addition, at least one child who was found to have an elevated blood lead level in a home with drastically elevated water lead levels was inexplicably dropped from the study altogether.

All of the federal and District agencies involved in this study, including the DC Department of Health, the CDC and the U.S. Public Health Service claim that they have been unable to identify any of the raw data, survey questionnaires or other key records which form the basis of this Cross-Sectional Study. A single spreadsheet of raw data for this study obtained from the DC government via a Freedom of Information Act (FOIA) request by water expert Dr. Marc Edwards from Virginia Polytechnic Institute and State University in 2006 shows such fundamental flaws as individuals with test dates *after* the study was completed. The NCEH study, however, was used to reassure the public that there was no evidence of public health harm due to elevated water lead levels in the District of Columbia. The Cross Sectional Study was widely cited by local public health officials dealing with their own elevated water lead issues in Michigan, North Carolina and Washington State, for instance, and they used it to publicly discount any correlation between their own elevated water lead levels and elevated BLLs that could result in public harm. In 2007, Dr. Edwards wrote a formal letter to CDC requesting clarification regarding concerns he had about the data used in the 2004 MMWR article and the public health conclusions reached by the CDC. Dr. Edwards will testify about his experience attempting to gain answers to his questions and his own independent research on the DC lead-in-water crisis that completely contradicts the findings of the MMWR article and the CDC.

The Subcommittee has found that the 2004 CDC MMWR article was based on flawed, misleading and incomplete data. Key problems with the underlying scientific integrity of the data used to write the MMWR were known to the article's primary author, Dr. Mary Jean Brown, head of the CDC's lead program, *before* the report was published, yet these flaws were not shared with co-authors, the publication's editors, CDC's leadership or the public. Efforts to resolve critical data integrity issues *after* the report was published were belated, weak and ineffective. Despite the clear scientific integrity questions that surrounded the CDC's blood lead screening data it obtained from the District of Columbia in early 2004, by 2007 scientists at the CDC were pushing forward with attempts to publish a peer reviewed journal article in the aftermath of the DC lead crisis based on the same faulty and incomplete data.

Remarkably, despite the clear gaps in the data the CDC was using for this new study, they reached drastically different conclusions from the original 2004 MMWR article. The new study, for instance, concluded that children living in homes with partial lead pipe replacements were four times more likely to have an elevated blood lead level than children living in homes without lead pipes. This issue has national implications since many cities have conducted partial lead pipe replacements as a means of reducing elevated water lead levels. The conclusions reached by CDC clearly have significant public health consequences as well.

Rather than attempting to broadly inform the public about these results and local public health officials or water utilities by publishing the CDC's findings in the agency's Morbidity and Mortality Weekly Report (MMWR) the agency has spent years trying to get their findings published in a peer reviewed scientific journal. Early last year the report was rejected twice by the CDC's Associate Director for Science. In the end, NCEH/ATSDR's Deputy Director, Dr. Tom Sinks, became a co-author of this proposed article and the paper was then cleared for release. It was rejected by one peer review scientific journal and sent to a second. The new CDC Director put a hold on trying to publish this article until all of the surveillance data this article is based upon could be obtained and reviewed by CDC. That data has now been obtained by CDC and they are attempting to publish their new study in a peer reviewed scientific journal. This is a welcome step, but it has taken the CDC six years to follow through on something that should have been done back in 2004.

In addition, because this information reveals significant public health concerns it would seem more appropriate to use the CDC's MMWR to get the information out rapidly rather than waiting many more months to get it accepted and published in a scientific journal.

The mission of 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 to toxic substances."[12] But, nearly since its inception ATSDR has been criticized for not living up to that charge. Stephen Lester, Science Director at the Center for Health, Environment and Justice has been one of those critics and will testify about his own efforts to help the agency reform itself for the past two decades. Lester and others have criticized ATSDR for repeatedly failing to adequately investigate public health concerns. Last year, at the Subcommittee's ATSDR hearing we looked into some of the cases listed below and ATSDR committed to re-visiting some of these past investigations as a result.

Vieques Island, Puerto Rico

From 1941 to 2003 the U.S. Navy engaged in live bombing practice activities on and off the coast of Vieques Island in Puerto Rico spreading munitions containing 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.[13] Those assessments have been widely criticized. One of those critics has been Dr. John Wargo, Professor of Environmental Risk Analysis and Policy at Yale University, who has investigated the public health consequences of toxic contamination on Vieques for the past seven years and will testify at Thursday's Subcommittee hearing.

In the wake of last year's Subcommittee hearing, ATSDR management engaged in some positive actions regarding Vieques. The former NCEH/ATSDR director, Dr. Howard Frumkin, visited Vieques and committed to re-evaluating ATSDR's past public health assessments of the island. The agency held a meeting last year with Puerto Rican scientists and other experts in what it described as a "scientific consultation" to discuss steps ATSDR should take to re-evaluate its past public health reports and recommendations regarding future action to evaluate toxic contamination on Vieques. Some scientists are frustrated, however, that ATSDR has been slow in developing any plans to launch new public health evaluations and these scientists are uncertain whether that will ever happen. The agency, for instance, never conducted a comprehensive food intake survey on the island, a critical step in evaluating potential chemical exposures to the island's residents and it is unclear if ATSDR plans to conduct one in the future. ATSDR had intended to issue a report for public comment in March that details information gaps, research needs and recommended actions regarding Vieques. But the agency now says that report won't be ready for release until mid-to-late summer.

Midlothian, Texas

At our last ATSDR hearing, the former ATSDR director also committed to re-focusing the agency's attention on Midlothian, Texas home to three cement plants and one steel mill that have released more than one billion pounds of toxic chemicals into the local environment since 1990. In 2005 the agency accepted a public petition to conduct a health consultation on the potential health effects of toxic substances released from Midlothian's cement kilns. A draft version of the study was released in 2007 and received wide-spread criticism from independent scientists and local community members. A final version of the health consultation has still not been released. In addition, a second health consultation which was supposed to address air monitoring data of specific toxic chemicals was never initiated.

In the wake of our hearing ATSDR did get more involved in Midlothian, although actual progress has been more difficult to measure. The agency held a public meeting, it conducted a survey of the local community's public health concerns, it formed a Community Assistance Panel (CAP) and it detailed two veterinarians to help examine health concerns regarding the town's animal population, including dogs,

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

[13] "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*.

horses and goats that have exhibited what appears to be abnormally high numbers of stillbirths, birth defects and deformities.

Virtually all of these actions, however, have been criticized by local community members. It is unclear to them when the veterinarians' evaluation will be completed or what to expect from it. One local resident says it seems ATSDR is treating the animal investigation as simply a veterinarian issue and not an important and urgent indicator of potential human health harm from exposure to toxic contamination. Local residents also complain that ATSDR's public meetings were not well publicized. ATSDR established a local Community Assistance Panel (CAP) to reportedly help provide input to ATSDR's activities regarding public health evaluations in Midlothian. Yet, the panel formed by ATSDR had an overwhelming number of representatives from the very industries that have contributed to the toxic contamination in and around Midlothian in the first place. There were reportedly six industry representatives, one representative from the local school board, one from the city and two community representatives. ATSDR apparently hand-selected the two community representatives that it believed were "fair and balanced" based on interviews that were conducted with local residents last summer.

The Subcommittee and many others have repeatedly criticized ATSDR for paying undue heed to the corporate interests or local politicians that have vested interests in concluding that there are no actual or potential public health hazards due to toxic exposures in local communities. In the Midlothian case, for instance, ATSDR never offered a seat on the panel to the agency's most vocal critics from the community. But the town's corporate interests that were responsible for the pollution were well represented. The perception in Midlothian is that ATSDR was attempting to silence its critics once again. In the end, ATSDR disbanded the short-lived Community Assistance Panel because of these concerns. These sorts of clearly avoidable and continuing blunders by the agency do not instill confidence in its ability to reform itself.

Polycythemia Vera Cancer Cluster Funding

In another case, CDC approved $2.5 million in FY2010 funding for research into a cluster of rare blood cancers called polycythemia vera in eastern Pennsylvania, after our hearing last year. Senator Arlen Specter had been pushing for this funding to investigate the potential scope and cause of these cancers. Part of the funding was intended to fund research efforts that would investigate potential links between this cancer cluster and environmental contamination. Again, after our hearing drew attention to this issue ATSDR engaged in some positive actions. They assisted in forming a Community Action Committee (CAC) that would help provide information on the government's research into the polycythemia vera cluster to the public and ATSDR secured funding to support various research efforts regarding the polycythemia vera cluster.

Yet, a few weeks ago the agency apparently attempted to "reprogram" the $2.5 million in funds for this effort without informing Congress or the local affected communities in Pennsylvania. Once Senator Specter became aware of this issue and wrote to the Department of Health and Human Services the reprogramming effort reportedly ceased. The CDC says that it "considered a number of options for reallocating resources. At this point, CDC does plan to continue funding the polycythemia vera cancer cluster in FY2010."

The Value of a National Conversation?

The recommendations offered by GAO in its new report on ATSDR provide a guidepost for essential reform of the agency. None of the critical and constructive reforms necessary will occur, however, without strong leadership at the top of the agency that recognizes the agency's past miscues and missteps and is able and willing to step in a new direction. It seems clear to the Subcommittee that the current cadre of ATSDR's top management, many of whom have been at the agency for decades and have been in positions capable of executing necessary changes at the agency, have been unable or unwilling to implement the critical reforms necessary to help protect the public's health from potentially toxic contamination. They have simply failed to rely on sound science and rigorous reviews of the public health documents the agency releases to the public.

Unfortunately, over the past year, for instance, the agency's leadership has been focused on what it has described as a "National Conversation on Public Health and Chemical Exposures," "a 2-year project to create a national action agenda for strengthening the United States' approach to protecting the public from harmful

chemical exposures." The project is being sponsored by both CDC and ATSDR.[14] These extravagant efforts appear to have been a clear and present diversion from any real reform efforts at the agency. This process has refocused attention inside ATSDR away from rectifying the agency's own problems and strengthening its own public health procedures towards a broad ranging discussion of environmental contamination and public health that appears to overstep the agency's congressional mandate and its public health mission. This effort, begun under the agency's former director, has diverted attention, financial resources and energy from any attempt to quickly and aggressively fix the known and unambiguous problems that have hindered the agency's scientific credibility, data integrity and public health value since its creation two decades ago.

The former director of ATSDR was removed from his position late last year. The current director of the Centers for Disease Control and Prevention (CDC) now has an opportunity to appoint a strong, solid director and new management team at ATSDR that is committed to inaugurating sound scientific practices that will serve the local communities that the agency was established to both advise and help protect.

Dr. Robin M. Ikeda, Deputy Director for the Office of Noncommunicable Diseases, Injury and Environmental Health and Acting Director for the National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC) will be our last witness and will respond to Members' questions about CDC's environmental public health practices and inform the Subcommittee where CDC is on the road to reform at NCEH and ATSDR.

Witnesses:

Panel I

Ms. Cynthia A. Bascetta, Director, Public Health and Medical Services, Government Accountability Office (GAO)

Mr. Stephen Lester, Science Director, Center for Health, Environment & Justice (CHEJ)

Dr. John P. Wargo, Professor of Environmental Risk Analysis and Policy, Yale University

Dr. Marc Edwards, Charles P. Lunsford Professor, Department of Civil and Environmental Engineering, Virginia Polytechnic Institute and State University, Blacksburg, Virginia

Panel II

Dr. Robin M. Ikeda, MD, MPH, Deputy Director for the Office of Noncommunicable Diseases, Injury and Environmental Health and Acting Director for the National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC)

[14] See details here: *http://www.atsdr.cdc.gov/nationalconversation/index.html*.

Chairman MILLER. Good morning. Welcome to this morning's hearing: *Preventing Harm – Protecting Health: Reforming CDC's Environmental Public Health Practices*.

This is the third subcommittee hearing to examine the performance of the Agency for Toxic Substances and Disease Registry, ATSDR. Today, we will expand our work to examine the work of its sister agency, the National Center for Environmental Health, NCEH. Together, those offices are the Centers for Disease Control's experts in performing environmental health evaluations.

In previous hearings, we documented problems with ATSDR's work on formaldehyde and the safety of trailers provided to families that survived Hurricane Katrina. We also documented problems with ATSDR's environmental assessments at Camp LeJeune, Vieques, Puerto Rico, and Midlothian, Texas. Three of the four cases mentioned have seen the health evaluations withdrawn by ATSDR, and the fourth is under review. They are to be commended, we do commend ATSDR for their willingness to admit failings, but today we will hear reasons to worry about what they are doing to make sure there are not failings in the future. We will examine one of these past examples, looking into current actions by the CDC to launch a new public health evaluation at Vieques, Puerto Rico.

Additionally, we are releasing a staff report that documents serious flaws in an article written by CDC staff in 2004 to respond to the District's lead-in-water crisis. That article—the District of Columbia. That article was built on significantly incomplete data for one of the two studies and unreliable data in the other study. But the message to District residents in the article was very clear: no serious harm resulted from the elevated level of lead in their water.

After that article was published in the Morbidity and Mortality Weekly Report, the MMWR, in March 2004, the public clamor went away, press coverage died down, and most of the federal staff dispatched to assist the city validate the message, that there was no crisis by quietly returning to their home agencies. The authors knew there were problems with those studies, but in their disclosure on the limits of their data, they said not a word about missing data or confounding variables.

This subcommittee cannot possibly identify every mistaken evaluation, assessment, report or article done by ATSDR or NCEH staff. That is not the role of Congressional oversight. We do not do peer review. We are not peers. But the CDC must take the steps themselves to make sure that these offices get on the right path and proceed in a way that avoids those problems in the future. And sometimes to get on the right path, you have to determine what constitutes the right path and what constitutes the wrong path. Our previous hearings and today's testimony makes it clear that the wrong path includes or has included in the past conducting studies designed to make it impossible to find a health problem. It is not the role of the government to tell everybody that they have got nothing to worry about.

Analyzing data that is incomplete, inaccurate, or irrelevant to the underlying question without disclosing the known limits of the data, responding to critics by attacking their knowledge or their

motives, failing to have rigorous and consistent reviews of study design, data collection and quality, analytical methods and conclusions, failing to have consistent policies and procedures for conducting public health research and interventions and for publications, all of this needs to change if ATSDR and NCEH are to succeed.

We need more honesty and transparency and less attitude. When you work at a public health science agency and the words that are frequently used to describe your work are "haphazard", "hit or miss", "ad hoc", maybe you should pause and reflect.

This morning we have a new analysis that reworks part of the MMWR article on lead in D.C.'s drinking water, with more complete data on blood lead tests for District residents. The NCEH staff had more complete data, but they manipulated it, scrubbed it in a way that can't be evaluated by experts or by the public. They provide no real levels, no real numbers of children with elevated blood levels, something that residents would understand, and it makes it impossible to compare their raw numbers to numbers reported by the District or this subcommittee. Most important, the other years in this longitudinal study were treated in a different way that makes it almost impossible to compare, undermining the validity of the entire exercise.

Undoubtedly, much of ATSDR's and NCEH's problem is a failure to communicate, in the words of Cool Hand Luke. But we have heard a great deal of evidence that the quality of the science is simply not consistently what it should be.

I congratulate Dr. Frieden for initiating a search for a new leader of ATSDR–NCEH. A new team can do much to restore the confidence of the staff, to provide guidance about quality and procedures, processes, and give this country a function we desperately need: a reliable, expert evaluation of environmental health dangers.

There are many talented, committed professionals at ATSDR and NCEH. Our criticism of the agency has never been a criticism of the professionalism or the commitment of their employees. Eighty percent of the staff at ATSDR would like to have their work subject to peer review more often. That is obvious evidence that the staff is committed to their job and want to do the right thing, and the public and the employees of ATSDR deserve leadership that matches their own commitment.

I am attaching to my opening statement a report by the majority staff regarding the CDC's response to the lead-in-water crisis in Washington, D.C., back in 2004, and also attaching a statement submitted by the Hon. Pedro Pierluisi, the delegate from Puerto Rico and other documents for the record.

[The information follows:]

Hon. Pedro R. Pierluisi
Statement on "Preventing Harm- Protecting Health: Reforming CDC's Environmental Public Health Practices"
Committee on Science and Technology
Subcommittee on Investigations and Oversight
Thursday, May 20, 2010

Thank you, Chairman Miller.

I want to commend you for convening this hearing in order to examine the policies and procedures of the Centers for Disease Control and Prevention (CDC), including the Agency for Toxic Substances and Disease Registry (ATSDR), with respect to public health assessments. In particular, I want to express my gratitude to this Subcommittee for addressing the health assessments conducted by the ATSDR about the possible link between exposure to contaminants released from the Navy's military activities on Vieques Island, Puerto Rico and the negative health effects experienced by the residents of Vieques. Naturally, this issue is of great importance and concern to my constituents, especially those living in "La Isla Nena"—as we in Puerto Rico fondly call Vieques.

As Majority Staff for the Subcommittee observed in a March 2009 report, the 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. As the Majority Staff also noted in that report, multiple studies have shown that residents of Vieques have a 23% higher cancer rate than those on "mainland" Puerto Rico.

The series of public health assessments conducted by the ATSDR in Vieques between 2001 and 2003 concluded that human exposure to contaminants through air, soil, groundwater and fish consumption did not appear to be the cause of reported health effects among residents. These assessments have been the source of criticism, confusion and controversy. Various independent researchers who have studied environmental contamination on Vieques in recent years—including Dr. John Wargo, one of today's witnesses—have concluded that the contaminant levels are higher in some cases than the ATSDR has reported, that the potential health hazards are therefore likely to be greater overall than the ATSDR has found, and that there is a more definitive link between the Navy's past activities and the health problems being experienced by the island's residents.

On March 12, 2009, this Subcommittee questioned the ATSDR's findings about Vieques and other contaminated sites in an oversight hearing. Congressman Rothman and Congressman Grayson, who are both members of the Subcommittee, have been particularly vigilant on this issue, raising questions about the manner in which the ATSDR conducted these assessments in Vieques and the accuracy of the conclusions reached by the agency. On behalf of my constituents, I want to express my deep gratitude to both of them. I could not ask for better or more determined allies in this fight.

In May 2009, as a result of the March Subcommittee hearing, the ATSDR indicated it would re-examine its prior findings in order to determine whether the available evidence revealed a greater risk of human exposure to contamination than previously understood. This was heartening news for me and my constituents.

In August 2009, then-ATSDR director Dr. Howard Frumkin visited Vieques and met with community leaders and Puerto Rican health officials and scientists. At those meetings, ATSDR made a commitment to involve local experts in ATSDR's review, and requested that scientists from Puerto Rico and others who have studied environmental contamination on Vieques participate in a scientific consultation. That meeting was held in Atlanta in early November and, according to ATSDR, "entailed a thorough review of multiple studies." In a statement released at the time, ATSDR emphasized that it was taking a "fresh look" at environmental health concerns on Vieques.

Over the past year and a half, I have met personally with Dr. Frumkin and Dr. Henry Falk in order to underscore the importance and urgency of this issue, and to reiterate my expectation that the ATSDR will fulfill its mission "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." The U.S. citizens of Puerto Rico, like their fellow citizens in the states, deserve no less.

Chairman Miller, thank you again for your hard work on this issue.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF CHAIRMAN BRAD MILLER

Good morning. Welcome to the hearing: Preventing Harm, Protecting Health: Reforming CDC's Environmental Public Health Practices.

This is the third Subcommittee hearing to examine the performance of the Agency for Toxic Substances and Disease Registry (ATSDR). Today, we also examine the work of its sister agency, the National Center for Environmental Health (NCEH). Together, these offices are the Centers for Disease Control's (CDC) experts in performing environmental health evaluations.

In prior hearings we documented problems with ATSDR's work on formaldehyde and the safety of trailers provided to families that survived Hurricane Katrina. We also documented problems with ATSDR environmental assessments at Camp LeJeune, Vieques, Puerto Rico and Midlothian, Texas. Three of the four cases mentioned have seen the health evaluations withdrawn by ATSDR, and the fourth case is under review. They are to be commended for being willing to admit to mistakes—but today we will hear reasons to worry about what they are doing to set the record right. We will examine one of these past examples, looking into current actions by the CDC to launch a new public health evaluation in Vieques Puerto Rico.

Additionally, we are releasing a staff report that documents serious flaws in an article written by CDC staff in 2004 to respond to the District's lead-in-water crisis. That article was built on significantly incomplete data for one of the two studies and unreliable data in the other study. But the message to District residents in the article was very clear: no serious harm resulted from the elevated lead in water situation. After that article was published in the *Morbidity and Mortality Weekly Report*—the MMWR—in March 2004, the public clamor went away, press coverage died down, and most of the Federal staff dispatched to assist the City validated the message that there was no crisis by quietly returning to their home agencies. The authors knew there were problems with their studies, but in their disclosure on the limits of their data, they said not one word about missing data or confounding variables.

This Subcommittee cannot possibly identify every mistaken evaluation, assessment, report or article done by ATSDR or NCEH staff and that is not the role of Congressional oversight. The CDC must take all necessary steps to set these offices on the right path. Sometimes to get on the right path, we must understand what constitutes the wrong path. Between our previous hearings, and today's testimony from the Government Accountability Office (GAO) it is clear that the wrong path includes:

1. Conducting studies designed to make it impossible to find a health problem.
2. Analyzing data that is incomplete, inaccurate, or irrelevant to the underlying question without disclosing the known limits of the data.
3. Responding to critics by attacking their knowledge or their motives.
4. Failing to have rigorous and consistent reviews of study designs, data collection and quality, analytical methods and conclusions.
5. Failing to have consistent policies and procedures for conducting public health research and interventions and for publications.

All of this needs to change if ATSR and NCEH are to succeed.

We need more honesty and transparency and less attitude from these offices. When you work at a public health science agency and the words more frequently used to are "haphazard," "hit-or-miss" and "ad hoc", maybe you should pause and reflect.

This morning we have a new analysis that reworks part of the MMWR article on lead in DC's drinking water, with more complete data on blood lead tests for District residents. The NCEH staff had more complete data, but they scrubbed it in a way that can't be evaluated by experts or by the public. They provide no real numbers of children with elevated blood lead levels—something that residents would understand—and make it impossible to compare their raw numbers to numbers reported by the District or this Subcommittee. Most important, the other years in this longitudinal study were not "scrubbed" in the same way the newly complete 2003 report was, making the validity of the entire exercise questionable.

Undoubtedly much of ATSDR's and NECH's problem is a failure to communicate in the words of Cool Hand Luke. But we have heard a great deal of evidence that the quality of the science is simply not consistently what it should be.

I congratulate Dr. Frieden for initiating a search for a new leader of ATSDR–NCEH. We need a new team there that can restore staff confidence, provide guidance about quality and processes, and give to this country a function we so desperately need: reliable, expert evaluation of environmental health dangers. There are many talented committed professionals at ATSDR and NCEH. The public and those professionals deserve that leadership.

Chairman MILLER. I now recognize Dr. Broun for his opening statement.

Mr. BROUN. Thank you, Mr. Chairman. Good morning.

I want to welcome our witnesses here today and thank the Chairman for holding this hearing. As a legislator and as a physician, I am certainly concerned about environmental public health.

As the chairman noted, the Agency for Toxic Substances and Disease Registry and the Centers for Disease Control are no strangers 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 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 several internal reviews of those efforts and the Committee asked GAO to review the agency's processes. Additionally, this Committee held another hearing to hear from communities about their experiences with ATSDR and spent over a year examining how the CDC and the D.C. Department of Health responded to the D.C. lead crisis. Throughout these processes, it became abundantly clear that the processes by which scientific products are tasked, developed, reviewed, distributed and communicated are woefully inadequate. GAO's report offers a number of recommendations but it will take a concerted and a sustained effort to bring about the cultural change needed to ensure public trust.

While the work that the Agency does is critically important, it is also very difficult. Determining causation and making health determinations is not always black and white. Despite the complexity of their work, the public deserves to have an agency that they trust, and 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 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. Chairman, and I yield back the balance of my time.

[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. As a legislator and a physician, I am certainly concerned with Environmental Public Health.

As the Chairman noted, the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control (CDC) are no strangers 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.

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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.

Chairman MILLER. Thank you, Dr. Broun.

We will include any other opening statements from any members in the record.

Panel I

It is now my pleasure now to introduce our witnesses today. Ms. Cynthia Bascetta is currently the Director of Public Health and Medical Services at the Government Accountability Office, GAO. While at GAO, she has investigated the federal response to Hurricane Katrina and the delivery of federal health services to responders affected by the terroristic attack on the World Trade Center buildings. She holds a master's in public health from the University of Michigan. Mr. Stephen Lester is Science Director for the Center for Health, Environment and Justice, CHEJ. Mr. Lester has a master's degree in toxicology from the Harvard University School of Public Health and a master's degree in environmental health from the New York University's Institute of environmental medicine. He has worked for 20 years to help initiate reforms at ATSDR. Dr. John Wargo is Professor of Risk Analysis, Environmental Policy and Political Science at Yale. It says Yale University. He is the author of several books on toxic contamination and the impact on children, and he has served as an advisor on child health-related issues to the White House, EPA and CDC. He has spent the last seven years investigating toxic contamination on the Puerto Rican island of Vieques and will discuss his assessment of the CDC's failures to evaluate fully the potential human health hazards there. Dr. Marc Edwards is currently the Charles Lunsford Professor of Civil Engineering at Virginia Tech. He holds an undergraduate degree in basic medical sciences and a Ph.D. in environmental engineering. In 2007, he won a MacArthur fellowship, commonly called a Genius Grant, and he recently won the 2010 Praxis Award in professional ethics from Villanova University. His paper on the CDC lead-in-water crisis published last year in the Journal of Environmental Science and Technology was selected as the jour-

nal's best paper in the category of science, beating out nearly 1,500 other papers. We look forward to hearing from him and from all the witnesses today.

As our witnesses should know, you will each have five minutes for your spoken testimony. Your written testimony will be included in its entirety in record of the hearing. When you have completed your spoken testimony, we will begin with questions. Each member will have five minutes to question the panel. It is the practice of the Subcommittee, because we are an investigations and oversight subcommittee, to receive our testimony under oath. Do any of you have any objection to taking an oath? Okay. The record should reflect that all the witnesses nodded in the negative, that they did not have an objection. You also have the right to be represented by counsel. Do any of you have counsel with you today? The record should reflect that all the witnesses nodded in the negative, that they do not have counsel today.

Please stand and raise your right hand. Do you swear to tell the truth and nothing but the truth? The record should reflect that all of the witnesses have taken the oath. And now that you are at ease, we will start with Ms. Cynthia Bascetta. I want to thank you and the GAO for the hard work you have done in response to our Subcommittee's request for help with this, and your work was certainly thorough and diligent. You are recognized for five minutes.

STATEMENT OF CYNTHIA A. BASCETTA, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE (GAO)

Ms. BASCETTA. Mr. Chairman and members of the Subcommittee, thank you very much for inviting me to testify about the need for ATSDR to strengthen its policies and procedures for preparing public health products. My remarks will highlight the findings of our report to the Subcommittee. As you are well aware, concerns about the quality of ATSDR's public health products are long standing. Prior GAO work, other studies and investigative reports by your own staff document products that have had serious scientific weaknesses. Our findings focus on the organizational climate that contributed to publication of these products rather than an assessment of the products themselves.

To do our review, we used the Standards for Internal Control in the Federal Government to assess the agency's policies and procedures for the three phases of product preparation. These are initiating new work, developing a product and reviewing and clearing the product for publication. For all phases, we documented the lack of some critical controls needed to provide a reasonable assurance of product quality.

The first deficiencies we found were during the initiation of new work. ATSDR's policies and procedures establish neither an adequate assessment of risk nor a clear information flow. The agency previously incorporated some of the principles of risk assessment when it classified some hazardous chemical sites as high priority or focus sites and it required products for these sites to undergo a higher level of review and clearance. It no longer does this, and instead generally relies on various meetings held at different levels to inform management and staff about newly initiated work. As a

result, it cannot ensure that it is managing public health products commensurate with their risks.

For the product development phase, we found that ATSDR's policies and procedures neither clearly define management roles and responsibilities nor require that management monitor the development of key components of public health products such as exposure assessments and health effects evaluations. One official told us that the agency identified staff with the right expertise for assignments. However, we noted in our report that this is not a substitute for ongoing monitoring. Without monitoring, problems that occur during product development may not be identified until review and clearance if they are identified at all. This can undercut public confidence as well as waste valuable time and resources.

Finally, review and clearance policies do not reflect current practices. For example, the review of products in the division of health assessments and consultation usually stops with division branch chiefs, even though policy highly recommends clearance by the division director or the associate division director for science. Moreover, these policies and procedures direct management and staff to use discretion to identify products that should undergo higher levels of review rather than determining this through a comprehensive risk assessment process. The agency's criteria for discretionary review includes situations in which a document could have a high degree of visibility or contains highly sensitive information. However, because there is no consistent process, ATSDR again cannot ensure that its products receive the appropriate level of review and clearance.

Mr. Chairman, ATSDR has told us that factors such as scientific uncertainty and resource limitations affect its ability to conduct its mission. We believe that such challenges are precisely why the agency must be held accountable for strengthening its processes to improve product quality. In its current state, management has limited its own ability to monitor agency work and ensure that resources are being allocated appropriately. The Office of the Director is in a reactive rather than a leadership position with respect to the divisions and the public health work it manages. In our report, we recommend ways for ATSDR to provide reasonable assurance of the quality of its public health products.

This concludes my remarks, and I would be happy to answer your questions.

[Statement of Ms. Bascetta follows:]

PREPARED STATEMENT OF CYNTHIA A. BASCETTA

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the Agency for Toxic Substances and Disease Registry's (ATSDR) policies and procedures for product preparation. ATSDR investigates community exposures related to chemical sites and releases; works with federal, tribal, state, and local agencies to identify potential exposures; assesses associated health effects; and recommends actions to stop, prevent, or minimize these harmful effects. In conducting these activities, the agency publishes many types of public health products, including public health assessments, health consultations, health study reports, and exposure investigations. Recent reports by the Institute

of Medicine[1] and ATSDR's Board of Scientific Counselors[2] have identified various concerns such as the appropriateness and quality of the data used in ATSDR's products, the methodology and design of the studies, and clearance policies.

This committee has held two previous hearings that focused on its concern about the quality of ATSDR's products. In response, ATSDR has noted that multiple factors have posed challenges for the agency, including limitations in the ability of available science to answer community questions about the effect of chemical exposures, limitations in ATSDR's ability to collect data related to exposures, and reductions since 2004 in the number of ATSDR staff and resources available to conduct the agency's mission. My testimony is based on our April 2010 report,[3] which is being publicly released today, and addresses the extent to which ATSDR's policies and procedures for product initiation, development, and review and clearance provide reasonable assurance of public health product quality.

To address this question, we reviewed ATSDR's policies and procedures and interviewed officials to identify guidance related to the preparation of public health products. We focused our review on those policies and procedures related to public health assessments, health consultations, exposure investigations, and health study reports because these products are considered to be ATSDR's core public health products and concerns have been raised about the quality of products such as these, in which ATSDR identifies potential exposures to hazardous chemicals and assesses associated health effects. We compared the policies and procedures ATSDR uses to guide the preparation of its public health products to the standards described in the *Standards for Internal Control in the Federal Government*,[4] [5] and the related *Internal Control Management and Evaluation Tool.* [6]

We also interviewed employees in ATSDR's headquarters, employees in 3 of ATSDR's 10 regional offices, and employees in 3 of 30 cooperative agreement partner offices to gain a better understanding of ATSDR and the policies and procedures related to product preparation. Further, we conducted interviews with officials, experts, and researchers outside ATSDR to gain an understanding of ATSDR's relationship with other agencies, to get their perspectives on ATSDR's work, and to learn about the policies and procedures used by other prominent scientific research organizations. A full description of our scope and methodology is included in our report.

We conducted this performance audit from April 2009 to April 2010, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In brief, we found that the policies and procedures that ATSDR has established for public health product preparation lack some of the critical controls to provide reasonable assurance of product quality. To provide reasonable assurance that agency objectives are being met, federal internal control standards call for agencies to establish policies and procedures, assess risks associated with achieving agency objectives, ensure effective information sharing throughout the organization, monitor agency activities, and establish key areas of authority and responsibility for management and staff. We found that ATSDR's policies and procedures are deficient in the three phases of preparation of public health products: (1) initiation, which includes a decision by the agency to begin work on a public health product and the assignment of staff to prepare the product; (2) development, which includes management approval to proceed with the development of a product and the actual drafting of the public health product; and (3) review and clearance, which is the process by

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[1] See Institute of Medicine, *Review of ATSDR's Great Lakes Report Drafts (Letter Report)* (Washington, D.C.: National Academies Press, 2008).

[2] ATSDR's Board of Scientific Counselors is an advisory committee that provides advice and guidance to the ATSDR Director. At ATSDR's request, the Board of Scientific Counselors convened a work group to evaluate the agency's peer review processes. The board issued a report in March 2009; as of May 11, 2010, the report was not available on ATSDR's Web site.

[3] See GAO, *Agency for Toxic Substances and Disease Registry: Policies and Procedures for Public Health Product Preparation Should be Strengthened*, GAO–10–449 (Washington, D.C.: Apr. 30, 2010).

[4] See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD–00–21.3.1 (Washington, D.C.: November 1999).

[5] See Office of Management and Budget *Circular No. A–123, (Revised): Management's Responsibility for Internal Control* (Dec. 21, 2004).

[6] See GAO, *Internal Control Management and Evaluation Tool*, GAO–01–1008G (Washington, D.C.: August 2001).

which a product is internally or externally reviewed and disseminated as a final public health product.

- *ATSDR's policies and procedures for work initiation do not establish and describe an adequate assessment of risk or information flow*. When work is being initiated, we found that ATSDR lacks comprehensive policies and procedures for assessing and categorizing the risk of that new work. For example, ATSDR previously incorporated some of the principles of risk assessment when the agency officially classified some hazardous chemical sites as "high-priority" or "focus sites," and required any products resulting from review of those sites to undergo a higher level of review and clearance. However, it no longer does so. Because ATSDR does not currently have policies and procedures that describe how the agency is to comprehensively assess and categorize the risk of work it initiates to prepare public health products, management cannot ensure that it has consistently managed the risk related to new work. Furthermore, since ATSDR's policies and procedures do not establish how information about newly initiated work should flow between management and staff, ATSDR generally relies on various meetings to inform management and staff about new work. The agency is implementing a new database called Sequoia, which may improve the flow of information. However, officials told us that further evaluation is needed to determine if Sequoia could do everything required by management or if some information will have to be captured in separate databases.
- *ATSDR's policies and procedures for product development do not provide for clear management roles and responsibilities or consistent monitoring of product development*. During product development, many of ATSDR's policies and procedures do not clearly define management roles and responsibilities and do not consistently require that management monitor the development of key components of these products. For example, the primary document—the *Public Health Assessment Guidance Manual*—that guides the development of public health assessments and health consultations, which are among the agency's core products, identifies exposure assessment [7] and health effects evaluation as the two primary technical components of the public health assessment process. However, there is no requirement that staffs work in either of these areas be reviewed and approved by management during the development of a product to ensure its accuracy and appropriateness. Because of these deficiencies, management may be unclear about its responsibilities, and problems that occur during product development may not be identified or addressed until review and clearance, if at all. For example, ATSDR and Institute of Medicine reports show that because scientific concerns were not identified during development of an ATSDR report regarding chemical releases in the Great Lakes region, the document underwent several years of review, and a final report was not issued until more than 4 years after the first draft was written.
- *ATSDR's review and clearance policies and procedures do not always reflect current practices and do not establish a process for ensuring consistent review of all products*. We found that some review and clearance policies do not reflect current practices. For example, ATSDR's *Clearance Quick-Reference Guide* indicates that all public health assessments, health consultations, and exposure investigations must be reviewed and cleared by the division director or the division associate director for science. Yet according to Division of Health Assessment and Consultation (DHAC) management and staff, the review and clearance of DHAC products usually stops after review by branch chiefs within the division.[8] Furthermore, review and clearance policies and procedures direct management and staff to use discretion to identify products that require higher levels of review, rather than making this determination through a comprehensive risk assessment process. While ATSDR policy sets out criteria for when additional review may occur, such as when a document could have a high degree of visibility, there is no required point during a product's preparation when management and staff collectively determine

[7] An exposure assessment is the process of finding out how people come into contact with a hazardous substance, how much of the substance they are in contact with, and where the substance is located. An exposure assessment reviews data collected by other federal and state government agencies, and differs from an exposure investigation in which ATSDR staff collect and analyze site-specific environmental or biological samples to determine whether individuals have been exposed to hazardous substances.

[8] DHAC is one of four ATSDR divisions.

whether a product meets the criteria, and whether additional review is warranted. Thus, the agency cannot ensure that all products consistently receive the appropriate level of review.

In conclusion, while management controls alone cannot guarantee product quality, they can help ensure the development of timely and credible public health products at ATSDR. But ATSDR lacks some critical controls to provide reasonable assurance of product quality, particularly for public health assessments, health consultations, and exposure investigations. Without assessing the risk of work being undertaken by the agency and using those risk assessments to guide agency processes for public health product preparation, ATSDR cannot provide reasonable assurance that its products have undergone the appropriate level of monitoring and review. If established, a risk assessment process could be used to determine the proper level of scrutiny for the initiation, development, and review and clearance phases, thereby ensuring that this determination is made consistently across the agency. Additionally, the agency's policies lack guidance for management about its role in monitoring product development, and do not require management's monitoring and approval of key components of a product during its development. Without adequate monitoring by management during a product's development, product errors may not be caught or significant publication delays may occur during the review and clearance phase, potentially undermining public confidence in the agency's products.

Our report recommends that ATSDR develop policies and procedures to ensure that an assessment of the risk associated with a product is conducted at the time site-specific work is initiated, and that any assigned risk level be re-evaluated throughout product preparation to ensure that it remains appropriate. Our report also recommends that ATSDR revise existing policies and procedures, or develop new guidance, to provide documented direction for various levels of management on their roles and responsibilities in the monitoring of all products prior to review and clearance, such as requirements for management to monitor and approve key components of these products.

In commenting on a draft of the report from which this testimony is based, ATSDR neither agreed nor disagreed with our recommendations and did not address them directly, but stated that the agency has begun to incorporate our recommendations. Although ATSDR did not comment directly on our recommendation that the agency conduct a risk assessment at the time site-specific work is initiated and reevaluate the assessment throughout product preparation, in its comments ATSDR stated that senior management was looking into formalizing and unifying coordination, triage, and prioritization of all incoming requests across the agency. ATSDR also acknowledged a need to make its prioritization process more explicit throughout the agency. Related to our recommendation that ATSDR revise or develop policies and procedures to include direction for management in monitoring products prior to review and clearance, ATSDR noted that its process to formalize and unify coordination, triage, and prioritization of all incoming requests was expected to include the specification of management and staff roles and responsibilities from initiation through publication.

Mr. Chairman, this concludes my statement. I would be pleased to respond to any questions you or other Members of the Subcommittee may have.

Chairman MILLER. Thank you, Ms. Bascetta.

Next is Mr. Lester for five minutes.

STATEMENT OF STEPHEN LESTER, SCIENCE DIRECTOR, CENTER FOR HEATH, ENVIRONMENT AND JUSTICE (CHEJ)

Mr. LESTER. Mr. Chairman, distinguished members of the Subcommittee, thank you for this opportunity to testify on the policies and procedures used by the Agency for Toxic Substances and Disease Registry to evaluate health problems in communities. My name is Stephen Lester. I am the Science Director with the Center for Health, Environment and Justice. CHEJ is a national environmental health organization founded in 1981 by Love Canal community leader Lois Gibbs. I joined CHEJ in 1983, and as Science Director I have easily reviewed many hundreds of health studies, health assessments and health investigations including many con-

ducted by ATSDR. It is with this background and experience that I offer this testimony.

I would like to begin by stating that under no circumstances should the responsibility for evaluating health problems in communities be taken away from ATSDR. It is critically important that a federal agency be available to respond to concerns and questions raised by community organizations. While ATSDR has not done this well, the solution is not to throw the baby out with the bathwater but fix the problem and reform the agency so it does its work well.

CHEJ spent several years from 1990 to 1992 working closely with ATSDR to help reform the agency. We took on this task following a meeting with Barry Johnson, then the director of the agency. At the time ATSDR was feeling a great deal of pressure as the U.S. General Accounting Office at the time had begun an investigation into the quality and effectiveness of its work. Our organization sponsored two meetings with ATSDR, the details of which are described in my written testimony. I would summarize this experience by saying that ATSDR learned what people wanted and adopted their language in its literature but the agency did not change what they had always been doing, using inadequate or inappropriate methods to assess health problems in communities. Now 20 years later, little has changed.

CHEJ had a similar meeting in January of 2009 with Dr. Howard Frumkin, then director of the ATSDR. Dr. Frumkin came to our office to seek CHEJ's participation in a national conversation that would, among other issues, seek to improve the effectiveness of the ATSDR in addressing health problems in communities. We shared with Dr. Frumkin our previous experience with the agency and suggest that he begin by looking back at the recommendations that came out of our earlier work. Those recommendations were never acted on and are still applicable today. If the agency had implemented these recommendations, it is very likely there would be no need for a hearing today.

ATSDR's inadequate or flawed health studies, health assessments and health investigations have had a significant impact on communities because decisions are made as a result of these studies that affect people's lives and well-being. These decisions might include whether to require additional cleanup, provide supplemental drinking water, relocate people or take other steps to reduce exposures. None of these or similar actions were taken when ATSDR's studies find nothing or are inconclusive. Such conclusions might be appropriate if the study design were capable of providing a reasonably accurate evaluation of the potential health problems in a study population. Unfortunately, this is not usually the case. Instead, studies conducted by ATSDR consistently ask the wrong questions, use inappropriate comparison groups, are based on incomplete or inadequate information, and use other ill-conceived scientific methods that lead to irrelevant or inconclusive results. Consequently, people who live in contaminated communities are not getting the information and assistance or the medical treatment they need to protect themselves and their children from chemical exposures.

It is difficult to say why ATSDR has acted as it has over a period of more than 20 years. I do feel, however, that much of their behavior can be traced to a lack of respect and interest in listening to and working with impacted communities. ATSDR should seek community involvement and consider the community its partner in developing whatever work is done. I also believe that the agency has been strapped by legislative language that frames its work and restricts its responsibilities and authority.

To address some of these problems, I offer a few recommendations. First, ATSDR needs to meet with and include the community early on before it decides how to respond to the questions and concerns raised by the community. How it responds should be tailored to address these concerns and questions.

Second, ATSDR should be given the legal authority to provide financial resources to communities so they can participate as partners in the design and development of the studies and assessments they do. Perhaps a health assessment grant, similar to EPA's technical assistance grant, could be made available to these communities.

Third, ATSDR needs to acknowledge that the scientific methods and procedures currently used to respond to questions and concerns about increased health problems in a community are limited and rarely can provide accurate and useful information about these health problems. Research is needed to critique the scientific methods and procedures currently used.

And lastly, ATSDR should be given the authority it needs to achieve its mission to take appropriate actions to avoid and end public health exposures.

I have additional recommendations that are included in my written testimony. Thank you for your time and the opportunity for these comments, and I would be happy to answer questions.

[Statement of Mr. Lester follows:]

PREPARED STATEMENT OF STEPHEN LESTER

Mister Chairman, distinguished Members of the Subcommittee, thank you for this opportunity to testify on the policies and procedures used by the Centers for Disease Control and Prevention and its National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (ATSDR) to assess, validate and release public health documents. My name is Stephen Lester and I am the Science Director for the Center for Health, Environment & Justice (CHEJ). CHEJ is a national environmental health organization founded in 1981 by Love Canal community leader Lois Gibbs. We assist people to fight for justice, empower them to protect their communities, and lead national environmental health campaigns.

I would like to address five issues in my testimony.

1) I will provide some background on past efforts taken by CHEJ to reform the way ATSDR investigates and responds to potential public health hazards.
2) I will provide a brief description of how ATSDR's inadequate or flawed public health investigations have impacted local communities that have been exposed to environmental contamination.
3) I will briefly discuss my impression as a participant of the agency's initiative called the National Conversation on Public Health and Chemical Exposures.
4) I will provide brief comments on why ATSDR has failed to adequately protect the public in the past and has been unable to address the issues that have led to these failures for the past two decades.
5) I will provide specific recommendations that I believe are important to help reform ATSDR and help ensure that its future public health products are based on sound science, address critical aspects of potential human health

effects of environmental contamination and assist local communities exposed to toxic substances.

By way of background, I have master's degrees in toxicology from the Harvard University School of Public Health, and in environmental health from the New York University Institute of Environmental Medicine. I have been involved in evaluating health studies and health problems in communities since I was hired in 1978 by the New York State Department of Health to be the Science Advisor to the residents at Love Canal in Niagara Falls, NY. I joined the Center for Health, Environment & Justice in 1983 where I have been the Science Director since. One of my main responsibilities has been to provide scientific assistance and understanding to grassroots community organizations across the country. A key component of this work has been to evaluate both completed and proposed health studies conducted by state or federal agencies in response to requests from communities to address perceived increases in adverse health problems in their community. Over the 27 years that I have been doing this work I have easily reviewed many hundreds of health studies, health assessments, and health investigations, including many conducted by ATSDR. It is with this background and experience that I offer this testimony.

First, I want to make it clear that under no circumstances should the responsibility for evaluating health problems in communities be taken away from ATSDR. It is critically important that a federal agency be available to respond to concerns and questions raised by community organizations. While ATSDR has not done this well in the past, the solution is not to throw the baby out with the bath water but to fix the problem and reform the agency so that it does its work well. I will offer several recommendations later on how this may be done.

I. CHEJ's Efforts to Work with ATSDR

CHEJ (then as the Citizens Clearinghouse for Hazardous Waste or CCHW) spent several years, from 1990 to 1992, working closely with ATSDR to help reform the agency. We took on this task after Barry Johnson who was then the Director of ATSDR came to our office to meet with Lois Gibbs, CHEJ's Executive Director, and myself in early 1990. This meeting occurred at a time when ATSDR was feeling a great deal of pressure about the quality and effectiveness of its work. The U.S. General Accounting Office (GAO) had begun an investigation into the quality of the Public Health Assessments being conducted by the agency and several leading agency officials were called before Congress to address these concerns.

ATSDR was required by the Superfund Amendments and Reauthorization Act of 1986 to complete by December 1988 Public Health Assessments at all 951 Superfund sites that existed at that time. In response to this mandate, ATSDR made a poor decision that Barry Johnson would later acknowledge was a major mistake. The agency chose to sacrifice quality for quantity. ATSDR also acknowledged at the time that the use of data generated by EPA to evaluate the extent of contamination at a Superfund site was often inadequate to evaluate the public health risks posed by the contamination at a site, but they used it anyway. GAO released its final report on the ATSDR's Public Heath Assessments in 1991.

One had to ask why Barry Johnson came to CHEJ at that time in 1990. Was he looking to divert some of the pressure the agency was feeling and show that things were different now? In his own words, Barry Johnson told Ms. Gibbs and I that the agency was "turning over a new leaf."

Recognizing the importance of the work of ATSDR, CHEJ decided to work with the agency and we proposed in a letter to Barry Johnson a series of workshops involving community leaders from sites where ATSDR had conducted either a health study, health assessment, or some health investigation, and key agency staff. The initial concerns that CHEJ had with ATSDR and the proposed plan to conduct the workshops are described in a memo written to Barry Johnson on January 10, 1990. A copy of this memo is included as Attachment 1.

The first meeting was held on June 30, 1990. The purpose of that meeting was to provide communities with the opportunity to express their needs and concerns directly to ATSDR; to provide the agency with the opportunity to explain what the agency does and plans to do in the future; to look at how well ATSDR addresses the needs and concerns identified by the community representatives; and to look at ways the agency and communities can work together to address these needs and concerns. A summary of the meeting is included as Attachment 2.

The participants of this meeting generated a list of concerns/problems that community representatives had with ATSDR; a list of needs identified by the representatives; a list of issues that needed to be addressed, and a series of recommendations. The recommendations included:

- Change ATSDR's Congressional mandate to better and more directly serve community needs;
- Work with local community groups to help get relocation or medical care for those who need it;
- Increase citizen's role in health studies, health assessments, or health investigations—involve groups from the beginning—set up a process that allows for true public input.
- Consider community needs in establishing programs and setting priorities—meet with people/ask them what their needs are;
- Conduct a health study, health assessment, or health investigation that uses objective measures of health damage—stop using risk assessment, especially those that focus on cancer alone;
- Stop doing health assessments that measure only risks based on exposure data; instead conduct studies that answer the question "Is my health affected?"
- Educate family physicians and health care providers about the consequences of chemical exposures.

A second meeting was held in May 1991. A larger number of community representatives participated in this meeting as well as a number of scientists and agency staff. A summary of this meeting is included as Attachment 3. Barry Johnson made a number of commitments at this meeting, some of which were kept, but others were not. This began the deterioration of the working relationship not only between CHEJ and ATSDR, but between many community leaders and the agency. Community leaders expected to see changes in how a health study, health assessment, or health investigation was conducted by ATSDR. Instead, they saw few changes. They wanted another meeting, but ATDSR, who had paid for the first two meetings, wanted to limit a third meeting to 8 to10 people and to limit the conversation to the agency's draft public participation plan that they were developing. People did not agree with this agenda and refused to participate in a third meeting.

I would summarize this experience this way. ATSDR learned what people wanted and adopted the language of the people they had met with. They used this language in their literature to make it sound like they were doing the right thing while they continued to do what they had always been doing—using inadequate or inappropriate methods to assess health problems in communities. In my opinion, ATSDR used this experience to sharpen its image at the expense of meeting community needs. In the words of Dr. Nicholas Ashford, Professor of Technology and Policy at the Massachusetts Institute of Technology and a participant in the second meeting, "ATSDR became primarily concerned with public relations and not in developing public relationships."

Ms. Gibbs and I also had a meeting in January of 2009 with Dr. Howard Frumkin, then director of ATSDR that had a very similar feeling to the meeting in 1990 with Dr. Barry Johnson. Dr. Frumkin came to our office to seek CHEJ's participation in what was described as a National Conversation that would among other issues seek to improve the effectiveness of ATSDR in addressing health problems in communities. We shared with Dr. Frumkin our previous experience with ATSDR and suggested that he skip the national conversation and begin by looking back at the recommendations that came out of the work we did with ATSDR from. 1990 to 1992. Most of those recommendations were never implemented by the agency and they are still applicable today. Copies of the same materials found in Attachments 1–3 were sent to Howard Frumkin following our meeting, but we never heard back from him about these recommendations. If the agency had listened to the community leaders who attended the two CHEJ meetings back in 1990–91 and had implemented the recommendations offered at that time, then it's very likely there would be no need for today's hearing.

II. How the Studies, Assessments, and Investigations Conducted by ATSDR have Impacted Local Communities

Over the years, we have seen many examples of ATSDR's inadequate or flawed health studies, health assessments and health investigations. The impact of these studies is quite significant in the communities where these studies are conducted. Most importantly, decisions are made as a result of these studies that affect people's lives and well being. These decisions might include whether to require additional cleanup, provide supplemental drinking water, relocate people, or take other steps to reduce exposures. None of these or other similar actions are taken when an ATSDR health study, health assessment, or health investigation finds no relationship between exposure and health outcomes, or if it is inconclusive.

The recent report by the President's Cancer Panel also found that "weak, flawed and uncorroborated studies" are a barrier to taking steps to reduce exposures and protect the public. "Efforts to identify, quantify and control environmental exposures that raise cancer risk . . . have been complicated by the use of different measures, exposure limits, assessment procedures, and classification structures across agencies. In addition, efforts have been compromised by a lack of effective measurement methods and tools; delay in adopting available newer technologies; inadequate computational models; and weak, flawed or uncorroborated studies." [1]

Negative or inconclusive findings would logically follow if the design of a study was capable of providing a reasonably accurate evaluation of the potential health risks and health problems occurring in the study population. Unfortunately, this is not usually the case. Instead, studies conducted by ATSDR have consistently asked the wrong questions (Yukon, PA; Pensacola, FL), used inappropriate study design (Elmira, NY; Fort Hall, ID), dilute exposed populations with unexposed populations (Hopewell Junction, NY), suffered from omissions and scientific inaccuracies (Camp Lejeune, NC; Jacksonville, FL), used incomplete and or inadequate information (Midlothian, TX, Frederick, MD), and used other ill-conceived scientific methods that lead to irrelevant or inconclusive results.

Consequently, there have been hundreds of studies in hundreds of communities where the results are inconclusive by design, leading to a complete lack of trust and confidence in ATSDR and in government in general.[2] And as result, people who live in these contaminated communities are not getting the information and assistance they need to protect themselves and their children from the chemical exposures that they suffer. They are also are not getting the medical treatment they need to address their health problems. ATSDR's conclusions also tend to discourage both the individual and the local family physician from further evaluating their health problems.

III. The National Conversation

ATSDR has partnered with the U.S. Environmental Protection Agency (EPA) and the National Institute for Environmental Health Sciences (NIEHS) to create an initiative called the "National Conversation on Public Health and Chemical Exposures." [3] This project is intended to convene a wide range of stakeholders, including community groups, industry, environmental groups and public health groups to develop an "action agenda for revitalizing the public health approach to chemical exposures."

I am an appointed participant to the Scientific Understand Work Group (one of six contributing work groups) of this National Conversation. This process began in June of 2009 when Howard Frumkin was still director of ATSDR. The project is expected to continue until some time in mid 2011. There are some very good people involved in this effort (there are more than 180 participants in the 6 work groups plus another 30 or so on the leadership council) and at this point it would be premature to evaluate the process and its effectiveness. I will say however, that since Dr Frumkin left the project, there has been a noticeable leadership void for the project (no permanent replacement has yet to be named) and many of the participants including myself have raised questions about how the work product of the group will be used and who is the target audience of the final work product. These and related questions are being addressed by the addition of an implementation meeting to the end of the project period. This meeting was not part of the originally plan and there is concern that there is no funding to hold this meeting.

Another observation about the National Conversation is that we have been directed in our work groups to make our recommendations generic and not focused on a specific agency such as ATSDR, even though I and others have raised specific issues to address weaknesses at ATSDR. If this process holds true, I would expect the good work that comes out of this process will not be specifically targeted or necessarily taken up by ATSDR.

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[1] *Reducing Environmental Cancer Risk What We Can Do Now*, President's Cancer Panel, 2008–2009 Annual Report, Bethesda, Maryland, April 2010, Executive Summary, Page ii.

[2] *See Inconclusive by Design, Waste, Fraud, and Abuse in Federal Environmental Heath Research*, Environmental Health Network, National Toxics Campaign, May 1992 and *Centers for Disease Control: Cover-up, Deceit and Confusion*, Citizens Clearinghouse for Hazardous Waste, 1988.

[3] See *http://www.atsdr.cdc.gov/nationalconversation/index.html*.

IV. ATSDR's Failure to Adequately Protect the Public and Address the Issues that have Led to these Failures for the Past Two Decades.

It is difficult to say why ATSDR has acted as is has over a period of more than 20 years. Obviously some staff will have turned over during this time and some staff will have remained. I do feel, however, that much of their behavior can be traced to a lack of respect and interest in listening to and working with impacted communities. Perhaps it is arrogance and disdain for those with less education and perceived knowledge as Barry Johnson, Director of ATSDR from 1986 to 1998, warned a roomful of his staff and peers, "We may carry with us the presumption of education. It is evident in our language—in phrases such as "self- reported" or "anecdotal evidence"—and in our dealings with the non-toxicologists, non-physicians, non-epidemiologists, and non-engineers who live around sites."[4]

Johnson closed his presentation by telling the audience that they should "not discount their experience [the community leaders]. They are our guides, and we should hear them." Good advice. Ironically, this is exactly what ATSDR needed to do then and unfortunately, still needs to do today. ATDSR needs to recognize that in order to solve community health problems caused by exposures to toxic chemicals they need to partner with the impacted community, understand its needs and concerns, and develop a response that meets those needs. Together with the community, ATSDR should define the questions that people want the agency to address. In response, the agency needs to be honest and straightforward with the community in presenting the limitations of the scientific methods available to respond to these concerns and questions. Furthermore, the role and availability of resources needs to be addressed early in the site assessment process. If the most promising study design requires a labor intensive collection of information which will cost an inordinate amount of money, then this needs to be addressed right up front with the community.

ATSDR also needs to avoid the cookie-cutter one size fits all approach to evaluating health risk at a site that has been so popular with agency. This approach is favored because it is safe and helps address the many uncertainties inherent in evaluating the health impact from exposure to toxic chemicals. These uncertainties include specifics about exposure including the level and length of exposure, the susceptibility and vulnerability of the individual, cumulative effects overtime and due to exposure to multiple chemicals, and the special vulnerabilities of children. But these uncertainties should not be used to avoid taking action to reduce exposures and protect public health. As pointed out by the President's Cancer Panel, despite many uncertainties, "in a great many instances, we know enough to act."[5]

The agency has also been strapped by legislative language that frames its work and restricts its responsibilities and authority. For example, Congress said that the agency must conduct a health assessment for every Superfund site in the nation. This seems logical at face value, but the legislation provided little guidance on what should be included in this assessment or how it should be conducted. When most community leaders learn that ATSDR is going to do a health assessment, they immediately think that the agency is going to evaluate or assess some measure of the health of the people who are exposed in the impacted community. In most cases, these leaders are shocked to find out that this is not what happens. Instead, ATSDR's health assessment is little more than an assessment of the risks based on available exposure data. Barry Johnson described the health assessment as the agency's "principle statements on health risk" and that "health assessments are qualitative risk assessments."[6]

When CHEJ meet with Johnson and asked him to change the term "health assessment" because it was inaccurate and misleading, he refused, arguing that he could not change what Congress had mandated ATSDR to do. Consequently, the announcement that a health assessment will be done in a community immediately raises the expectations, and hopes, of the community. When they learn how the health assessment is actually conducted, they are disappointed, often angry and frustrated, which quickly leads to distrust of the agency and of government in general.

Another statute limitation is that EPA is not required to act on the results of an ATSDR health assessment unless the assessment concludes that a site poses a "sig-

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[4] Division of Heath Assessments and Consultations (DHAC) and Cooperative Agreement States Workshop, San Antonio, Texas, March 7, 1990.

[5] Reducing Environmental Cancer Risk What We Can Do Now, President's Cancer Panel, 2008–2009 Annual Report, Bethesda, Maryland, April 2010, Executive Summary, Page vi.

[6] Barry Johnson, "Quantitative Risk Assessment—Experiences and Lessons in Effective Risk Communication," V.T. Covello et al, Plenum Press, 1989, pp. 63–66.

nificant" risk.[7] In these instances, EPA is legally required to take steps to reduce exposures and eliminate or mitigate the risk, though how it does this is not defined. In 1991, when GAO first evaluated the effectiveness of ATSDR's Health Assessments, they found that only 13 of 951 posed a significant risk, a number that is extremely low.[8] It is unclear what criteria ATSDR uses to define this critical legal threshold. It is clear, however, that recommendations to take action at sites that do not meet this threshold are not likely followed by the agency. This may lead to frustration of ATSDR staff and a lack of enthusiasm to research and identify ways to reduce or eliminate exposures if the agency does not have the authority to carry out its recommendations.

There is also a lack of leadership at the top of the agency, not just because there is no current full-time director, but over the years, the agency has lacked a director with vision and a commitment to protecting the health of the public. The agency needs a champion who is willing to fully accept and carry out its mission to "serve the public by using the best science, taking responsive public health action, and providing trusted health information to prevent harmful exposures and disease related exposures to toxic substances."

To the extent that Congress can take steps to remove barriers to carrying out this mission, then I would welcome and encourage these changes.

V. Recommendations for Reforming ATSDR

1) ATSDR needs to meet with and include the community early on before it decides how to respond to the questions and concerns raised by the community. How it responds should be tailored to address the concerns and questions raised by the community. ATDSR should consider the community its partner and jointly develop the scope of work to be done at the site. A similar recommendation was made in 1990.

   Before beginning any work at a site, ATSDR should include members of the affected community in the design and development of any protocol for conducting a health study, heath assessment or health investigation that the agency is considering in response to a request or concerns raised by a community. This same recommendation was made in 1990.

2) ATSDR should consider providing financial resources to communities so that they can participate as partners in the design and development of the study/assessment. Perhaps a Health Assessment Grant, comparable to EPA's Technical Assistance Grant could be made available to community organizations. This same recommendation was made in 1990.

3) ATSDR needs to acknowledge that the scientific methods and procedures currently used to respond to questions and concerns about increased health problems in a community are limited and rarely can provided accurate and useful information about the health problems in a community. Research is needed to critique the scientific methods and procedures currently used to respond to questions about increased health problems in a community.

   ATSDR should overhaul its health study, health assessment, and cluster investigation methods and procedures. The fundamental direction of such studies should be to aid local communities in applying precautionary principles to end potentially harmful exposures. The local community should have the right to veto the undertaking of a health evaluation/investigation. This right should be codified explicitly in federal legislation. A similar recommendation was made in 1990.

4) ATSDR should be given the authority it needs to achieve its mission which is "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." ATSDR should have the authority to order the relocation of residents exposed to levels of toxic chemicals that pose an unacceptable health risk and to take appropriate actions to reduce or avoid public health exposures.

   ATSDR has the authority to declare and respond to urgent public health concerns, and to require EPA to take action on significant risks, but the agency has little if any authority to take action at sites where the risks are not as well characterized or defined, which likely include more that 90% of the sites

[7] U.S. General Accounting Office, *Superfund Public Health Assessments Incomplete and of Questionable Value*, GAO/RCED–91–178, August, 1991.
[8] Ibid.

that ATSDR is involved in. The agency needs to be given the authority to follow through with steps to reduce or eliminate exposures especially in situations where data is lacking or where uncertainty about the risks exists.

5) ATSDR should take a precautionary approach to environmental health. The primary role of a federal health agency should be to identify precautionary measures that could be taken to reduce public exposure to toxic substances. Clear thresholds should be established and adhered to that recommend actions such as relocation or providing alternative water supplies.

6) ATSDR should have its own budget for testing to collect and analyze environmental samples. The agency is too dependent upon data and information generated by EPA that is collected to define the degree and extent of contamination at a site, not necessarily to evaluate the health risks and health impacts posed by a site. With its own budget for testing, the agency would be able to address data quality concerns and to fill in data gaps and inconsistencies. The agency should also be empowered to challenge EPA when it identifies data of poor quality, data gaps, or data inconsistencies. It may also be helpful if ATSDR got involved earlier in the site investigation process in order to have input into the design of the data collection process as part of the Remedial Investigation/Feasibility Study (RI/FS).

7) ATSDR should review and perhaps alter its criteria for establishing if a significant risk exists at a site. It currently appears to have an overly stringent requirement for data to prove past or current significant health risks. A different framework is needed to allow ATSDR to use limited and incomplete data, which will always be the case, to reach conclusions on the basis of the weight of the evidence. It needs to focus more on qualitative information rather than on the kinds of data used by EPA in risk assessments.

8) In considering options to address the community's concerns and questions, ATSDR should be flexible and more creative and consider alternatives such conducting a pilot study to gather information rather than limit their options to a health assessment or other typical response. A pilot study might include conducting specific medical tests to help determine who has been exposed and how severely, collecting blood from a targeted group of residents, or conducting a disease or symptom prevalence study which could provide valuable information to the community and which could be the basis for further study and action. A similar recommendation was made in 1990.

9) There should be independent and timely expert peer review of ATSDR health studies, health assessments, and health investigations. The peer review members should include community representatives as well as scientists.

Thank you for your time and the opportunity to provide these remarks. I will be happy to answer any questions you may have.

Chairman MILLER. Thank you, Mr. Lester.

Dr. Wargo for five minutes.

STATEMENT OF JOHN P. WARGO, PROFESSOR OF ENVIRONMENTAL RISK ANALYSIS AND POLICY, YALE UNIVERSITY

Dr. WARGO. Mr. Chairman and distinguished members of the committee, thank you very much for inviting me. I feel honored to be here today, and I want to share my thoughts with you about the island of Vieques but also the effectiveness of the ATSDR and CDC in providing public health assessments. I would also like to conclude with some recommendations, some directed to reform the science and the quality of analysis done at ATSDR but also to suggest several legislative initiatives that I think are also necessary.

My name is John Wargo, and I spent seven years conducting research on the island, and my research is more fully presented in four chapters in a book just published by Yale Press called *Green Intelligence*.

The ATSDR concluded in 2003 that contaminants released by the United States and allied forces during the latter half of the 20th century posed no significant health to those who live on or formally

lived on the island of Vieques, Puerto Rico. My own conclusions, recognizing that more than 100 million pounds of munitions had been released on that island over a period of nearly 60 years, including nearly 200 different types of munitions, have created a toxic soup, a mess that I have never seen anything similar to in my experience. My conclusions are that the ATSDR's public health assessments, one on fish and shellfish, another on air, another on soils and another on water, contain serious flaws in scientific methods, analyses and interpretations of evidence yet the agency consistently concluded that human health risks are not significant.

In brief, the agency concluded that the absence of evidence of contamination is sufficient to conclude that the absence of significant health effects occurred on the island. However, the poor quality of environmental monitoring and surveillance make it impossible to justify the sweeping declarations of safety that are made by the ATSDR. One problem with the agency is that it rarely has conducted its own research on environmental contamination, human exposure, disease prevalence, and these flaws are carried through to their analyses and conclusions. For example, the ATSDR on Vieques has conducted no human tissue testing, so they have no firm evidence of what exposures may have occurred and whether or not the body burdens of Vieques residents still show evidence of the exposures.

Finally, I would like to suggest that the agency's public health assessments are not peer reviewed, and I would also argue from my analyses that they would not stand up to peer review. They would not be published in high-quality scientific journals.

Congressman Miller asked me several questions, and I wanted to make a couple of comments about the ATSDR's fresh look effort. I had the opportunity to go to CDC's headquarters and to review with them their progress and interpretations of data last fall, roughly six years following the release of their public health assessments. I believe that the ATSDR scientists and administrators realize that their 2003 public health assessments and conclusions of safety were premature and poorly supported by available evidence. Is this really a fresh look? Well, I am not clear about that, and I think that we need to hear directly from them about it. It is certain to me that they are analyzing other data that is now available to them but they are still not collecting human tissue data. They are still not trying to reconstruct human exposure to the chemicals that were released on the island. They have not conducted their own independent testing of plants, chemicals in plants or in fish or in wildlife that can become components of the viequenses' food supply.

I believe there is an underlying cultural problem here that was alluded to earlier. The ATSDR I think has misperceived its intended mission. The public health assessments demonstrate the agency believes that its purpose is to search for conclusive evidence that hazardous chemicals have caused health loss. Since the data necessary to demonstrate and to prove health loss associated with chemical exposures is rarely sufficient, the agency almost always concludes no significant threat to human health and it declares safety. Yet these conclusions are illogical and scientifically flawed. ATSDR may not have sufficient evidence to conclude community

danger but it similarly does not have sufficient evidence to conclude safety.

So I would like to conclude just by referring to certain principles that might help to reform the agency's efforts. One is, they need to track the sources of contamination on the island. There is still no good accounting for what the Navy released, when they released it and where they released it. This makes the scientific process of understanding human exposure and health risks just about impossible. The agency really does need to do human tissue testing. It needs to study disease prevalence. We need fundamental epidemiology on the island to be able to distinguish health outcomes that the population experienced and try to relate those to intensities of exposure. They need to express their findings and critique their data with analyses of the certainty and quality of each component of a risk assessment, and they do not do that.

So in conclusion, I would just like to suggest that the central problem seems to be their predisposition, the need to prove danger, and I suggest that the standard be reversed. The burden of proof should be on the agency to demonstrate a reasonable certainty of no harm. Now, that phrase is taken from the Food Quality Protection Act. Switch the burden of proof on the agency to demonstrate safety, a reasonable certainty of no harm. If they needed to do that, I think we would get a much more thorough evaluation of the data, a much more realistic assessment of patterns of exposure and ultimate health effects.

I am going to close with one thought. I went back this morning and I reviewed the Superfund law. I looked at title 42, chapter 103, subchapter one, section 9604, that describes Congress's intent for the ATSDR. If you read that paragraph carefully, you will find that the agency is directed to understand patterns of exposure, to assess human health risks, to conduct tissue testing when necessary, and all of these requirements of Congress, had they occurred on Vieques, then I don't believe that we would be here today.

Thank you very much for your attention.

[Statement of Dr. Wargo follows:]

PREPARED STATEMENT OF JOHN P. WARGO

My name is John Wargo and I am here this morning to provide testimony to evaluate the public health assessments (PHA'S) prepared by the Agency for Toxic Substances Disease Registry (ATSDR) concerning human health risks on the island of Vieques, Puerto Rico. I also hope to provide my thoughts on what might be done to improve the quality of the CDC/ATSDR's public health assessments for communities lying near Superfund National Priority sites.

I have been a professor at Yale University for the past 25 years, and I specialize in the estimation of human exposure to hazardous chemicals with a special focus on children and women's health. I have conducted research in Vieques, Puerto Rico during the past 7 years. I also have provided advice to several EPA administrators, testified in both Senate and House committees, worked with several National Academy of Sciences committees, provided advice to the Vice President's office, the Food and Drug administration, the World Health Organization, the Food and Agriculture Organization, and I have served on EPA's Scientific Advisory Panel and Review Board for nearly 5 years.

My research Vieques is more fully presented in a book titled *Green Intelligence* that includes 4 chapters on the history and toxic aftermath of the Navy's actions on the island. This book was peer reviewed and published by Yale University Press in late 2009, and I am attaching relevant chapters to today's testimony as background for the committee to review.

Response to Congressman Miller's Question 2:

"Describe your assessment of ATSDR's 2003 environmental health evaluations of Vieques which determined that there were no adverse human health effects caused by U.S. military bombing operations there that have left a legacy of environmental contamination on the island."

1. The ATSDR concluded in 2003 that contaminants released by the U.S. and allied forces during the latter half of the 20th century posed no significant health threat to those who live on, or formerly lived on the island of Vieques, Puerto Rico. My own conclusions are that the ATSDR's public health assessments contain serious flaws in scientific methods, analyses and interpretations of evidence, yet the agency consistently concludes that human health risks are insignificant.
2. In brief, the Agency concluded that the absence of evidence of contamination is sufficient to conclude the absence of significant health threat. However, the poor quality of environmental monitoring and surveillance makes it impossible to justify the sweeping declarations of safety made by ATSDR.
3. The Agency routinely relied on studies previously prepared or data collected by others rather than designing new studies that are appropriate for local conditions and problems. The Agency did collect fish and examined them to identify the presence of hazardous chemicals, however their sampling designs were inappropriate and insensitive.
4. The Agency rarely conducted its own research on environmental contamination, human exposure, and disease prevalence, and flaws in any available studies leads them to conclude there is no credible evidence of a causal relation between hazardous materials and disease within communities that lie adjacent to Superfund sites. ATSDR conducted no human testing on Vieques to determine whether hazardous chemicals released by the Navy were present in the tissues of island residents. Nor did the Agency conduct any original epidemiological studies to understand patterns of disease prevalence on the island. These types of data are fundamentally necessary to understand the relations between hazardous chemicals and human illness.
5. I believe the Agency has overlooked the role of food contamination as a source of human exposure in its health assessments on Vieques. Research on food intake in many island communities demonstrates the importance of fish and shellfish as routes of human exposure to methylmercury. The National Academies of Science concluded in 2000 that the most scientifically defensible limit for human intake of methylmercury is 0.1 ug/kg/day. This is also EPA's recommended limit on daily intake. ATSDR throughout most of this final report assumed in 2003 that a level 3 times higher than the NAS and EPA recommendation is the appropriate benchmark.
6. A careful review of the ATSDR public health assessments reveals an agency determined to find no causal relation between the Defense Departments 60 year history of dropping nearly 100 million pounds of weapons on a small island, and the exceptional incidence of human illness among those that lived through this history.
7. Soil Contamination Public Health Assessment: The Navy and ATSDR failed to collect soil contamination data associated with military operations. The absence of these data prevented them and others from understanding when and where soil might pose a public health threat. This could occur from soil particles exploding into the atmosphere, drifting downwind in the atmosphere, eventually settling on plants, soils, and perhaps open cisterns.
8. Grazing Animals and their Products: The Navy, EPA, and ATSDR neglected research on grazing activities by cattle, goats, sheep, pigs and chickens. Their importance to the diet of Vieques population is poorly understood, but could potentially have been a significant additional pathway of exposure. The Navy leased lands to those who grazed their stock, some in close proximity to the Live Impact Area.
9. The Navy has carefully controlled access to the bombing range in a manner that has precluded the conduct of scientific research by independent scientists such as myself. It is reportedly spending hundreds of millions of dollars in efforts to clear the area of metal wreckage, but little has been spent to understand historical patterns of resident exposure. When the government controls the science, they control the narrative risk to human health. There is a clear need to create an alternative institutional to conduct these health assessments by independent and unbiased scientists.

10. Finally the Agency's public health assessments are not peer reviewed. And I believe that given the limitations I have described in my detailed attachments, they would not withstand peer review in top-tier journals such as Environmental Health Perspectives, or the American Journal of Public Health.

Response to Congressman Miller's Question 3:

"Given your experience over the past year interacting with ATSDR regarding their commitment to take "a fresh look" at available data regarding potential public health threats from toxic exposures to the Vieques residents what lessons do you believe ATSDR has learned, if any, from their original environmental health evaluations?"

1. *Premature Findings of Safety*: I believe that ATSDR scientists and administrators now realize that their 2003 public health assessments and conclusions of safety were premature, and poorly supported by available evidence.
2. *Fresh Look?* The ATSDR may produce update PHA's based upon additional data collected by other government organizations. It is unclear whether the agency intends to collect original data. During our meeting in the fall of 2009 at CDC headquarters in Atlanta, a group of independent scientists strongly recommended that ATSDR collect original data.
3. *Underlying Cultural Problem*: The ATSDR has, I believe, misperceived its intended mission. The PHA's demonstrate that the agency believes its purpose is to search for conclusive evidence that hazardous chemicals have caused health loss.

   Since data necessary to demonstrate the cause of health loss from rarely exist, the agency normally finds "no significant threat to human health", and it declares the safety of surrounding communities. Yet these conclusions are illogical, and scientifically flawed. ATSDR may not have sufficient evidence to conclude community danger, but it similarly does not have sufficient evidence to conclude "safety".
4. *Resource Limitations May be Driving Premature Conclusions*: ATSDR has a budget of nearly $15 million per year to spend on PHA's. Consider for example that 150 Superfund sites require investigation to understand community health risks. This would allow the Agency to spend $100,000 per site per year to conduct research. This limited budget would normally preclude the conduct of original research specifically tailored to individual sites. ATSDR appears to have dealt with its resource constraints by developing generic PHA's that rely on data and analysis previously conducted by others.
5. *Can ATSDR be Expected to Adopt Health Protective Recommendations?* I find this to be unlikely unless additional decision protocols are adopted to guide the agency's data collection, analyses, interpretations, and recommendations. My specific recommendations follow in response to question 4.

Response to Congressman Miller's Question 4:

"Provide any specific recommendations you may have about how ATSDR can help ensure that its future public health products are based on sound science and address critical aspects of potential human health effects of environmental contamination."

Principles for Improving ATSDR Public Health Assessments: ATSDR should:

1. Track the Sources and Movement of Hazardous Chemicals
2. Pay More Attention to Chemical Persistence and Mobility
3. Test Appropriate Media for the Presence of Chemical Residues
4. Understand the Magnitude and Variability of Human Exposures
5. Consider Exposure to Chemical Mixtures
6. Consider Variability in Human Susceptibility: Pregnant Women, Children
7. Conduct Human Tissue Testing
8. Evaluate Disease Prevalence in the Community of Concern
9. Explicitly Evaluate the Quality and Uncertainty of Each Data Source
10. ATSDR's Burden Should be to Prove Safety, Not Significant Risk
11. Establish Rigorous Standards Before Declaring Safety
12. Answer the Question: Is there Reasonable Certainty of No Harm?

13. Recommend Realistic Guidelines for Exposure Reduction.

This concludes my testimony, however I am providing a detailed critique of the 2003 Vieques Public Health assessments in the following four attachments.

Attachment 1: Critique of "Public Health Assessment: Fish and Shellfish Evaluation, Isla de Vieques Bombing Range, Vieques, Puerto Rico", dated June 27, 2003.

1. *Sampling Design:*
   - *Insufficient Sample Sizes*: The size of samples collected and tested for individual species is insufficient to reach any conclusion about the extent and variability in fish contamination among sites. No more than 5 individuals were tested for each species at each site. This small sample size does not permit statistical comparison among locations. Table 7 describes the number of each species collected at each of the 6 sampling sites. For example, only 11 yellowtail Snapper were collected, although they are among the most commonly consumed fish by island residents. At two sites, no Yellowtail were collected, only 1 was collected at another, 2 at another, 3 at another and 5 at the last location. This sampling plan is fundamentally flawed to test the hypothesis that higher concentrations would be found in fish in closer proximity to the Live Impact Area. It also does not take into account intensity or direction of currents, or direction of prevailing winds.
   - *Areas Commonly Fished?* ATSDR did not structure its sampling design based upon knowledge of areas commonly fished by Vieques fishermen and residents, nor did it investigate which species are most likely to be consumed on the Island, compared with those sold off-Island.
   - *Testing Fish Purchased At Markets?* ATSDR collected fish at the market in Isabel Segunda and tested them for the presence of mercury. Yet the Agency has no knowledge of where these fish were caught. These fish might have originated tens of miles offshore from Vieques.
2. *Vieques Islanders' Fish Intake*: Before any conclusion may be reached about the hazard posed by fish contaminated at different concentrations, patterns of fish intake should have been carefully studied. Understanding the species most often consumed and the amounts consumed are both necessary to estimate exposure and health risk. Also some groups such as commercial fishermen's families and subsistence fishermen are likely to have far higher intake of fish than predicted by a random survey of Vieques residents, or by U.S.D.A. national food intake surveys. This has been well demonstrated for Republic of the Seychelles, and other island communities.
3. *Mercury:*
   a. There are important conflicts in the analyses that ATSDR presents to justify its conclusions regarding the safety of consuming fish caught near Vieques.
   b. The key issue is whether mercury exposures exceed the health guidelines recommended by the U.S. National Academy of Sciences (NAS). The NAS concluded in 2000 that the most scientifically defensible limit for human intake of methylmercury is 0.1 ug/kg/day. ATSDR throughout most of this final report assumes that a level 3 times higher than the NAS recommendation is the appropriate benchmark. See Tables D3 and D4.
   c. Using average concentrations of mercury detected in fish collected at 6 locations, all exceeded the NAS recommended limit by 6–11 times for children, and by 3–5 times for adults.
   d. In many instances in the report, ATSDR compares exposure estimates to its recommended limit of 0.3 ug/kg/day. If exposures exceed the limit, ATSDR places a star (*) next to the estimate, and the accompanying note states: "Estimated exposure exceeds health guideline . . ."
   e. ATSDR presents data on Snapper concentrations (Tables D17 and D18) and *in this case only*, they have changed their recommended limit to be in accordance with the NAS recommendation (0.1 mg/kg/day).
   f. Even though both the adult and children's estimated exposure to mercury in snapper is 2–4 times higher than the recommended limit, ATSDR does not highlight the estimate with an asterisk and cautionary language.

g. If ATSDR had employed the lower, more health protective limit, the threat to children, even average Snapper intake appears to place them at significant risk.

h. Given these problems, how can ATSDR conclude: "It is safe to eat snapper every day"?

4. *Cumulative Exposures*: The ATSDR does not address the potential for Vieques residents to exceed safe levels of exposure to contaminants such as methylmercury in fish caught nearby in addition to other sources such as canned tuna fish. ATSDR should explain why it believes that pregnant women and children are safe from typically detected levels of methylmercury in tuna, in addition to mercury detected in Vieques fish. Cumulative exposure should be addressed for other contaminants released by the U.S. military on the island.
5. *Half-life of Methylmercury: ATSDR neglected to consider the extended half-life of methylmercury in the human body*; estimates range between 40–180 days. Half life is defined as the amount of time necessary to reduce the body's concentration by 50%. Given this extended period, frequent fish consumption can cause concentrations to build in the body. Vieques fishermen often consume fish 5 or more times per week, yet ATSDR did not study their intake patterns, or their tissue Hg concentrations.
6. *Uncertainty, Error Estimates, and Statistical Significance*: ATSDR does not follow standard scientific practice and report sources and magnitudes of uncertainty—including error—surrounding estimates of exposure? Nor does the Agency present quantitative estimates of the statistical significance of their findings. This would be difficult and damaging to their conclusions due to small sample sizes.
7. *ATSDR Conclusions*: Despite limitations in sampling design and sample size, the ATSDR reached three aggressive and unsupportable conclusions:
   - "It is safe to eat a variety of fish and shellfish every day."
   - "It is safe to eat fish and shellfish from any of the locations sampled, including from around the LIA and the two sunken Navy target vessels."
   - "It is safe to eat the most commonly consumed species, snapper, every day." (ATSDR 2003 pp. 2–3).
8. *Other Foods*: ATSDR assumes that fish constitute the only significant food that might carry contaminants of military origin to the dinner table. It is well recognized that the Navy leased rights on the Eastern end of the island to graze cattle. Since cattle grazed for years immediately downwind from the Live Impact Area, it seems prudent to consider the potential for metals, explosives, and other contaminants of military origin to be taken up by plants that are in turn consumed by cattle. Due to the propensity of many of these compounds to persist and bioaccumulate, beef and dairy consumption could have been an additional source of exposure. Similarly, other plants used for food and grown in contaminated soils should be considered potentially important pathways for human exposure. The restriction of ATSDR attention to fish seems convenient rather than scientifically justified.
9. *Conclusions:*

   a. The Navy admits responsibility for intense release of munitions and other hazardous substances to the Vieques environment—tens of millions of pounds of ordnance—during the last half of the 20th century.

   b. The ATSDR's conclusions that fish intake by Vieques residents poses no health threat is not supported by the data the Agency relied upon to reach the finding.

   c. Mercury levels detected in fish sampled by ATSDR may pose a specific threat to fetuses, infants, and children, depending on their bodyweights, fish intake, and fish contamination levels. This threat is well recognized by many scientists. The level deemed safe has varied among government agencies, including FDA, EPA, ATSDR, and the World Health Organization. EPA's standards have been the most rigorous.

   d. Detected mercury concentrations result in ATSDR's own human exposure estimates that are 2–11 times higher than maximum levels recommended by both the National Academy of Sciences and the Environmental Protection Agency.

e. Lead, mercury, cadmium, chromium, arsenic, and uranium have all been released into the Vieques environment by U.S. and allied armed forces. These elements are well recognized to hazardous substances, and they have the potential to be absorbed by plants, wildlife, fish and shellfish.

f. The ability of mothers to transfer mercury to unborn fetuses, the low body weight of fetuses and children relative to adults, and the rapid growth and development of fetal and childhood tissues, all combine to make young children especially vulnerable to toxic effects that threaten normal growth and development. Age-related physiological susceptibility is not part of the ATSDR health risk assessment, and it should be fully considered.

Attachment 2: Critique of Vieques ATSDR Water Public Health Assessment

- The Vulnerable Period: The 35 year period between 1943 and 1978 (when a public water supply from mainland Puerto Rico was completed) is the most likely time when the island's population might have been exposed to hazardous compounds released to the environment by the Navy via drinking water. Yet this is also a period when government testing of environmental quality on the island was minimal.
- Absence of Water Quality Testing: The poor history and quality of water quality testing make it difficult to reconstruct a history of exposure with precision. Water supplies on Vieques were not tested routinely for chemicals that were intensively released to the environment by the Navy.
- No New Data: ATSDR did not conduct any tests of its own. Instead, the Agency relied on former studies conducted by the Puerto Rican Department of Health (1999, 1995), the USEPA (1999–2000), the U.S. Geological Survey (1996), and a consulting firm hired by the Navy (1999).
- Most Likely Routes of Exposure: The most probable routes of exposure to chemicals released to the Vieques environment by the Navy include 1) contamination of drinking water wells from airborne chemicals that drifted and settled in the watersheds surrounding municipal wells; 2) contamination of cisterns from airborne chemicals that drifted and settled into the tanks; 3) contamination from Naval use of pesticides and herbicides; 4) contamination from fuel releases-both intentional and accidental; and 5) waste disposal practices.
- No Peer Review: The ATSDR studies are not peer reviewed, remain unpublished, and are often based upon sampling designs and exceptionally small sample sizes (ranging between 1–12 samples). Degradation products were not tested or reported.
- No Dose Reconstruction: The ATSDR did not attempt to reconstruct possible doses experienced by island residents. This normally should be done in a way that accounts for the special vulnerability of fetuses, infants and small children, who normally consume far higher amounts of water per unit of their bodyweight per day. Given uncertainty, simulation modeling would be the most appropriate analytic method to estimate the range of exposures most likely experienced by the island's population.
- Pesticides and Herbicides Neglected: The EPA studies cited by ATSDR routinely neglected to test for pesticides and herbicides. The Puerto Rico DOH did test for pesticides and herbicides in 1995. However, the Navy has not disclosed its use of pesticides and herbicides, and this could help guide water quality sampling designs.
- Cisterns: ATSDR did not evaluate exposures that may have resulted from contaminated cisterns. It is probable that chemical residues from the explosion of ordnance drifted westerly with prevailing winds over inhabited areas on Vieques. It is also probable that these residues settled down in open cisterns, leading to human exposures via drinking water consumption. Exposures via this route were likely higher prior to the completion of the public water supply pipeline from the main island in 1978. Cisterns are still used when power is interrupted on the island, or when water pressure drops.
- Detections of Explosives: ATSDR also reported the presence of RDX (0.04 ppb) and Tetryl (0.05) in the drinking water supplies of Isabel Segunda (0.5 ppb), and RDX (0.04 ppb) in the drinking water of Esperanza in May of 1978, referencing a Naval Surface Weapons Center report (Hoffsommer and Glover 1978; Lai 1978). Neither the Navy nor the ATSDR provide a plausible explanation for these findings, nor did the Navy follow these findings with addi-

tional sampling efforts. This same 1978 study reported detection of RDX above the limit of detection in sea water west of the NAF area. This is significant given the enormous dilution potential of the ocean. Higher concentrations of RDX were then reported in a lagoon, to the west of the NAF, and in surface water runoff from the NAF area. These findings—a declining gradient in concentration of RDX from the bombing range to a nearby lagoon, and then to seawater—suggest a logical pathway of chemical movement from the Live Impact Area to coastal waters.

- Sampling Design: The ATSDR conclusion that "public drinking water supplies pose no health hazard" is not supported by a statistically valid sampling design, and discounts exposures that most likely occurred (given the Navy's findings of RDX and Tetryl in the community water supply) during the third quarter of the 20th century.
- Nitrate and Nitrite: The ATSDR found several wells on the island had high nitrate and nitrite levels, and attributed contamination to either agricultural activity or septic system leakage. Nitrate and nitrite are also common components of military ordnance, yet this was not considered by the Agency.
- Absence of Risk or Absence of Testing? The studies interpreted by ATSDR do not demonstrate the absence of health threat associated with Naval activities. Instead, they demonstrate the absence of the Navy's testing of the community's drinking water supplies.

Attachment 3: Critique of Vieques Air Pathway Evaluation Public Health Assessment

1. *Failure to Collect and Manage Air Pollution Data*: On numerous occasions, the ATSDR concluded that air pollution data was mismanaged by the Navy and therefore provides unreliable information regarding the magnitude and distribution of air contaminants during high activity training periods on the Live Impact Area.

   The following excerpts from the *ATSDR Soil PSA* demonstrate this problem:

   a) "Over the last 2 years, ATSDR has identified two documents indicating that PREQB conducted air sampling on Vieques in 1972 (Cruz Perez 2000; TAMS 1979), but original documentation for this sampling effort apparently cannot be located."

   b) "ATSDR has identified two references suggesting that another air sampling project took place on Vieques in 1978, starting on May 16 and continuing through July (Cruz Perez 2000; EPA 1999). However, original documentation of this sampling project has not been located."

   c) "The Navy's 1979 Environmental Impact Statement (EIS) for continued use of the bombing range documents results from a 2-month air sampling program (TAMS 1979). . . . No information is provided on the sampling methods used or on data quality . . . . ATSDR finds that the measured concentrations from this sampling effort are of an unknown quality, because no documentation can be found describing the sampling methods used or the quality assurance measures taken."

   d) "ATSDR has identified two accounts of an EPA air sampling project that reportedly took place on Vieques in the 1970s (ViequesLibre 2001, ViequesWar 2001). Neither account cites an EPA document where these findings are published or provides critical information ATSDR would need to interpret this sampling project, such as the number and locations of sampling stations, the sampling methods, and the measured air concentrations."

   e) "Based on the best information available, ATSDR has reason to believe that EPA never sampled air on Vieques in the 1970s. Because valid sampling data form the best basis for evaluating the public health implications of exposure to air pollution, ATSDR encourages any individuals with detailed information on past sampling projects to submit them to the agency for review."

   f) "Because no sampling programs extensively characterized air quality on Vieques during live bombing exercises, ATSDR relied entirely on a modeling study to evaluate this exposure scenario."

   Why would ATSDR and EPA fail to collect data during live fire exercises, especially given the intensity of litigation and criticism of these activities by island residents?

2. *Exposures to Releases from Military Training Exercises Using "Live" Bombs*
    a) *Averaging Periods*: The ATSDR has averaged pollution levels over two periods, one year and 24 hours. This may be relevant for chronic respiratory disease prevalence, however it neglects the potential for short term bursts of pollution to exacerbate existing respiratory problems such as asthma, allergies, and chronic bronchitis. Averaging pollution over 24 hours could make short term high intensity releases caused by explosions disappear. However, these episodes may be quite relevant to estimating respiratory distress among the sensitive. This is especially problematic for young children who have immature and narrower airways than adults.
    b) *Particle Size*: As mentioned above, low diameter particles (less than 2.5 microns in size) were not measured. These fine and ultrafine particles stay suspended for longer periods of time, move longer distances, and may become more deeply embedded in the lungs of young children, or others with restricted airway diseases. These finer particles were not measured by ATSDR, the Navy, or EPA. These particles may also act as nuclei for other hazardous VOC's.
3. *Wind Blown Dust*: "ATSDR concludes that wind-blown dust from the LIA on days when bombing did not take place is not a health hazard." Wind blown dust near the LIA is likely to have contained fine diameter particles that are likely to have become airborne under dry and windy conditions. This could have led to range worker exposures to mixtures of chemicals released when weapons exploded and settled to the ground.
4. *Chaff*: "ATSDR can only conclude that the previous chaff usage at Vieques was not greater than 133 tons per year." ATSDR notes that no one has quantified the fate of chaff released above Vieques. Chaff is dropped from aircraft to confuse radar and disguise airborne military operations. "Chaff fibers typically are 25 microns (μm) thick and between 1 and 2 centimeters long". Chaff fibers are visible to the human eye and have the appearance of short, very fine, hair-like fibers. (Naval Research Laboratory 1999)."
    a. Each year ATSDR estimates that 266,000 pounds of chaff may have been deliberately dropped over or near Vieques.
    b. Ground level concentrations of chaff were never monitored by the Navy or other government authorities.
5. *African Dust Storms:*
    a) The Navy suggested that the source of metals and other contaminants on Vieques could have been Sub Saharan dust storms thousands of miles away.
    b) It is difficult to understand why this hypothesis generated more credibility with the Navy than a more plausible hypothesis, namely that airborne chemicals released to the atmosphere could move with prevailing winds to reach island villages, only 6–9 miles away.

Attachment 4: Critique of Vieques Soil Pathway Evaluation Public Health Assessment

1. *Failure to Collect and Manage Soil Contamination Data*: The Navy consistently failed to collect soil contamination data associated with training operations. The absence of these data prevented them and others from understanding when and where soil might pose a public health threat. This could occur from soil particles exploding into the atmosphere, drifting downwind in the atmosphere, eventually settling on plants, soils, and perhaps open cisterns.
2. *Grazing Animals and their Products*: The Navy, EPA, and ATSDR neglected research on grazing activities by cattle, goats, sheep, pigs and chickens. Their importance to the diet of Vieques population is poorly understood, but could potentially have been a significant additional pathway of exposure.

    "Community members expressed concern over the possibility that livestock are accumulating heavy metals by grazing on contaminated plants . . . . To date, ATSDR has not been able to obtain the original data or report that support these findings."

3. *Plant Contamination*: "ATSDR could not quantify exposures from these reports nor draw any health conclusions about whether consuming plants grown in Vieques would result in harmful health effects."

Why would ATSDR not test soil, edible plant tissues, and edible animal products for hazardous compounds released to the environment by Navy activities?

Chairman MILLER. Thank you, Dr. Wargo.

Dr. Edwards for five minutes.

STATEMENT OF MARC EDWARDS, CHARLES P. LUNSFORD PROFESSOR, DEPARTMENT OF CIVIL AND ENVIRONMENTAL ENGINEERING, VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Dr. EDWARDS. Yes, and thank you for cuing up the PowerPoint I will use to support my experiences and observations related to the 2001–2004 D.C. lead-in-water crisis.

The D.C. lead crisis was a historic violation of the public trust by government. Lead in D.C.'s drinking water was very high from 2001 to 2004 due to corrosion of plumbing materials in tens of thousands of homes, apartments, buildings, schools, even the U.S. Congress was impacted. The levels of lead were very high, some of which exceeded hazardous waste levels, and this danger was hidden from the public for nearly three years. When this was revealed in a January 31, 2004, front page *Washington Post* article, there was understandably public concern and outrage because lead is perhaps the best-known neurotoxin. It affects every vital system in the body. The damage is irreversible, and infants and developing fetuses are most vulnerable.

The publication of the *Washington Post* article set in motion five different Congressional hearings, an investigation led by current U.S. Attorney General Eric Holder, lawsuits and an investigation by the GAO, all of which were to be derailed by the CDC.

In early April 2004, the CDC published what they purported was their assessment of the impacts of the high lead in blood on residents of Washington, D.C., and their conclusion was very clear and unambiguous. They stated that although lead in tap water contributed to a small increase in blood leads, no children were identified with blood lead levels above the 10-microgram-per-deciliter CDC level of concern, even in the homes with the highest water lead of greater than 300 parts per billion. In other words, according to the CDC, all health impacts were below their level of concern by definition.

This publication was little more than a cheap publicity stunt. What the CDC did not reveal was that they had data in their possession that 75 percent of the consumers whose blood lead they tested had been drinking bottled water for weeks, months or even a year before their blood lead had been tested, removing all evidence of harm that would have been done. CDC knew about potential forgery in the blood lead data and that thousands of children's blood lead records had gone missing and they further skewed their data analysis, deleted other critical information that could have put their conclusions into some kind of context.

For years, the CDC refused to correct the scientific record, and what is more, they actively blocked any of my attempts to try to

figure out what occurred. They did not release data, records or follow FOIA law. They would not investigate obvious data irregularities and other credible questions I raised, and they did nothing or even encouraged the spread of their misguided conclusions, creating untold harm. So when their report hit the press, the news story about the D.C. lead crisis was it was much to do about nothing and that the real problem was public hysteria because CDC had proved there were no health effects. In Seattle, the CDC study was cited as reason why parents should not be the slightest bit concerned about high level in Seattle schools' drinking water because of the great work CDC had done in Washington, D.C. And I attended workshops and conferences in Europe, Australia and Canada where the CDC work was cited as definitive proof that high lead in water did not cause harm to humans.

Fed up with this stonewalling by the CDC for over two years, I collaborated with Children's National Medical Center, Dr. Dana Best and a Ph.D. in my research group, and we reevaluated using Children's National Medical Center data the effects of elevated blood lead on young children, and what we discovered was that the high lead in D.C. water caused a 240 percent increase in lead poisoning for kids less than 30 months of age in neighborhoods that had the highest lead in water and a greater than 900 percent increase in lead poisoning for infants less than 15 months of age, many of whom were drinking formula made from reconstituted tap water.

So in conclusion, we determined that high lead in water is a public health concern, and this was known 2,000 years ago, and this is the knowledge that CDC's publicity stunt erased from the public consciousness. I have also concluded that there is a culture of scientific corruption in branches of this important agency, and there is no evidence it has the capability for self-correction.

[Statement of Dr. Edwards follows:]

PREPARED STATEMENT OF MARC EDWARDS

EXPERIENCES AND OBSERVATIONS FROM THE 2001–2004 "DC LEAD CRISIS"

INTRODUCTION

I am the Charles Lunsford Professor of Civil and Environmental Engineering at Virginia Tech, where I conduct research at the interface of basic science, public health, corrosion control and environmental engineering. I have published over 100 peer-reviewed journal articles, made hundreds of technical presentations, and have been recognized with numerous awards including a Presidential Faculty Fellowship from the White House/National Science Foundation (1996) and a MacArthur Fellowship (2008). *Time* magazine named me amongst the 4 most important "Innovators" in water from around the world (2004) and just this year Villanova University awarded me the Praxis Award in Professional Ethics.

My undergraduate training in the basic/medical sciences (BS in Bio-Physics), my graduate degree in Environmental Engineering (MS/PhD), and my experiences with the Centers for Disease Control and Prevention (CDC) from 2005 to the present make me highly qualified to discuss key aspects of the agency's public health practices. I have worked on the issue of elevated lead in Washington DC drinking water from 2001–2004, an event widely referred to as the "DC Lead Crisis," since I was hired by the United States Environmental Protection Agency (US EPA) in 2003 to evaluate causes of the contamination. I testified on this issue before the US House Government Reform Committee in March 2004 and have worked on the issue as a volunteer ever since.

Before relating my experiences and observations, I disclose my position on certain matters discussed in this testimony. I believe that in some instances, elevated lead

in US potable water is a public health concern. Other countries have studied this issue, determined that lead in water is a major correlate to elevated levels of lead in children's blood, but have rationally weighed the different needs and decided that other problems are more deserving of public funding.[1] I respect, appreciate and can support such honest and open assessments. I also believe that lead paint and dust hazards pose a serious health threat, and I support all rational efforts to address them. I also believe that the vast majority of scientists and public health officials in the water industry, US EPA, local Departments of Health, and the CDC are conscientious and uphold very high ethical and scientific standards. I believe in the CDC's mission. I also believe it is critically important that the CDC retain the public's trust. My testimony today should not be construed contrary to the above statements. Indeed, I offer today's testimony in hopes of saving the CDC from itself.

My experiences and knowledge are primarily related to a publication entitled **Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water—District of Columbia, 2004**.[2] This paper was coordinated, prepared, and published by the CDC in their March 30, 2004 *Morbidity and Mortality Weekly Report* (MMWR) series. The MMWR series is often called "the voice of CDC" and "is the agency's primary vehicle for scientific publication of timely, reliable, authoritative, accurate, objective. and useful public health information and recommendations."[3] This particular paper is henceforth referred to as the "CDC MMWR." The paper had 21 coauthors, actions of three of whom are discussed in this testimony:

1) Mary Jean Brown, ScD, RN, Chief of the Lead Poisoning Prevention Branch at the National Center for Environmental Health (NCEH), CDC. Dr. Brown prepared the paper.
2) Lynette Stokes, PhD, MPH, who at the time of the paper's writing was overseeing the blood lead testing program at the Washington DC Department of Health (DC DOH). Dr. Stokes was previously employed by CDC's sister agency. the Agency for Toxic Substances and Disease Registry (ATSDR). Dr. Stokes is listed as 1st author of the paper.
3) Daniel R. Lucey, MD, MPH, interim head of the DC DOH. Dr. Lucey was involved in the DC Lead Crisis for just a few weeks before publication of the CDC MMWR. In his public statements, Dr. Lucey made it clear that he did not have experience on lead health issues, and that his actions and responses relied on the expertise of Dr. Brown and Dr. Stokes.

According to the CDC, contributions to the MMWR series "must contain new or original information or guidelines/recommendations that substantially increase understanding of a public health problem."[3]

My testimony begins with a review of what was known about lead in drinking water prior to publication of the CDC MMWR and then gives a brief overview of the DC Lead Crisis. After describing how the destructive impacts of the CDC MMWR were amplified by reckless omissions destined to mislead readers, it briefly discusses some of the intermediate and longer-term repercussions of the publication. Speculation as to the CDC's possible motivation to mislead readers and the public at large, and failure to clearly correct their misleading conclusions for years after being made well-aware of serious problems with them, set the stage for highlighting some of my own experiences with the CDC. The testimony provides substantive insights to deficiencies in the agency's environmental public health practices.

HEALTH EFFECTS OF LEAD IN WATER: BEFORE THE CDC MMWR

Knowledge that elevated lead in water poses a public health concern dates back more than 2,400 years. In 312 BC, Vitruvius noted that ". . . water ought by no means to be conducted in lead pipes, if we want to have it wholesome."[4] Later work on the subject was succinctly summarized on March 5, 2004 in the Congressional testimony of MacArthur Fellow and Johns Hopkins University Professor Ellen Silbergeld, PhD:[5]

> " . . . ***lead exposure via drinking water alone can by itself be sufficient to induce toxicity, especially in young infants***. In a landmark paper in 1967, Sir Abraham Goldberg and his colleagues traced the etiology of a cluster of mentally retarded children in Glasgow to the storage of drinking water in lead lined tanks (Gibson et al 1967). Shannon and Graef (1989) reported the case of an infant poisoned by drinking water with a lead concentration of 130 ppb. EPA considers that '***lead at concentrations of 40 ppb or higher poses an imminent and substantial endangerment to the health of children and pregnant women***'" (bold italic emphases in original).

Dr. Silbergeld's written testimony was accompanied by an extensive list of peer-reviewed scientific papers that linked elevated lead in drinking water to lead in blood, and by extension to adverse human health effects.

Additional research is noteworthy. For instance, to examine the role of (then legal) lead solder as a potential hazard, Ryu et al. (1983) tracked a group of 7 infants fed formula contaminated with 70 parts per billion (ppb) lead and another group of infants formula containing 10 ppb lead.[6] The blood lead of the infants exposed to the lower level of lead increased by 1.1 ug/dL, whereas that of infants exposed to the higher level of lead rose by 8.3 ug/dL (Figure 1). A blood lead level of 10 ug/dL or higher is termed "a level of concern" by the CDC for children less than 6 years of age. Blood lead levels exceeding the CDC level of concern are also commonly referred to as "elevated" or "lead poisoning" in different localities. The blood lead of infants consuming formula with 70 ppb lead rose above the CDC 10 ug/dL level of concern after about 1 month of exposure (Figure 1).

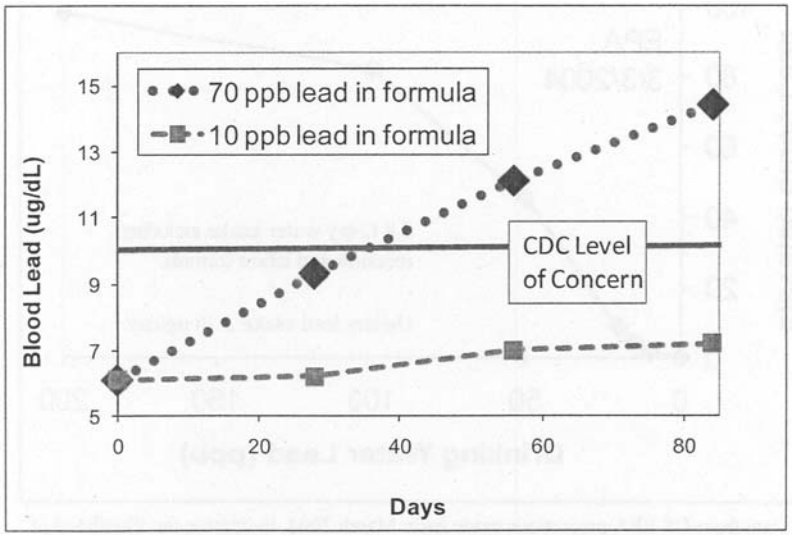


Figure 1. Effects of infant formula contaminated with lead on blood lead of infants (data from Ryu et al., 1983).[6]

Numerous other peer-reviewed research publications were consistent with the Ryu et al. results, including one co-authored by CDC's Dr. Brown entitled "Childhood lead poisoning: Case study traces source to drinking water."[7 8] In that study, an infant whose blood lead rose to 42 ug/dL had no other lead source in the home but contaminated drinking water, and the flushed water contained just 20–80 ppb lead. These publications served as the basis for the US EPA Lead and Copper Rule (US EPA, 1991), the nation's only federal regulation designed to protect consumers from exposure to elevated levels of lead in their drinking water.[9]

In early March 2004, after public disclosure of DC's serious lead in water contamination problems, and several weeks before the CDC MMWR's publication, researchers at the US EPA National Center for Environmental Risk Assessment used projections based on human health data to predict the likelihood of lead poisoning for DC infants consuming reconstituted infant formula for one year. I obtained copies of this work via the Freedom of Information Act (FOIA).[10] The US EPA determined that if lead in DC tap water exceeded about 200 ppb, it was a virtual certainty that a DC infant's blood lead would rise above the CDC's 10 ug/dL level of concern (Figure 2). Even if the drinking water contained just 50 ppb lead, the agency calculated, blood lead levels of nearly 1 out of every 2 infants (i.e., 50% probability of elevated blood lead) would rise above CDC's level of concern. According to an inter-agency e-mail, the US EPA sent Dr. Stokes memos and results summarizing their work as part of an on-going conversation between the US EPA and DC DOH.

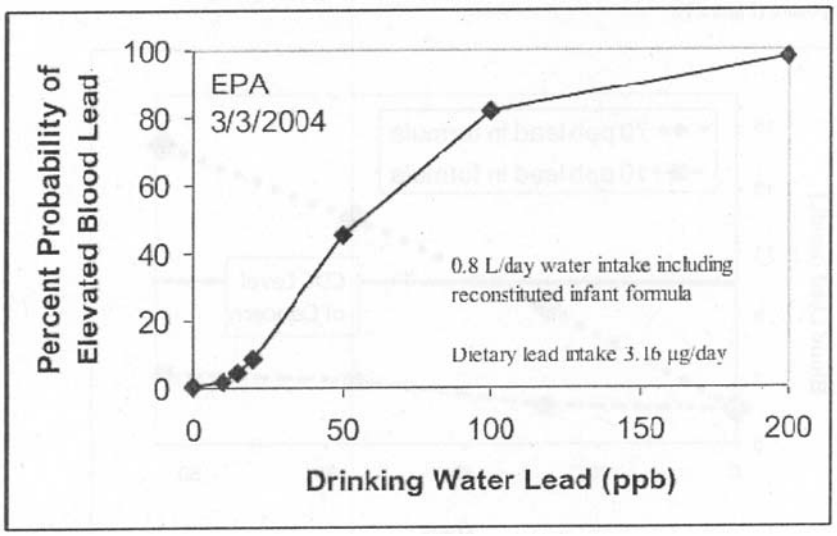


Figure 2. Data from US EPA projections made early March 2004, indicating the likelihood of elevated blood lead in DC infants as a function of water lead level. Infants were assumed to consume reconstituted formula for 1 year of exposure.

As a further point of reference, on February 2, 2005, the US Consumer Product Safety Commission (CPSC) was to classify a lead dose of 175 ug as an "acute health risk" to children: [11]

> "To avoid exceeding the 10 µg/dL level of concern from acute exposure, CPSC staff recommends that *children not ingest more than 175 µg of accessible lead in a short period*" (red underlined emphasis in original).

The new CPSC standard was used as a trigger for recalling millions of products. If this standard, which was applied to jewelry and toys (products *not* intended for human consumption), were applied to lead in water (a product intended for human consumption), the one-time ingestion of 1 liter of water at 175 ppb lead would also be classified as an "acute health risk" due to concerns related to elevated blood lead.

In conclusion, prior to publication of the "new information" in the CDC MMWR on March 30, 2004, there was extensive knowledge in the US public health community that water lead levels in the range of 20–70 ppb would constitute a serious public health concern (Table 1). Canada and the World Health Organization (WHO) also have health-based guidelines of 10 ppb for drinking water.[12 13]

Table 1. Relevant lead in water standards and associated public health guidance as of early March 2004; the key conclusion of the CDC MMWR, published on March 30, 2004; and the CPSC acute health risk criteria of early 2005, as applied to drinking water.

Source	Lead (ppb)	Health Guidance and Warning	Reference
Health Canada	10	Do not consume water	Health Canada (2003)[12]
WHO	10	Health-based guideline	WHO (1993)[13]
US EPA	40	Imminent and Substantial Endangerment to Children	US EPA (2004)[5]
CPSC#	175	Acute Health Risk	CPSC (2005)[11]
CDC MMWR	300	"..no children were identified with BLLs >10µg/dL, even in homes with the highest water lead levels" of greater than 300 ppb	CDC MMWR (2004)[2]

#Translated to water, based on assumed consumption of 1 liter water containing 175 ppb

THE DC LEAD CRISIS AND THE CDC MMWR

The lead levels in DC drinking water from 2001–2004 were unprecedented in modern history. Some samples exceeded "hazardous waste" criteria (>5,000 ppb) and the contaminated water was present in tens of thousands of DC buildings including homes, apartments, offices, schools, daycare facilities and even the US Congress. From 2001–2004 the extent of the problem was hidden from the public by illegal actions, unethical behavior and bungling of numerous government agencies as detailed in investigations led by current US Attorney General Eric H. Holder, the US Government Accountability Office (GAO), hearings before five Congressional Committees, and hundreds of articles in the *Washington Post* and elsewhere.[14–20] Some findings from these investigations and the role of each agency are briefly summarized in Table 2.

Due to the actions and inactions of these government agencies, consumers of DC tap water including pregnant women and their fetuses, children attending schools and daycare centers, commuters, tourists and even members of the US Congress were at relatively high risk of exposure to lead in water hazards from 2001–2004. The public was for the most part entirely unaware of the contamination, and for almost three years did not receive adequate warnings to use simple actions that would reduce or eliminate the hazard (e.g.. use of filters, bottled water or flushing).

Table 2. Key agency involvement in the DC Lead Crisis. For details see references.[14–20]

Agency	Key Role
Washington DC Water and Sewer Authority (DC WASA)	Distributed water to DC consumers. Hid the extent of the contamination from early 2001 by failing to report sampling data that showed high lead in water, firing a whistleblower who tried to alert US EPA to the high water lead levels, and distributing consumer education materials that downplayed the severity of the hazard.
Washington DC Department of Health (DC DOH)	Knew about the lead in water problem in 2002. Head of DC DOH refused to help DC WASA with public health response, and several DC DOH employees were fired for their role in the lead crisis. Dr. Stokes, listed first author of the CDC research which is the focus of this testimony, was coming under scrutiny by the press for not considering water as a possible source of lead poisoning for children throughout 2003, despite personal knowledge of DC's lead in water hazards in 2002.
US EPA Region III (US EPA R3)	Knew about the emerging lead in water problem as far back as August 2001. Approved DC WASA's consumer education language that downplayed the extent of the hazard. Because Washington DC is not a state, US EPA R3 has primacy (or direct responsibility) for problems with the District's water.
US EPA Office of Water (US EPA OW)	Developed well-intentioned regulation on disinfection by-products that prompted Washington DC to switch from chlorine to chloramine disinfectant, which inadvertently triggered the lead contamination.
US Army Corp of Engineers	Responsible for treating the water. Failed to implement a sound corrosion control plan, which coupled with chloramine use, created corrosive conditions when the water came into contact with DC WASA's lead pipes, and the lead-containing plumbing systems of DC residents.
Centers for Disease Control and Prevention (CDC)	Initially portrayed as an uninvolved third party, CDC was responsible for the CDC MMWR, which is the focus of this testimony. The CDC paper concluded that during the lead crisis "no children were identified with BLLs >10 μ g/dL, even in homes with the highest water lead levels."

When the extent of the lead in water problem was first revealed in the *Washington Post* on January 31, 2004,[21] the public was fearful of the harm done to DC's children, and outraged at the responsible agencies' multi-year and gross negligence. Lead, which is perhaps the best-known environmental neurotoxin, affects adversely and irreversibly every major organ system in the human body. Developing fetuses and infants are most vulnerable to harm from exposure.

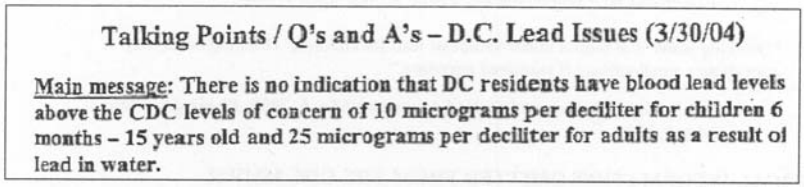
On March 8, 2004, the international law firm Paul Hastings filed a class action lawsuit against DC WASA and DC City Government, and gave formal notice to the US EPA, and the Army Corps of Engineers of a potential lawsuit. The press release stated that the lawsuit was brought on behalf of two young children with lead in

water levels of 435 and 310 ppb, and that potentially tens of thousands of ". . . DC residents have been unwittingly exposed to lead, a serious toxin." [22]

A few weeks later the CDC released the CDC MMWR. purportedly investigating the impacts of the high lead in water on the blood lead of DC residents. Contrary to reasonable expectations based on prior research (Table 1), the CDC paper concluded that no children had experienced elevations to blood lead levels that exceeded CDC's level of concern as a result of the DC Lead Crisis:

> ". . . although lead in tap water contributed to a small increase in BLLs in DC, no children were identified with BLLs >10 μg/dL, even in homes with the highest water lead levels. . . . Water was collected from homes with a high probability of having lead service pipes; the March 2004 BLL screening program was limited to families living in homes with the highest water lead levels, and the routine blood lead surveillance program focused on identifying children at highest risk for lead exposure. For these reasons, the percentages of BLLs >5 μg/dL or >10 μg/dL reported probably are higher than those found in the general population."

In conjunction with the release of the CDC MMWR, CDC also prepared an internal agency "Talking Points" memo produced to me via FO1A (Figure 3). The memo's "main message" was that "There is no indication that DC residents have blood lead levels above the CDC levels of concern . . . as a result of lead in water."



Talking Points / Q's and A's – D.C. Lead Issues (3/30/04)

Main message: There is no indication that DC residents have blood lead levels above the CDC levels of concern of 10 micrograms per deciliter for children 6 months – 15 years old and 25 micrograms per deciliter for adults as a result of lead in water.

Figure 3. CDC MMWR "Talking Points" Main Message.

The CDC's reassuring conclusion brought a collective sigh of relief from government officials and anxious parents. Reinforced at numerous press conferences and in sworn testimony by the paper's DC DOH co-authors, including Dr. Lucey and Dr. Stokes, it rapidly fostered a new—albeit false—understanding regarding one of the best-understood and widely studied environmental health hazards. The "no significant harm" echo chamber reverberated with statements such as the following:

> "Overall, what we have been finding, and again this is primarily from the CDC publication that just came out this week . . . we have not found evidence that lead in the water has increased the percent of elevated blood lead levels in young children, so that is very, very good and important information."

Sworn Testimony of Dr. Lucey to the DC Council, April 1, 2004

> ". . . that's good news, that's good news . . . . the homes we went to with the public health service, that had the highest levels of lead in the water, greater than 300 ppb and this was published last week March 30 in the Morbidity and Mortality Weekly Report. 201 people who live in those homes with the highest levels of lead in the water. Zero. None. Zero out of 201 had elevated blood lead levels . . . ."

Dr. Lucey at the Mayor's Press Conference, April 7, 2004

> "None of the 201 persons we tested who live in homes with the highest measured levels of lead in the drinking water (i.e. > 300 parts per billion (ppb)) had elevated blood lead levels."

Written Testimony of Dr. Lucey, US Senate Oversight Hearing of Drinking Water in the District of Columbia, April 7, 2004

Not to be outdone in exploiting the public relations opportunity that the CDC MMWR created, DC WASA hired a consultant. Tee L. Guidotti, MD, MPH, via a contract with George Washington University, who was to meet regularly with the CDC and DC WASA on DC lead in water issues through at least late 2007. In the immediate aftermath of the CDC MMWR publication, Dr. Guidotti made numerous public statements about the insignificance of very high lead in water levels (>300 ppb):

"Dr. Tee Guidotti . . . has advised the Water and Sewer Authority . . . that: A discernable effect on BPb <blood lead> of children requires at least sustained levels of 300 ppb."

Jerry N. Johnson, former General Manager, DC WASA, Testimony to US Senate Committee on Environment and Public Works, April 7, 2004.

"Drinking water is at most a minor source of lead for children. Drinking water may contribute a small amount if *sustained* exposure."

Tee L. Guidotti report to DC WASA, see also May 6, 2005; *Washington Post*, May 9, 2005.

CRITICAL INFORMATION OMITTED FROM THE CDC MMWR

The public, and apparently some of the agencies themselves, had been successfully duped. The CDC MMWR may have been authoritative but it was not trustworthy—the paper's conclusions were skewed by omission of several critical facts. Just how skewed, was not to be revealed, until my colleagues and I published a peer reviewed journal article in 2009 that proved hundreds (and in all likelihood thousands) of children had their blood lead elevated above the CDC level of concern as a result of exposure to DC's contaminated drinking water from 2001–2004.[23] Our paper was recently acknowledged with an award for Best Science paper appearing in the prestigious journal *Environmental Science and Technology* during 2009.

Details of my initial concerns regarding omission of critical data in the CDC MMWR were provided in two letters to the CDC Office of Scientific starting in 2007. Both of my letters are currently available on-line.[24] I await, and defer to, two forthcoming investigative reports by the US House Committee on Science and Technology and the Washington DC Office of Inspector General for additional information about actions of the CDC and DC DOH co-authors. In this section, I mention 4 representative omissions (which are not necessarily the worst ones) so that the remainder of my testimony can be placed into context. Thereafter, I reveal what I currently know about the authors' knowledge and rationale for each of these omissions.

First, the portion of the CDC MMWR that was to be most cited in testimony and press coverage, involved blood lead testing for a group of 201 DC residents who lived in homes with over 300 ppb lead in their flushed tap water. These residents had volunteered for a special water lead sampling event conducted by DC WASA in 2003, and had been informed that their tap water was severely contaminated (>20 times the 15 ppb US EPA lead action limit) several months to a year before DC DOH began testing residents' blood. By the time their blood lead was collected for the CDC MMWR study in March 2004, the residents had been taking measures to protect themselves from the high lead in water for an extended period of time. Given that the half-life of lead in blood is on the order of 28–36 days,[25] by the time these residents" blood was drawn for analysis, ***the evidence of harm*** would have largely disappeared from their blood. Ironically, in contrast to statements in the CDC MMWR and associated sworn testimony suggesting that the "worst case" of lead exposure had been captured in this study, this particular group of 201 residents tested, were actually amongst the *least* likely groups in the city to show evidence of harm from high lead in water. The CDC's discovery that none of these residents had elevated blood lead, therefore, provided little or no insight into what their blood lead had been months to a year before taking actions to protect themselves.[23]

Second, the CDC MMWR authors did not reveal detailed knowledge, in their possession, proving that virtually all of the 201 residents targeted for their study were taking active protective measures, as anyone would if told months to a year previously that their drinking water was contaminated with astronomical levels of lead. Specifically, a spreadsheet I obtained from the DC DOH via FOIA revealed that for residents who answered a DC DOH questionnaire and had an indicated blood lead collection date, all but 6 (of the 201) were using bottled water or a filter. Of 174 residents who answered a question about bottled water use, 130 indicated "Y" and 44 indicated "N." Assuming that Y meant "yes" (i.e., consistent with the symbols used for lead filter use in the paper and in the spreadsheet), then 75% of the residents who responded to the questionnaire were using bottled water. Moreover. none of the 6 residents who were potentially drinking tap water (without use of filters or bottled water) were children. The only statement appearing in the CDC MMWR that even alludes to some of these critically important facts, was a confusing single sentence that made no mention whatsoever of bottled water use:

"Of the 201 residents, a total of 153 (76%) reported drinking tap water, and 52 households (53%) reported using a water filter."

Sworn verbal testimony by Dr. Lucey, sometimes mentioned the use of water filters but repeatedly emphasized that the researchers had determined that a majority of residents in their study "were drinking tap water." The precise question in the DC DOH questionnaire asking residents about their consumption of tap water is important, and has never been produced to me. For example, the residents may have been asked "how much tap water do you generally consume," which might have caused residents to provide answers based on their experiences in the months to a year before they had been told their flushed water was contaminated with more than 300 ppb lead. If that were the case, the answer might not have any relevance to their water consumption in the weeks, months or year before their blood lead was finally analyzed in March 2004. To my knowledge. Drs. Lucey, Stokes and Brown never once publicly mentioned that their data demonstrated that 75% of their supposedly "worst case" DC residents were drinking bottled water.

Third, at no point did the CDC MMWR authors discuss, acknowledge, or cite a single reference to decades of prior scientific research that unambiguously linked elevated lead in water to elevated lead in blood, and which could have put their novel MMWR conclusions into context. The impact of this omission was amplified by the authors' repeated statements in public press conferences and under oath that virtually nothing had been known about links between lead in water and lead in blood prior to conducting the CDC MMWR study. For example, responding to DC City Council Members' questions about the health effects of lead-contaminated drinking water and with Dr. Stokes at his side, Dr. Lucey asserted that:

> ". . . What we have been doing here in the District of Columbia for about the last 5 weeks, that is, we are trying to generate scientific data to answer that question because the answer doesn't exist in the medical literature . . . we published this article in the CDC MMWR . . . trying to answer the question . . . . What is the correlation between the EPA action level of 15 ppb, or really any concentration of lead in the water, and the effect on health, even as assessed though blood lead levels? It seemed to me the best way to try to answer this question, after not finding the answer in the medical literature, after not finding the answer by talking to lead experts within at the Department of Health or at the Centers for Disease Control that's my answer, to generate the data."

Testimony of Dr. Lucey, DC Council Hearing, April 1, 2004

Indeed, the first lawmaker exposed fully to the picture portrayed by the CDC MMWR enthusiastically asserted that when it came to links between lead in water and lead in blood:

> ". . . . there is no real data out there to see the correlation. So we really do believe, by the enormous amounts of blood testing that we are doing related on this lead in the water issue, we are doing a public service not only for the District of Columbia, but for the United States of America and probably even the World on this issue . . . ."

DC Council Member Carol Schwartz, Mayor's Press Conference, April 7 2004

Taking on the role of medical pioneers, the CDC MMWR authors even spoke about speculative bio-mechanistic theories, which are flatly contradicted in the scientific literature, to support the astounding CDC MMWR "no significant harm" discovery:

> "<Lead from water> may not get into the bloodstream as readily as potentially, inhaling dust, or eating a chip which has large concentrations of lead . . . we're learning that, and we really did not know what we'd see."

Lynette Stokes, *Your Health Matters*, aired May 2004

Fourth, the CDC MMWR omitted knowledge about the high degree of uncertainty, as to which DC residents had what type of service line pipe. The CDC knew that DC WASA's database regarding service line material occurrence was little more than a guesstimate, because the data sent to CDC was grouped into three categories: 1) homes with lead service lines, 2) homes without lead service lines, and 3) homes suspected to have lead service lines. Even these categories grossly misrepresented the utility's knowledge, because DC WASA later revealed that there were thousands of more lead service lines in DC than they initially suspected. DC WASA's underestimation of homes with lead service lines was important because it confounded the CDC's analysis, and also, because residents known to be living in homes with lead service lines have historically been targeted for specialized public health protection by DC WASA and DC DOH. Some of the strongest evidence of

childhood elevated blood lead from water, was later linked to homes in which DC WASA had only suspected had a lead service line.[26]

For the CDC MMWR, the actual blood lead data for residents living in homes with suspected lead service lines were analyzed, but no mention of this analysis, or even an acknowledgement that the data existed, was to appear in the published paper. The analysis indicated that of 144 DC residents tested in homes with suspected lead service lines in 2000 (before lead in water was high), only 12 (or 11.5% of the total) had blood lead > 10 ug/dL. But for 141 residents tested in 2001 (when lead in water was high) 18 (or 18.4% of the total) had blood lead > 10 ug/dL. A similar increase occurred in 2003 versus 2000. The trend in this dataset showing increased incidence of elevated blood lead for these residents, after the lead in water had increased, was contradictory to the conclusions eventually published in the CDC MMWR.

According to the Federal Register (2000), scientific misconduct via *falsification* refers to ". . . changing or omitting data or results . . ." so that the overall presentation is inaccurate.[27] Further, "A finding of research misconduct requires that (a) There be a significant departure from accepted practices of the relevant research community; and (b) The misconduct be committed intentionally, knowingly, or recklessly; and (c) The allegation be proven by a preponderance of the evidence." In response to the question "Aren't there circumstances when omission of data or results is appropriate?," the Federal Register states that:

> " . . . . omission of data is considered falsification when it misleads the reader about the results of the research."

Internal agency documents provided to me via FOIA in late 2009 shed light on important aspects of the authors' knowledge about the omission of data. Although the record is incomplete, it strongly suggests that several CDC MMWR co-authors did not see a draft copy of the paper before a "nearly final" version was distributed by Dr. Brown on March 23, 2004—seven days before the paper was published. Two days before the distribution of the "nearly final draft," one co-author wrote a comment about the study of the 201 residents with > 300 ppb lead in their flushed water. He asked about the government employees who questioned the residents:

> "Did they ask about bottled water."

On March 23, 2004 at 12:04 pm, Dr. Brown e-mailed a copy of the "nearly final draft" to several potential co-authors, with a message that included the following statement:

> "By COB today I need every officer who believes he/she contributed sufficiently to merit authorship to forward an e-mail to Dr. Mary Jean Brown at <e-mail> which states that you've read the final draft, concur with the results, and your involvement is sufficient to merit authorship."

Dr. Brown's e-mail message did not solicit her co-authors' feedback on the content of the nearly final draft. It just gave the recipients slightly less than five hours on a workday, to decide whether or not they wanted to be listed as co-authors. Again, the record in my possession suggests that many of the recipients had never seen the paper prior to this time. Despite these constraints, a few recipients responded with questions and comments, gently revealing concern about some of the key omissions in the draft they had received. Specifically:

One co-author, responding at 1:17 am on March 24, 2004—already well after Dr. Brown's ambitious deadline of "COB"—sent an e-mail response that included several co-authors. asking:

> "Do we want to mention that many of DC residents (couldn't give you #'s though) have been drinking bottled water before any of this went public? Or does that just confound the data some more?"

An e-mail from another co-author, date deleted, but presumably written after the previous comment, stated:

> "I am not sure if the bottled water consumption would skew the data, but it does present another piece that might confuse the reader."

Still another e-mail, date deleted, but written in response to Dr. Brown's March 23 e-mail, revealed that some of the co-authors clearly knew about the long time that had elapsed between the water testing the previous year (i.e., 2003) and the blood lead testing during the month of the paper's writing (i.e., March 2004). It also indicated how the disclosure of this gap in the paper would be important to help the CDC MMWR readers understand "why currently no persons have blood lead levels above the levels of concern":

> "Do you want to point out that the water samples that were tested in many of the homes were done last year, but the blood lead measures were determined this month? Between those two time periods, some people stopped drinking water supplied by WASA; some people starting using filters, and some people had the lead supply lines to their home replaced before blood lead levels were measured. **The point is that this may help to explain why currently no persons have blood lead levels above the levels of concern**" (bold emphasis added).

The fact that the above remarks were unsolicited suggests that the co-authors who took the initiative to write them may have felt especially uncomfortable with the omissions. Moreover, it may explain their rather passive tone and unassertive suggestions for changes. It may also be the case that other co-authors had similar concerns, or even other concerns, but Dr. Brown's e-mail indicated that there was no time or even the opportunity to raise them. I have no evidence that Dr. Brown ever responded to any of the above co-authors. However, in the end, Dr. Brown did not reveal the important facts the authors possessed, and which are clearly mentioned in the above e-mails, in the published CDC MMWR. Instead, she proceeded to publication with a version of events, that was, at a minimum, a reckless presentation of what the blood lead level data meant.

In relation to her decision not to make any mention of bottled water use. in 2009 Dr. Brown shared her rationale via e-mail to a reporter, who forwarded the answer to me for comment:

> "This was not included in the report because CMDR Tim Coté, US Public Health Service, a partner in the investigation. had reported that he found on average only a 1 μg/dL difference in the average BLL comparing those who did drink water with lead levels greater than 300 ppb to those who did not (4.6 compared to 3.6), **making the information about use of bottled water incidental to the overall findings. CMDR Coté planned to publish these data himself** . . ." (bold emphasis added).

Neither of Dr. Brown's reasons for omitting this critical information are sound, either ethically or scientifically. Certainly, the fact that 75% of the residents in her study were using bottled water is not "incidental" to the results of the research, and the revelation that the authors were entitled to withhold this critical information from the current paper for a possible later publication is outrageous.

Other critical omissions occurred not by failing to put important information into the paper, but by actually editing important information out. For example, before the "nearly final draft," a version of the CDC MMWR featured the following conclusion about blood lead levels for residents in homes with "suspected lead service line" before and after lead in the city's drinking water spiked:

> "In addresses with suspected lead service lines, the percent of test results > 10 ug/dL showed an increase, however, there were fewer than 50 test results available for these addresses between 2001 and 2003 . . ."

This version of the paper also included a graph that illustrated the incidence of elevated blood lead for residents living in "suspected lead service line" homes increasing from 11.5% in 2000 (when lead in water was low) to 18.4% for 2001 (when lead in water was high). The incidence of blood lead > 10 ug/dL was also much higher in homes with suspected lead service lines, versus lead service lines, which might also be important, given that homes with lead service lines had obtained more public health interventions not offered to homes with suspected lead service lines. Sometime before the "nearly final draft," the above facts and associated text were deleted. Again, all mention of "suspected lead service lines" was deleted from the CDC MMWR.

Three more important editorial changes even occurred **after** the 3/23/2004 "nearly final draft" had been signed off on by the CDC MMWR co-authors. Such changes clearly violate CDC policies for clearance of publications. For example, the "nearly final draft" featured the sentence:

> "Elevated levels of lead in the water are a public health concern."

This key sentence was completely deleted from the CDC MMWR.

The "nearly final draft" version of the paper had also qualified the conclusion about the lack of elevations in blood lead levels above 10 ug/dL:

> "However, neither longitudinal surveillance data nor BLL testing in addresses with the highest water lead levels indicate that exposure to lead in tap water in Washington, DC resulted in blood levels above 10 ug/dL, **although this cannot be completely ruled out**" (bold emphasis added).

In the published paper, the same conclusion appeared without the qualifier, and with a change of words that created a major shift in perception and certainty:

> "The findings in this report indicate that although lead in tap water contributed to a small increase in BLLs in DC, no children were identified with BLLs >10 μg/dL, **even in homes with the highest water lead levels**."

Replacement of "although this cannot be completely ruled out," with "even in homes with the highest water lead levels." was a regrettable shift in emphasis.

The "nearly final draft" version of the paper, also had at least one clear reference to a citation about prior research linking lead in water to lead in blood, which stated:

> "Consistent with previous work . . . <water lead > levels well above the EPA action level of 15 ppb may result in an increase in the percent of blood lead levels > 5 ug/dL.[5]"

Although none of the documents in my possession allow me to see what reference "5" is, this statement and citation to prior research were also completely deleted from the published CDC MMWR. The deletion supported later public presentations that virtually nothing had been previously known about links between lead in water and increased blood lead.

Ultimately, others will have to pass judgment on actions of the CDC MMWR authors in relation to these and other omissions of data, and other critical information from the CDC MMWR. But the record is clear, that at the height of a historic public health crisis, the CDC crafted an account of the public health impact that was destined to mislead not only the public, but also the public health and scientific communities nationally and internationally about the lessons learned from the DC Lead Crisis. The CDC not only deleted the statement that "Elevated levels of lead in the water are a public health concern" from the wording and skewed presentation of research results in the research paper, but in the process, deleted this fact from the public consciousness. Even more egregious than possible falsification and scientific misconduct, is CDC's repeated refusal to correct the scientific record, or highly misleading statements made about the work (as will be revealed in the sections that follow), because their inaction magnified and perpetuated the CDC MMWR's harmful repercussions.

IMMEDIATE REPERCUSSIONS OF THE CDC MMWR CONCLUSION

The damaging repercussions of the CDC MMWR conclusion and the associated public relations campaign (including the CDC "Talking Points" memo) cannot be understated. Some of the impacts were realized even before the paper was published. Specifically, on March 18, 2004, Dr. Brown sent a draft copy of the CDC MMWR to her US EPA R3 contact with the subject line "Re: EPA cite for 40 ppb." Shortly after Dr. Silbergeld's testimony on March 5, 2004, Dr. Brown had queried US EPA about their unambiguous health warning concerning the dangers of elevated lead in water, which was featured prominently on the agency's website in 2 locations:

> ". . . lead at concentrations of 40 ppb or higher poses an imminent and substantial endangerment to the health of children and pregnant women."

By transmitting the draft CDC MMWR, Dr. Brown communicated to US EPA the obvious: that the forthcoming CDC publication would find no evidence for elevated blood lead in DC children who had been exposed to water lead levels far above the US EPA's 40 ppb threshold. Days later, on March 26, 2004, US EPA R3 and US EPA HQ, who were under intense criticism for their own role in the DC Lead Crisis, and all too willing for an excuse to hide their true understanding of health impacts of elevated water lead on children, removed all versions of the 40 ppb warning from their websites without any announcement or explanation. Earlier that week, responding to concerns of a US EPA scientist about the dubiousness of certain statements relating to the plumbing sources of lead in DC water, a US EPA R3 manager frankly revealed the agency's vulnerable state of mind at the time:

> ". . . this is being driven as much by public relations and politicians as what makes sense most other ways."

Rick Rogers, Chief of the Drinking Water Branch, US EPA R3, March 23, 2004

At around that same time, US EPA R3 posted confusing and ambiguous information about the health effects of 15 ppb lead, on a special web page that the agency designed for DC residents:

> "The Action Level for lead is 0.015 milligrams per liter (mg/1) which is equivalent to 15 parts per billion (ppb). For copper, the Action Level is 1.3 mg/1 or

> 1,300 ppb. This Action Level was not designed to measure health risks from water represented by individual samples. Rather, it is a statistical trigger value that, if exceeded, requires more treatment, public education and possibly lead service line replacement" (*http://www.epa.cov/dclead/oversight.htm*).

The US EPA R3 statement that the 15 ppb lead action limit "was not designed to measure health risks from water represented by individual samples" was then cited repeatedly by the CDC MMWR authors in sworn written/oral testimony under oath starting April 1, 2004. The fact that this new "public health message" had been specially crafted for DC and, to my knowledge, was not replicated on any other US EPA web pages, was never revealed to the public. Upon hearing Dr. Lucey read US EPA's confusing message in the immediate aftermath of the CDC MMWR publication, one reporter wrote in amazement:

> "This incredible information was offered by the city's interim medical director, Dr. Daniel Lucey just hours before a U.S. Senate committee held public hearings on the issue of the city's drinking water. Lucey seemed as baffled by the website admission as TBR. If the EPA standards don't measure the health risk, why have them? How can there be an action level, triggering specific action by state and local officials, when the health risk level hasn't been determined? Is the EPA engaging in CYA (cover your @#$) or does it really not know what level of lead contamination constitutes a risk for individuals? . . . The EPA's admission that it is completely ignorant is unconscionable."

The Barras Report (TBR), April 10 2004

The combination of: 1) the CDC MMWR's skewed "main message" that exposure to more than 300 ppb did not elevate residents' blood lead above levels of concern, 2) the authors' failure to cite, discuss or acknowledge prior contradictory human health research in the CDC MMWR or in public testimony, and 3) the US EPA's removal of the agency's 40 ppb health warning and dissemination of confusing new language, created a public relations coup that protected the agencies' interests at the expense of public health.

The CDC MMWR was immediately cited by revisionists, who defended the agencies responsible for the DC Lead Crisis, and concluded that the real problem was the public's uninformed "hysteria":

> "The ongoing hysteria about lead in D.C.'s drinking water is much ado about nothing, according to a new report from the Centers for Disease Control and Prevention . . . Despite this three-ringed media-lawyer-government circus, there is no actual "problem." No health effects whatsoever have been attributed to the lead in D.C.'s water . . . the EPA can reasonably claim "no harm, no foul" with respect to the unintended consequences of its actions this time." (*http://www.washingtontimes.com/commentary/20040405-095052-3607r.htm*)

This "no harm" message was delivered brazenly to the US Congress in May 2004, when an invited witness used the CDC MMWR to assert that while DC did not do the best job of informing the public about the 2001–2004 contamination, the agencies involved had been proven correct in trying to prevent citywide panic by downplaying the dangers of the unprecedented lead in water elevations and by hiding information from the public:

> "The notification provisions of the Safe Drinking Water Act are also too inflexible. Every community must notify the public when violations occur. . . . the problem is that these notifications are not educating people. Instead, they are being used to trigger alarm scenarios that are amplified by the media. The resulting crisis mentality is not educating the public, it's scaring them needlessly . . . . I am not saying they did the greatest job on earth . . . It is worth noting that D.C. was correct in its assessment that the lead issue didn't warrant a panicked response. The science and the history related to lead exposure strongly indicates that lead in drinking water—even at levels that are multiple times higher than federal standards—does not warrant the frenzied reaction we've seen in D.C. A recently released Centers for Disease Control and Prevention (CDC) study reinforces these findings. It found that the elevated lead levels in D.C. water did not raise the level of lead in anyone's blood to a level of concern."

Statement of Angela Logomasini, Competitive Enterprise Institute, Testimony to US House Government Reform Committee, May 21, 2004

The CDC MMWR was also prominently cited in, and clearly tempered, all subsequent investigations into the DC Lead Crisis in Congressional Hearings, the GAO investigation, and newspapers.[16–20] Afterall, if the CDC had proven that under the

worst case in Washington DC no one experienced blood lead elevations above their level of concern, then the potential health implications of the DC Lead Crisis were also "below concern" by definition. What little debate there was about health effects, was relegated to nebulous discussions about "how safe is safe," and the possible impacts of lead on health if blood lead had been only "slightly" elevated (but well below the CDC level of concern).

LONGER TERM REPERCUSSIONS OF THE CDC MMWR

The CDC MMWR was intended to influence decision makers. The CDC itself notes that the MMWR readership ". . . consists of physicians, nurses, public health practitioners, epidemiologists and other scientists, researchers, educators. . .,"[3] and as was emphasized in the CDC MMWR "Talking Points" memo:

> "The use of complementary data, in this case existing childhood blood lead surveillance data combined with current BLLs in residents of homes with the highest water lead levels, provided important information for decision makers. Such data are essential to identifying and responding to populations at risk."

Dr. Brown herself provides a first-hand illustration in how the "important information for decision makers" was to be applied henceforth in the public health community. On July 16, 2004, when lead in DC water was still astronomically high but the CDC MMWR had been solidly embraced and had gone unchallenged for over three months, Dr. Brown e-mailed CDC MMWR co-author Dr. Stokes to affirm that the DC Lead Crisis was effectively over. The first sentence of her e-mail read:

> "Now that there is a better understanding of the public health impact of lead in the drinking water in the District, I hope we will be able to focus on the issue of lead-based paint hazards."

In the aftermath of the CDC MMWR, Dr. Brown also applied her wisdom to edit a memo entitled "LEAD, WATER, PAINT AND CHILDREN." Excerpts of the memo read:

> "Childhood lead poisoning is making headlines once again, this time because of the drinking water scandal in Washington, DC. . . . At the same time, policy makers and parents alike must keep in mind that drinking water is only one way that children are exposed to lead. Lead-based paint and dust hazards in children's homes pose far greater risks to children than lead in drinking water . . . . The higher lead levels in the District's water over the past three years have undoubtedly raised children's lead levels, probably by an average of one or two micrograms per deciliter. **Of course, children who drank water with lead levels many times the EPA action level may have experienced greater elevations**" (bold emphasis added).

Dr. Brown's written editorial comment regarding the bold sentence above? "I guess I wouldn't say this."

After the CDC MMWR had eliminated lead in water as a public health concern, the possibility that "decision makers" would learn anything useful from the DC Lead Crisis relative to mitigating lead in water hazards vanished. Investigative reporting by the *Washington Post* in late 2004, demonstrating that numerous water utilities from around the US were conducting misleading testing of lead in water, created relatively little impact locally and nationally.[28] The Lead Free Drinking Water Act,[29] a Congressional bill that had gained momentum in the early days of the DC Lead Crisis to fill obvious gaps in the US EPA Lead and Copper Rule, failed on three separate occasions (2004, 2005, 2007). The Paul Hastings lawsuit was dropped. And Washington DC's first ever lead poisoning prevention bill was passed in 2008, only after the DC City Council eliminated all references to drinking water that had been recommended by key members of the District's lead poisoning prevention community.

The US EPA, relieved by the CDC findings and by the determination that they could reasonably claim "no harm, no foul," cited the research repeatedly. Eager for even broader coverage of the CDC MMWR conclusions, a US EPA R3 employee wrote to the CDC:

> "One story that should be told to a larger audience is the results of the historic blood lead level analysis . . . I thought a good way to do that would be the development of a short paper summary of those results either as a joint EPA/CDC paper or just CDC or CDC and DC DOH."

E-mail from Rick Rogers, Chief of the Drinking Water Branch, US EPA R3, January 7, 2005

US EPA R3 even offered to hire sub-contractors to assist with the writing of this paper. When CDC did not take up the offer, US EPA R3 went ahead on their own, and paid for the creation and distribution of blood lead fact sheets and other materials re-hashing the results of the CDC MMWR and other misleading information, at least some of which was later proved false. CDC reviewed and approved these materials, which featured the following conclusion:

> "**Residents with high lead levels in their tap water did not have elevated blood lead levels**. DC DOH also tested people who live in homes with elevated lead in their tap water (over 300 ppb). Of the 201 residents from 98 homes with elevated lead in their water, no children aged 6 months to 15 years had blood lead levels over 10 mg/dL."

Revised version of blood lead fact sheet accessed May 10, 2006 at *http://www.epa.gov/dclead/BloodLevelsFactSheetlO_06_rev.pdf*

Most personnel at the responsible agencies were not held accountable for their role in the crisis, and some who were partly responsible for its precipitation and handling, were even rewarded. In March 2005 the US EPA R3 "Lead Response Team" received the highest recognition the agency offers for outstanding employee performance, as announced in an e-mail from the Director of the US EPA R3 Water Protection Division:

> "I am very pleased to report that . . . members of the DC Lead Response Team . . . took the Gold!!! . . . The Gold Medal is the highest Honor Award granted by the Agency. It is . . . for distinguished service of major significance to environmental improvement and to public service."

Jon Capacasa, US EPA Region III, March 22, 2005

More than matching US EPA's eagerness to celebrate the landmark discoveries in the CDC MMWR, DC WASA gave its own regurgitation of the "no significant harm" conclusion:

> "The results of the tests confirmed that there was **no identifiable public health impact** from elevated lead levels in drinking water." . . . ."It is important for customers to understand that although environmental lead exposure can be very hazardous over a long period of time, large numbers of tests conducted by the D.C. Department of Health in 2004 have detected **no measurable health effects** from potential exposure to lead in drinking water in the District of Columbia." (bold emphasis added)

DC WASA Web page and Mailing to Consumers, January 10, 2006

To further enhance the visibility and scientific credibility of the CDC MMWR's "historic blood lead level analysis," starting in 2005 DC WASA funded Dr. Guidotti to re-package the CDC MMWR data and other misleading information into a peer-reviewed publication. Fortified with an erroneous timeline and numerous additional inaccuracies and omissions, the Guidotti paper—published in 2007—effectively rewrote history and portrayed DC WASA's and DC DOH's management of the DC Lead Crisis as a model public health response. Following in the pioneering footsteps of the CDC MMWR, Dr. Guidotti's main conclusion was that "There appears to have been no identifiable public health impact from the elevation of lead in drinking water in Washington, DC."

The Guidotti paper came under fire in 2009. In response to press coverage that raised serious questions about the integrity of the work, Dr. Guidotti himself e-mailed a "Dear Colleague" defense, which stated that his paper's conclusions had received the CDC's stamp of approval:

> "The data are valid and the conclusions were agreed upon by the Department of Health, EPA, and CDC."

Tee L. Guidotti, e-mail communication to "Clean Water Network," Feb. 2, 2009

At the request of an Independent Review Panel that examined only two of numerous concerns about the integrity of the Guidotti paper, the "no identifiable public health impact" conclusion was eventually removed, and Dr. Guidotti himself apologized for writing the unfounded statement. Remaining allegations about the Guidotti paper have not been addressed (for the complete list of allegations, see letter to the journal *Environmental Health Perspectives*): [24]

The dangerous "lesson" of the DC Lead Crisis as packaged in the CDC MMWR began to achieve its goal of influencing decision makers and policy, and spread quickly to cities across the US and even internationally (Figure 4). A pattern formed. Whenever a significant problem with elevated lead in potable drinking

water of homes, schools or other buildings was discovered, local public health officials and reputable scientists referenced the conclusions of the CDC MMWR as the most authoritative and—in the understanding of many—"only" reliable information on the subject. Again and again, consumers that had just learned about risks of lead contaminated water in their community, were assured that consumption of over 300 ppb lead in Washington DC had not caused an increase in blood lead of concern.

Clearly, the main message and unambiguous conclusions of CDC's Chief of Lead Poisoning Prevention, Dr. Brown, had been transmitted down through the chain of command of the public health community. The fact that individuals with expertise in science and public health accepted the preposterous absurdity that consumption of lead in water over 300 ppb did not elevate the blood lead of even a single child over the CDC's level of concern, despite the scientific understanding that existed prior to 2004 (Table 1 and associated discussion), is testament to the enormous persuasive power that the CDC wields over the public and the public health community. When the CDC's research is based on sound scientific reasoning and reliable data, this power can be wielded to great benefit. But when it is based on faulty reasoning and misleading data it can create untold harm. This was the case with the CDC MMWR.

"Parents should not be overly concerned about lead in Seattle schools' drinking water because it is unlikely any child has been harmed ….The chances of neurological damage are "extremely, extremely low," says Dr. Catherine Karr, director of the Pediatric Environmental Health Specialty Unit at the University of Washington. …A public water utility in Washington, D.C., discovered that 163 homes with lead service pipes had lead levels over 300 ppb in flushed-water samples from their taps….None of the adults or children had an elevated blood lead level, even though most reported drinking tap water."

("Seattle Schools Lead Danger Disputed," *The Seattle Times*, July 16, 2004, http://seattletimes.nwsource.com/html/education/2001981032_lead16m.html)

"The Board of Water and Light's effort to replace lead service pipes to 14,000 Lansing area homes understandably raised concerns regarding the potential threat of lead exposure for persons consuming BWL water. However, our evidence suggests this community-wide concern has reached an unjustified level. …our water supply represents only a marginal threat, if at all. …dramatic data come from a U.S. Centers for Disease Control and Prevention study in Washington, D.C. That study found that among 201 residents from 98 homes with water lead levels exceeding 300 ppb, no one - child or adult - had a blood lead level that was above the CDC's level of concern… We all should be concerned about the health threat from environmental lead. But the scientific evidence shows that lead in water makes, at best, a marginal contribution."

(Dr. Dean Sienko, *Lansing City Pulse* [Editorial], September 5, 2004)

"…a joint study by the D.C. Department of Health and the Centers for Disease Control and Prevention (CDC) published in March 2004….. described efforts …to conduct blood lead monitoring for residents of homes whose drinking water test indicated a lead concentration greater than 300 ppb. None of the 201 residents tested were found to have blood lead levels exceeding the levels of concern for adults or children, as appropriate."

Testimony of John Stephenson, GAO, US House Subcommittee on Environment and Hazardous Materials, July 22, 2004

"Montrealers living in homes whose lead levels exceed provincial standards don't have anything to worry about, says McGill chemistry professor Joe Schwarz. "The best studies ..surveyed really large numbers of homes..in Washington, D.C., ...they got thousands of people to actually give blood and they found that although the water level was sometimes as high as 300 parts per billion, which is astounding, it didn't influence the blood levels."

(Joel Goldenberg, "No worry on water," *The Suburban*, 2007)

Figure 4. Representative quotes of those applying the CDC MMWR to public policy and health messaging.

SPECULATION REGARDING CDC's MOTIVATION

Dr. Brown's actions, and those of the CDC, to allow such an egregious and historic violation of basic scientific principles, and to jeopardize the public's health and trust, are mystifying. In this section I highlight information that might help shed light on some of the reasons behind the unfortunate decisions that were made.

The dramatic reduction of blood lead levels in children over the last few decades is a public health triumph. Phase-outs of lead in gasoline, lead solder in canned food tins, lead paint, and reduced levels of lead in drinking water due to the Lead and Copper Rule created landmark improvements in public health. I would be the first to acknowledge Dr. Brown's contributions to this spectacular success story. However, childhood lead poisoning has still not been eliminated and further work is clearly needed.

One would assume that the CDC Lead Poisoning Prevention Branch would exert leadership to ensure that all lead health threats are acknowledged properly and addressed as best as possible within existing financial and regulatory constraints, but I do not believe that this is how the CDC is approaching childhood lead poisoning prevention today, or did so in the past. For example, historical accounts of US EPA's efforts in the early 1990s to regulate lead in drinking water reveal that the then CDC director of the former Center for Environmental Health ". . . railed against doing much in drinking water because he did not want to disarm lead in paint."[30] The same viewpoint, that health concerns related to lead in water somehow compete with and threaten the CDC's efforts to address lead in paint, seem to persist at the CDC to this day.

Almost a decade after the passage of the US EPA Lead and Copper Rule of 1991, a President's Task Force adopted a strategy to eliminate childhood lead poisoning by 2010. The focus was the elimination of lead paint hazards. Underlying the narrowness of the Task Force's approach was the assumption that "The U.S. Environmental Protection Agency (EPA) has . . . placed strict limits on the amount of lead in drinking water . . . ," and thus that lead at the tap was already being addressed.[31] Such misunderstandings of the scope and effectiveness of the US EPA Lead and Copper Rule also permeate the CDC's literature. In reality, the US EPA Lead and Copper Rule does not put any limit whatsoever on the allowable lead in residential tap water (9% of collected samples can be any value whatsoever), and the regulation does not address the vast majority of child care centers and schools. Indeed, a recent 2009 *Associated Press* article demonstrated that lead levels in thousands of schools nationwide have problems with elevated lead in water,[32] and many schools have some taps dispensing water lead concentrations well over the CPSC acute health threshold or even hazardous waste levels.[33]

Maintaining a strict focus on lead paint as the primary cause of childhood lead poisoning, even at the expense of potentially serious non-paint lead sources, seems to guide much of the CDC's and Dr. Brown's work and reasoning. Characteristically, a few years ago, the Chief of the CDC's Lead Poisoning Prevention Branch responded to a peer-reviewed article about the relationship between lead in blood (BPb) and lead in contaminated soil by castigating the researchers for, amongst other things, not placing adequate emphasis on lead paint. In her critique, Dr. Brown mentioned the article's failure to cite ". . . the compelling body of scientific evidence demonstrating that deteriorated lead-based paint and the contaminated dust and soil it generates is highly correlated with BPb levels in children."[34]

The perplexed authors responded that the subject of their paper was lead in soil, not lead in paint, and that:[35]

> "We are concerned that people working at agencies that should champion the reduction of lead exposure do not appreciate the fact that multiple sources of lead have accumulated in urban environments and that all major sources and reservoirs need full attention if we expect to meet the goals of *Healthy People 2010 (2005)* [the national program that aimed to eliminate childhood lead poisoning by 2010]."

Why, when writing about the worst lead in water contamination event in modern history, would Dr. Brown in her CDC MMWR paper, commit a much more serious scientific omission, and not cite the compelling body of scientific studies demonstrating that lead in drinking water can be highly correlated to blood lead? A clue to Dr. Brown's tunnel-vision mindset can be found in a quote in the *New York Times*, which appeared on September 30, 2003, just months before the *Washington Post* broke the story on the DC Lead Crisis:

> "Lead paint remains the most concentrated and readily accessible source, and nothing should detract from our interest in eliminating it," said Dr. Mary Jean

Brown, chief of the lead poisoning prevention branch at the Federal Centers for Disease Control and Prevention in Atlanta." [36]

Indeed, from the earliest phases of the lead crisis and well in advance of data collection for the CDC MMWR, a key concern expressed amongst the public health community that follows Dr. Brown's leadership, was that the unprecedented media attention focused on DC's lead in water problems would draw attention and funding away from efforts to control lead paint.[37] The handling of the DC Lead Crisis, and omission of critical data and deletion of key words and phrases from the CDC MMWR, suggests that Dr. Brown may have been blinded by her commitment to bolster her crusade against lead paint, and illustrates exactly how far she was willing to go in preventing a non-paint lead source from detracting focus from it.

In 2005 when I first began to suspect serious problems with the CDC MMWR, one of Dr. Brown's colleagues told me confidentially that no matter how distorted the CDC MMWR proved to be or how serious the wrong-doing, Dr. Brown would never willingly correct the public health misconceptions her work had created. At first I was in disbelief But more than 6 years after the publication of the CDC MMWR, and more than 4 years since Dr. Brown was clearly made aware of serious problems with the CDC MMWR's main message, Dr. Brown has doggedly failed to clear the scientific record of the misunderstanding that she herself created and promoted. In the end, unfortunately, one has to wonder if the repercussions of the CDC MMWR were exactly as Dr. Brown intended.

One final example gives insight not only to Dr. Brown's motivation, but also to her temperament, which tragically feeds her conduct. In early 2009 when some lead poisoning prevention advocates from the Alliance for Healthy Homes, Clean Water Action and Parents for Nontoxic Alternatives in Washington DC began to try and correct the record, and to start promulgating more accurate public health messages and policies about lead in drinking water, Dr. Brown reacted with outright hostility and began to spread the word to lead poisoning prevention officials and advocates across the country that she was being unfairly attacked by an "unholy alliance" seeking to get her fired.[37] This was not true, the groups' longstanding work on the issue had in fact never focused on Dr. Brown, and what they were actually doing was directing efforts to persuade the CDC to correct the takeaway message of the CDC MMWR. But as a major funder of the nation's lead poisoning prevention community, Dr. Brown's power would have been sufficient to deter many stakeholders from joining the call for CDC's accountability. In fact, Dr. Brown succeeded in intimidating some Alliance for Healthy Homes board members into restraining the staffs advocacy, because they worried she might damage the organization's reputation and jeopardize its funding. Ultimately, in late 2009, one Alliance for Healthy Homes employee who led the organization's work on the issue was not offered employment when his organization merged with another national healthy housing nonprofit that receives significant CDC funding. This employee, who has offered decades of laudatory service to the goal of childhood lead poisoning prevention, was explicitly told that he would be a financial liability to the organization because his advocacy work on the CDC MMWR had upset Dr. Brown.[37]

In the end, I have come to suspect that the CDC and Dr. Brown were driven, at least in large part, by an over-zealous, misguided, and unscientific compulsion to exclusively focus attention and funding on the lead source they consider most important. Their "mission" may have even contributed to "missing" hundreds (and quite possibly thousands) of cases of elevated blood lead in Washington DC children due to contaminated water from 2001–2004,[23] and twisting the DC Lead Crisis into a public relations coup for lead paint, rather than acknowledging it for the environmental health tragedy it was.

For those interested in further elaboration on CDC and Dr. Brown's motivation, see Appendix 1.

MOTIVATION FOR MY OWN JOURNEY WITH THE CDC

The first time I read the CDC MMWR, based on my knowledge of prior research, I knew its conclusions were a scientific impossibility. On the other hand, I also knew that the neurological harm to DC children could not be undone, steps were seemingly underway to partly mitigate the worst of DC's lead in water contamination, and if lessons could be learned from the DC Lead Crisis that could prevent future harm, perhaps a "cover-up" of the public health impact was not the worst thing that could have happened. I expected that the responsible agencies would work hard to redeem themselves and once again make themselves worthy of the public trust. Moreover, while I had suspicions and concerns about the CDC MMWR from the start, I did not know, with certainty, the true extent of the falsification that had occurred until late 2009. Early on, I simply assumed that the authors had tried to

faithfully present the data and their methods, and perhaps, something along the way unintentionally went awry.

For a while I flirted with theories that the accepted laws of chemistry, biology and physics did not apply to Washington DC children, and that the lead in DC's water was somehow not harmful. A colleague, research chemist Michael Schock at the US EPA, had discovered that DC's lead problem was linked to formation of Pb(IV) rust on the lead pipes, as opposed to Pb(II) rust per prior conventional wisdom. Devising and conducting experiments throughout 2004 to test the hypothesis that Pb(IV) in water might not be harmful if ingested by DC consumers, I eventually proved to myself that there was no scientific support for such an explanation. The accepted laws of nature would apply. By late 2005, alarmed by the growing influence of the CDC MMWR, concerned about its implications for public health not only in DC but also nationally and internationally, curious about the quality of the science and data the CDC had used to arrive at its conclusions, and confused about how two millennia of human experience with harmful effects from lead in water could be rendered irrelevant almost overnight—I resolved to pursue this issue via investigative science.

Additional factors gave me resolve to begin this particular journey. I had heard engineers at water utilities cite the CDC MMWR as justification to "game" the Lead and Copper Rule sampling requirement, by conducting water monitoring for lead in ways that almost guarantee compliance with the standard, even when serious lead in water contamination was present. I began to cringe at public health meetings in the US and Canada when officials inevitably laid the CDC MMWR on the table, and stated that it was their duty to publicly downplay the adverse impacts of water to avoid needlessly alarming the public. Indeed, wasn't that the takeaway lesson from the DC Lead Crisis and applied by Dr. Brown herself? Of course, unfortunately, their reassuring public health messages would make it far less likely that precautionary measures would be taken seriously by the public, and that children and developing fetuses would be protected from harm. This highlights the impacts on the public of misconduct in public health research, via distortion and misinformation, "which ripples from the large scale of federal organizations to the personal level of individuals."[38]

I was appalled at the actions of US EPA R3 and US EPA HQ, who in late March/early April 2004, selfishly and cowardly gutted the health basis for their own lead in water regulation, by replacing clear and understandable warnings with misleading gibberish. The US EPA even stood silent. in April 2004, when they were publicly ridiculed in DC for arriving at their 15 ppb lead in water action limit by "pulling a number out of a hat."

Lead in DC Public Schools. I was also particularly disturbed by behavior of DC WASA and US EPA R3 employees. To this day, for example, I believe that the 2004 sampling at DC Public Schools was devised to hide problems with elevated lead in water. When the testing was complete, DC WASA trumpeted the "good news" about the relatively low incidence of lead in water hazards, reassuring DC residents that all was well, without revealing the flawed water collection methods that could have missed serious lead problems. Some of the methods used were later effectively banned by the US EPA for that very this reason. As a result, I believe, DC WASA ensured future needless harm to DC schoolchildren, in partnership with US EPA R3, which backed the water utility up on their claims. It took me 3 years to confirm and expose the fact that there were very serious problems with lead in much of the DC school system, with some taps dispensing lead concentrations over hazardous waste levels (>5,000 ppb).[33] Still, the CDC MMWR conclusions seemingly rendered the health implications of that work insignificant.

Partial Lead Service Line Replacements. My worry was reinforced when, in 2008, in partnership with a coalition of public health advocates in DC, we discovered that DC WASA's 5-year and $100 million "accelerated" lead in water "remediation" program was not nearly the success that DC WASA and US EPA R3 had claimed. Thousands of lead water pipes were dug up and replaced with copper pipe, but only the publicly owned portion of the old lead pipe was replaced. The privately owned portion was left in the ground. This program of partial lead service line replacement-worsened lead in water levels in many homes for an undetermined duration. For years the agencies repeatedly claimed in public and in written scientific reports (again contradicting decades of prior experience and research), that partial replacements in DC were not causing lead to spike:

> ". . . there was no immediate change, or immediate increase in lead levels in the tap water" . . . "there is no evidence that the lead levels increase" . . . "remove half the lead . . . you have a lot less lead in your tap water as a result."
>
> Rick Rogers EPA R3, Interview on WAMU Radio, May 2004

In 2004, I had testified to the US Congress that partial lead service line replacements were a waste of money and that my research had shown the procedure could increase residents' risk for lead exposure. After years of denial and false statements by DC WASA and US EPA R3, I eventually proved that the two agencies had themselves collected hundreds of data points showing severe problems with DC residents' exposure to high lead in water, following DC WASA's partial lead service line replacement "remedy" at their homes.

But the public health implications of our work were to be neutralized by what was becoming a well-oiled tag team effort by Dr. Guidotti and the CDC. Dr. Guidotti provided testimony and "public education" at community meetings, asserting that even the highest levels of lead in DC's water after partial lead service line replacement (sometimes exceeding 100,000 ppb) probably did not pose a health risk. Dr. Guidotti wrote:

> "It has been alleged that spiking lead levels after partial lead service line replacements present a health risk. This is probably not correct."

Testimony of Dr. Guidotti, March 10, 2008

The CDC attended two of several DC WASA public meetings on this issue, and consistently supported Dr. Guidotti with silent acquiescence, no matter how outrageous the George Washington University professor's proclamations. The CDC repeatedly refused to answer direct questions from DC residents, that could have put Dr. Guidotti's testimony into some context. At these meetings, DC WASA distributed written "public education" materials embellishing on the already ludicrous CDC MMWR conclusion. For instance, the water utility's fact sheet stated that:

> "In 2004, the CDC analyzed results from a District Department of Health examination of blood lead levels among children during the period of elevated lead levels in tap water at many homes. 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."

Even ignoring the already distorted analysis of the 201 residents portrayed in the original CDC MMWR, clearly, the CDC MMWR never looked at 201 children. The CDC MMWR itself stated that only 17 of the 201 targeted "worst-case" residents were under the age of 6. Moreover, the CDC MMWR study involved no environmental risk assessments at the homes of DC children with elevated blood lead levels. Finally, although the CDC MMWR implied that virtually all detected blood lead elevations in DC were due to lead paint, it never stated this.

When two DC public health advocates called on the CDC to demand that DC WASA correct the misleading presentation of the CDC's own research results, the CDC failed to do so. A CDC employee who claimed to have consulted a CDC lawyer, claimed that there was nothing CDC could do to redress the inaccuracies in already distributed versions of DC WASA's fact sheet. However, the official assured the two advocates that he would request all future versions of the DC WASA fact sheet prior to dissemination in order to correct any misleading statements. Despite that assurance, the fact sheet was once again distributed on May 1, 2008 with the same misleading language in place.

As perplexing as CDC's behavior was in relation to the above incident, what was going on behind the scenes was even worse. Unbeknownst to either myself or the DC residents who were pleading with the CDC in 2008 to correct Dr. Guidotti's and DC WASA's assertions that lead-contaminated drinking water does not pose a significant public health concern, the CDC had been researching the impacts of partial lead pipe replacements on blood lead levels of DC children probably since at least 2005.[39] Based on accounts of individuals who attended a November 2007 meeting between EPA, CDC, DC DOH and Dr. Guidotti, and as substantiated in later e-mails in my possession, the CDC actually had data in late 2007 that indicated public health risks from DC's partial lead service line replacements. It was not until February 2009, long after the time when disclosure of their results could have been used to prevent more needless harm to DC children, and to properly guide public debate, that CDC eventually issued online an "important update" based on their research in DC:

> "CDC's Healthy Homes and Lead Poisoning Prevention Branch has conducted an epidemiological study of the relationship between children's blood levels and lead water service lines. **Our preliminary results suggest that when lead service lines are partially replaced, that is the public portion of the line from the the main to the meter is replaced, children are more likely to have blood lead levels greater than or equal to 10 μg/dL, compared to**

> **children living in housing with either undisturbed lead service lines or service lines that are not made of lead**" (bold emphasis added).

The ethics of how CDC conducted its "research work" given extensive prior knowledge about lead spikes after partial pipe replacement, their duplicity in covering up what was actually occurring to children in these homes, and their failure to inform the public about their knowledge of the potential harm throughout the numerous public meetings on this subject in 2008, strikes me as highly unethical and deserving of future scrutiny. Yet it is also completely consistent with CDC's past actions, to withhold and control any information that may cast doubt on their message that lead in water is not a significant public health concern.

DC WASA Sampling Inconsistent with Intent of LCR. The coalition of concerned DC residents also discovered that since 2005 DC WASA, again with the full knowledge and

approval of US EPA R3, had achieved compliance with the Lead and Copper Rule by monitoring DC's water via the use of a sampling protocol that required flushing taps for 10 minutes the night before sampling. In the water industry, pre-flushing is understood as a well-known method to game the US EPA lead standard, by temporarily reducing lead concentrations at the tap. After reviewing the coalition's appeal of DC WASA's protocol, Cynthia Dougherty, the Director of US EPA HQ Office of Ground Water and Drinking Water, determined in a letter to the coalition that flushing on the eve of compliance sampling was inconsistent with the intent of the Lead and Copper Rule:

> "We believe that [requesting flushing only in the households participating in the sampling] goes against the intent of the monitoring protocol, since it changes the normal water use of the homeowners in the sample."

However, without acknowledging or giving any consideration to the potential ramifications of DC WASA's 4-year-long reliance on the flawed flushing practice—in terms of reported compliance with the Lead and Copper Rule and associated potential health impacts on DC residents—Ms. Dougherty closed her letter by reinforcing the CDC's lead source hierarchy:

> "Thank you for bringing this matter to our attention. However, **we hope that this new issue does not deflect from the importance of addressing more serious sources of lead** in housing that your association has highlighted in the past. The nation has a goal of eliminating childhood lead poisoning by 2010 and, while our program is focused on reducing exposure from drinking water, **it is critical for us to not lose sight of the importance of directing resources and attention at more serious sources**" (bold emphases added).

With this letter, US EPA shamelessly abdicated all responsibility for having allowed DC WASA to achieve compliance with federal lead standards via the use of a sampling protocol that violated the intent of the Lead and Copper Rule, and that may have hid years of problems with lead in water contamination. Moreover, it forcefully downplayed the health risks from lead-contaminated drinking water, knowing full well that the community it was addressing had just recently experienced the most severe lead in water crisis recorded in US history, and that the preponderance of scientific evidence—including work by US EPA's own scientists—had predicted that serious public health harm should have occurred.

In short, I began this journey with the CDC, and have been able to sustain it in the face of repeated agency backstabbing and personal attacks, because I was convinced that lead in water does sometimes pose a serious public health concern, and that innocent children in DC, all over the US, and around the world have been put in harms way by the deception of the CDC MMWR.

TRYING TO GET THE FACTS FROM THE CDC

I started my investigation into the CDC MMWR via a FOIA request to DC DOH on October 23, 2005. In this FOIA, I asked for all information related to the "300 ppb" study in the CDC MMWR and certain e-mails written by Dr. Stokes, who was the listed 1st author of the report. I followed up with dozens of phone calls and e-mails through February 2006. The DC DOH FOIA Office did not return a single phone call, e-mail, or otherwise acknowledge that I existed. I submitted a FOIA appeal in early February 2006, which resulted in the DC Mayor's Office ordering DC DOH to produce the information I had requested within 20 days. The 20 days came and went without DC DOH even acknowledging the Mayor's order. The Mayor's Office then threatened to report the DC DOH FO1A officer for misconduct. On April 27, 2006, the DC DOH FOIA officer informed me that Dr. Stokes had left DC DOH shortly after I had submitted my FOIA for information about the CDC MMWR, and

that her e-mails had been destroyed. He refused to tell me exactly when she left. DC DOH repeated this maneuver in early 2008, when I submitted a similar request for e-mails of CDC MMWR co-author and DC DOH employee, Christine Onwuche. Within weeks after submission of my FOIA, Ms. Onwuche too had left DC DOH, and the e-mail records I had requested had been destroyed. The maneuver is illegal, because from the moment a FOIA request is received, the FOIA Office is supposed to protect the integrity of the requested documents.

A couple of months into my phone call and e-mail marathon trying to reach DC DOH in relation to my October 23, 2005 FOIA, I realized that DC DOH was going to stonewall my access to any information about the CDC MMWR, and I began making dozens of attempts to contact the editor of the CDC MMWR series for a few simple answers to my questions. The editor did not return my phone calls, e-mails or letters. I then decided to submit my first FOIA to the CDC on December 27, 2005, with a request for e-mails between DC DOH and CDC related to the preparation of the CDC MMWR. On May 17, 2006 I submitted to the CDC a second FOIA for the data used in the "300 ppb" study. To date, I have submitted more than 10 FOIA requests to the CDC, any one of which makes for a compelling story of governmental abuse of the public and credible scientists, but I will limit my testimony to these two CDC FOIAs as examples.

Playing the CDC Shell Game. Sharing of data amongst scientists, and responding to straightforward questions about research methods, is central to the conduct of good science. These concepts seem to be foreign to the DC DOH and CDC. Given the 1) "historic" nature of the CDC MMWR findings concerning DC residents who were supposedly consuming water with over 300 ppb lead, 2) numerous associated sworn testimonies about the 300 ppb study to the DC City Council and the US Congress, and 3) the CDC's stated desire to have the CDC MMWR impact policy and having great success in doing so (Figure 4), I assumed I would receive the data behind this study within weeks after requesting it from DC DOH on October 23, 2005 and then again from the CDC on May 17, 2006. Instead, the two agencies played what I consider to be an irresponsible and unethical shell game, implying that the data existed, but appearing to act as if they could not figure out whose responsibility it was to produce them.

On April 13, 2006, the DC DOH FOIA officer informed me that the data for the CDC MMWR were housed at the CDC. He also stated that he had been in contact with the CDC about my request, but that I would have to submit another FOIA directly to the CDC. I did so on May 17, 2006. On May 31, 2006, I received a spreadsheet via e-mail from DC DOH, without any written explanation. This spreadsheet obviously included some data related to the 300 ppb study, parts of which I cited earlier in connection to DC residents' bottled water use. But the spreadsheet raised dozens of questions and in many ways was completely inconsistent with the information presented in the CDC MMWR. Eight months later, on January 23, 2007, the CDC informed me that that the 300 ppb data was "housed at the FDA."

In summary, more than 4.5 years after first requesting the 300 ppb data, nothing that could possibly be the blood lead data behind this historic analysis in the CDC MMWR has been produced to me. In fact, I am highly doubtful that the blood lead data portrayed in the CDC MMWR ever existed, and have come to suspect that at least some of that data is a complete fabrication.

Pages from the CDC's FOIA Playbook. A chronology of my first FOIA to the CDC, submitted on December 27, 2005, highlights the abusive practices of the CDC FO1A Office in relation to those seeking critical information about the agency's environmental public health practices. After following up my FOIA request with 5 e-mails and voice messages that were never answered, on April 16, 20061 decided to file an appeal concerning the CDC's delay in responding to my request.

Over 7 months later, on November 3, 2006, I received a phone call from the CDC FOIA Office. They stated that my documents had been ready to mail for 4 or 5 months, but that because I had filed an appeal, the release of the documents had been placed on hold. If I wanted to receive the documents I had been waiting for, I first had to withdraw my appeal. I immediately memorialized this bizarre "Catch-22" conversation in an e-mail to the FOIA officer, and withdrew my appeal. Later that day, the CDC FOIA Office mailed me a letter that did not contain the documents I had just been promised. Rather, the letter stated that the agency was withholding the documents, and if 1 did not agree with their action, to submit an appeal. The appeal clock would have to be restarted. Dismayed at CDC's childish antics and mind games (i.e., Sike!), I promptly resubmitted an appeal on the FOIA, to replace the appeal CDC had just duped me into withdrawing—not that it mattered because FOIA appeals were ignored at CDC as well. More than 2 years went by without a response of any sort.

In a letter dated January 21, 2009, a day after the Obama administration took office, my hopes were raised when I received a letter from the CDC stating in part:

> "This letter is a response to your November 2006 Freedom of Information Act (FOIA) Appeal for specific documents between CDC and the D.C. Department of Health during the 2004 lead crisis. I apologize for the delay in responding to your request. This office has experienced a significant turnover in staff, and we are working through our backlog of requests. . . . If you are still interested in receiving the requested information, please contact <name> . . . If you are no longer interested in the information, you need to do nothing."

I immediately responded that I was still interested in receiving the documents. When the US House Committee on Science and Technology began investigating the CDC MMWR in March 2009, I had still not received the documents I had requested, and I made the Committee aware of CDC's FOIA abuses. Perhaps because of that, in early November 2009, I received a phone call from a CDC FOIA officer, asking me yet again, whether I still wanted the documents from my 2005 FOIA. I said that I did.

Finally, in a package dated November 20, 2009, nearly 4 years after my initial FOIA request, the CDC released to me 108 pages of documents. While I am grateful for finally getting a partial response, numerous pages are clearly missing for reasons that I do not understand. For example, only every other page of the CDC MMWR drafts was included (i.e., page 1, 3 and 5), so it is possible that I was given a single-copied version of double sided originals. This week I reinitiated efforts to get a full response to my 2005 request.

I close by noting that in the past 4-plus years I have experienced numerous other abuses by the CDC, but will mention one last one that strikes me as especially flagrant. I am pursuing my investigation as a volunteer, and as such I routinely submit requests for a fee waiver. The CDC has repeatedly denied my requests, on the grounds that my FOIA will not "advance the understanding of the general public as distinguished from a narrow segment of interested persons," and that the "public's understanding of the government" will not be "substantially greater as a result of the disclosure." I mention this because I have had to pay the CDC several thousand dollars. much of it toward CDC employees' salary, for the privilege of being abused by their FOIA system. I also freely disclose to anyone who reads this document—the CDC has determined that my research and testimony does not enhance the general public's understanding of government operations.

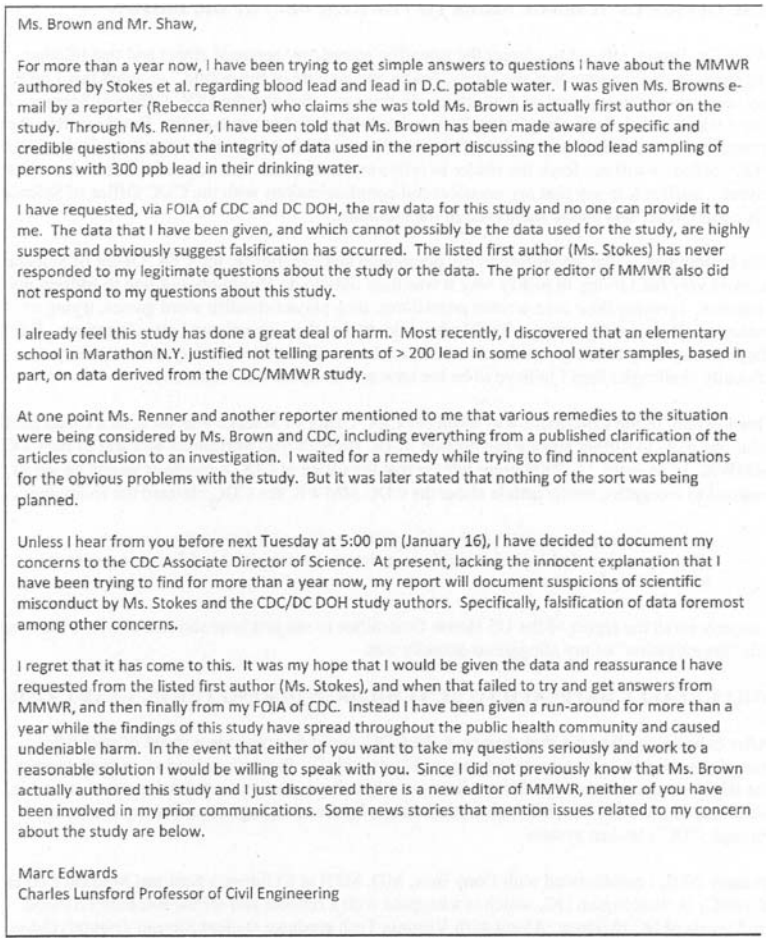
CDC REFUSED TO CORRECT THE SCIENTIFIC RECORD

When I began this journey 5 years ago, the last thing I ever wanted was an exhausting, voluntary ordeal, that would ultimately cost me tens of thousands of dollars in FOIA charges alone to the agencies, and which would lead to the unpleasant experiences which culminate in today's testimony. The record shows I did everything in my power to avoid this from happening. However, that was not the path that fate, or Dr. Brown or CDC's actions, would choose for me.

Through my FOIAs of CDC and DC DOH, Dr. Brown was well aware of my serious concerns about the CDC MMWR since at least late 2005. Safely ensconced behind the twin parapets of an abusive FOIA Office and a Science Office that would spare no effort to avoid upholding accepted standards of scientific integrity (see later section), Dr. Brown must have felt empowered to ignore me. Reporters who raised substantive questions about the CDC MMWR based on facts I provided them, were rebuffed by the CDC press office, with statements that either questioned my integrity, intellect and intentions. I was once told they stated:

> "No one has a problem with our paper except an Engineer with no formal training in, or appreciation of, public health."

Despite my dismay at CDC's arrogance, misconduct, and growing concern about serious problems with the CDC MMWR, I did my very best to work within the system and to stop the harm it was creating. After more than a year and just a few weeks after discovering Dr. Brown had actually authored the paper (she is listed as the 18th author), I wrote an e-mail that was both a plea for correcting the record, and an ultimatum (Figure 5). At that point, January 11, 2007, Dr. Brown could have avoided all of the revelations presented in this testimony, the US House Investigation into the CDC, and exposure of her actions skewing the data and analysis of the CDC MMWR, which she clearly knew about. To repeat this point for emphasis, had Dr. Brown corrected the CDC MMWR's public health message in early 2007, and stopped the harm it was (and would continue) to perpetuate, I would have dropped the matter. Her supreme arrogance and unfortunate temperament would not allow herself to do so.



Ms. Brown and Mr. Shaw,

For more than a year now, I have been trying to get simple answers to questions I have about the MMWR authored by Stokes et al. regarding blood lead and lead in D.C. potable water. I was given Ms. Browns e-mail by a reporter (Rebecca Renner) who claims she was told Ms. Brown is actually first author on the study. Through Ms. Renner, I have been told that Ms. Brown has been made aware of specific and credible questions about the integrity of data used in the report discussing the blood lead sampling of persons with 300 ppb lead in their drinking water.

I have requested, via FOIA of CDC and DC DOH, the raw data for this study and no one can provide it to me. The data that I have been given, and which cannot possibly be the data used for the study, are highly suspect and obviously suggest falsification has occurred. The listed first author (Ms. Stokes) has never responded to my legitimate questions about the study or the data. The prior editor of MMWR also did not respond to my questions about this study.

I already feel this study has done a great deal of harm. Most recently, I discovered that an elementary school in Marathon N.Y. justified not telling parents of > 200 lead in some school water samples, based in part, on data derived from the CDC/MMWR study.

At one point Ms. Renner and another reporter mentioned to me that various remedies to the situation were being considered by Ms. Brown and CDC, including everything from a published clarification of the articles conclusion to an investigation. I waited for a remedy while trying to find innocent explanations for the obvious problems with the study. But it was later stated that nothing of the sort was being planned.

Unless I hear from you before next Tuesday at 5:00 pm (January 16), I have decided to document my concerns to the CDC Associate Director of Science. At present, lacking the innocent explanation that I have been trying to find for more than a year now, my report will document suspicions of scientific misconduct by Ms. Stokes and the CDC/DC DOH study authors. Specifically, falsification of data foremost among other concerns.

I regret that it has come to this. It was my hope that I would be given the data and reassurance I have requested from the listed first author (Ms. Stokes), and when that failed to try and get answers from MMWR, and then finally from my FOIA of CDC. Instead I have been given a run-around for more than a year while the findings of this study have spread throughout the public health community and caused undeniable harm. In the event that either of you want to take my questions seriously and work to a reasonable solution I would be willing to speak with you. Since I did not previously know that Ms. Brown actually authored this study and I just discovered there is a new editor of MMWR, neither of you have been involved in my prior communications. Some news stories that mention issues related to my concern about the study are below.

Marc Edwards
Charles Lunsford Professor of Civil Engineering

Figure 5. Text of 1/11/07 e-mail to CDC's Dr. Brown and CDC MMWR Editor Shaw.

CDC OFFICE OF SCIENCE RIDES TO THE RESCUE . . . OF DR. BROWN

When Dr. Brown refused to correct the scientific record, my personal ethics and that of other engineers to "hold paramount the safety, health and welfare of the public," dictated that I take my concerns to the appropriate authorities. In this case, that was the CDC Office of Science. At first I was hopeful. In the beginning, they at least responded to my e-mails. But thereafter, their treatment of me fell into the routine of abuse with which I had become so familiar via the CDC FOIA office. I will not force the reader to relive my ordeal here and now, nor do I wish to do so myself. Suffice it to say that my unsuccessful communications with the CDC Office of Science via e-mail, letter and phone numbered in the hundreds.

The bottom line is that, according to my perception and experience, the CDC Office of Science worked very hard trying to justify why it was their duty to do absolutely nothing to address my concerns. Ignoring their own written procedures, they played childish word games, trying to make me give up and go away. To this day I doubt that they investigated my allegations. But if they did, and they found no evidence of the problems outlined herein, they are even more ethically challenged than I believe to be the case as I compose this testimony.

One lowlight of the experience was when the CDC Office of Science was used, as a cheap public relations ploy, to further sustain the illusion of Dr. Brown's trust-

worthiness and that of the CDC MMWR. In an April 11, 2009 press release that the office of CDC's media relations issued to respond to a negative media article about the CDC MMWR, the CDC claimed the following:

> "Scientific integrity is CDC's hallmark . . . . CDC's Office of Science takes any such allegation very seriously; it thoroughly investigated this complaint and found no evidence of scientific misconduct."

I eagerly await the report of the US House Committee to see just how serious, and how thorough this "investigation" of my allegations actually was.

WHAT REALLY HAPPENED TO DC's CHILDREN DURING THE DC LEAD CRISIS

After exhausting all hopes that anyone at the CDC would demonstrate a shred of scientific integrity or backbone in acknowledging problems with Dr. Brown's behavior, or even express the slightest concern about children who were still being left unprotected from elevated lead in water due to the CDC MMWR's flawed message. I gave up trying to resolve my concerns through CDC's broken system.

In early 2008, I collaborated with Dana Best, MD, MPH at Children's National Medical Center (CNMC) in Washington DC, which is a hospital with a reliable and robust database on blood lead levels of DC children. Along with Virginia Tech graduate student Simoni Triantafyllidou, we conducted a very simple and straightforward analysis which was eventually written into the paper "Elevated Blood Lead in Washington D.C. Children from Lead Contaminated Drinking Water: 2001–2004" and published in the peer-reviewed journal *Environmental Science and Technology*.[23]

Given the authority of the CDC and Dr. Brown on the subject of lead health effects, and presumptions of most scientists about high standards of scientific integrity at the CDC, getting our paper through the scientific review process was difficult. One reviewer had concerns about publishing our paper, because it cited some data collected via FOIA, and was disturbed that this information would give readers the impression that CDC and other agencies did not supply their data willingly. Another reviewer stated that the paper should not be accepted because it "relies on a lot of data the authors did not collect, were apparently not involved in the original studies, and with which they do not provide sufficient information concerning the conditions and methodology under which the data were collected." In other words, because the CDC and Dr. Brown would not follow established principles of scientific conduct and share information/data with us, reviewers were reluctant to approve publication of our own paper. In writing the final draft, I therefore had to create an imaginary world, in which the CDC's actions were interpreted in an unreasonably positive light. I even wrote the following in reference to the CDC MMWR:

> "Differences in conclusions between this work and the earlier CDC study are mostly attributed to the type of analysis and interpretation . . ."

This statement should not be construed as support for Dr. Brown's analysis in the CDC MMWR. Our research determined that the decades of prior peer-reviewed literature, demonstrating that lead in water can be a serious public health concern, were correct. It further demonstrated very strong links between elevated lead in water and lead in blood for the most vulnerable children in DC from 2001–2004. Our work directly refuted the CDC MMWR "main message" that there "*is no indication that DC residents have blood lead levels above the CDC levels of concern . . . as a result of lead in water*." It also exposed the misleading work of the CDC's close collaborator in DC, Dr. Guidotti and his DC DOH co-authors, who published a misleading paper which concluded that "*There appears to have been no identifiable public health impact f from the elevation of lead in drinking water in Washington, DC*." Based on our analysis, hundreds, and in all likelihood thousands, of DC children had their blood lead elevated above the CDC level of concern as a result of elevated lead in water from 2001–2004.

EPILOGUE

Since publication of our paper, the CDC has doggedly defended the CDC MMWR against all criticism. The paper stands on the agency's website to this day, unscathed; a monumental public health fiasco, where it continues to mislead and place children all over the world in harm's way. Contradicting 2000 years of human knowledge and experiences related to adverse health effects from lead in drinking water, for a contaminant that is perhaps the best-known environmental neurotoxin—how can anyone trust CDC's integrity on more controversial subjects?

Some have said that my experiences and testimony prove that "science works," and that falsification by scientists will always get exposed. That is simply not the case. Science is no match whatsoever for the bullying, abuse of authority and lack of integrity of powerful government agencies. Had I not volunteered nearly 10,000 hours of my time to expose wrongdoing by these agencies, spent tens of thousands of dollars of my family's funds, sacrificed my personal life and career. and endured years of back-stabbing and personal attacks by the CDC and other agencies, I am doubtful that lead in water would ever again have been seriously considered a public health concern. Indeed, as I write this testimony, I am still uncertain that this will occur.

I also thank all those who volunteered to work with me on this effort. I am humbled by, and stand in awe of, the sacrifice of scientists, victims and activists who stand against agency misconduct, many of whom end up destroyed or disillusioned in the process. Although no one emerges from these experiences unscathed, collectively, our actions do make a difference.

CONCLUSIONS

As long as the CDC continues to defend the CDC MMWR, the agency will not have a shred of scientific credibility. As I first stated publicly in May 2006, the CDC MMWR has to be retracted.

To the extent that my experiences with individuals in the CDC Lead Poisoning Prevention Branch and the CDC Office of Science are any indication, there is a culture of scientific corruption in branches of this important agency, and there is no evidence that it has the capability for self-correction. I know highly ethical and outstanding scientists in other parts of the CDC, and I sincerely hope that they too, will not face insurmountable obstacles in achieving the public good.

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APPENDIX 1: ADDITIONAL SPECULATION ABOUT CDC MOTIVATION

In retrospect, when the DC Lead Crisis became front-page news on January 31, 2004, it presented both problems and opportunities for the CDC and their DC DOH colleagues. Both agencies had been almost exclusively focused on and trained to address lead paint hazards, and this "worldview" would have been undermined by finding significant adverse health impacts from the crisis. On the other hand, if it were found that lead-contaminated water could not be linked to a single DC child with a blood lead elevated above the CDC level of concern, the problems would be eliminated and the agencies' approach would be vindicated.

The problems were multi-fold. First, from the earliest phases of the crisis, the public health community worried that the unprecedented media attention to lead in drinking water could divert public attention and funding away from addressing lead paint.[37]

Second, in the weeks just before the publication of the CDC MMWR, media attention was shifting to DC DOH's ignorance about, and mismanagement of, DC's lead in water issues.[40] Contrary to initial claims that DC DOH first learned about problems with high lead in water in January 2004, the *Washington Post* was on the verge of informing the public that DC DOH's knowledge went back to October of 2002. In particular, former ASTDR employee and CDC MMWR co-author Dr. Stokes was in the cross-hairs, because in October 2002 she (together with other DC DOH officials) "ignored the mounting health threat and failed to issue clear instructions to residents about how to reduce their risk of lead poisoning."[40] Although obviously responsible for her actions, Dr. Stokes' inattention to the water problem fully conformed with the CDC's "lead-paint-centric" approach to childhood lead poisoning prevention, so any further press coverage of Dr. Stokes' lapses would also risk drawing attention to deficiencies in CDC policies. The CDC MMWR, rushed to publication just one day after this *Washington Post* article, effectively immunized both Dr. Stokes and the CDC from further criticism.

Third, any serious investigation of who knew what and when at DC DOH, would have led to public revelations about agency bungling that went far beyond anything that had ever been previously revealed in the press. Specifically, on September 26, 2001, a DC WASA employee called the DC OIG hotline and reported that DC WASA had "intentionally" hidden many lead in water test results from early 2001 that "exceeded the EPA action limit."[14] Also, later research would demonstrate that at this exact time frame, DC WASA was collecting data showing that DC's water lead levels were spiking to dangerous levels and that hundreds of DC's children had elevated blood lead levels due to exposure to the high lead in water.[23] It is now undisputed that DC WASA and US EPA R3 knew that the US EPA water lead action

standard would likely be exceeded by July 19, 2002, and had certainly knowledge of some problems as far back as August 2001.[14]

My FOIA request of US EPA reveals that on June 21, 2002, a DC DOH water quality division employee wrote a letter to US EPA R3 requesting funding for "a lead service line replacement program." It seems likely the employee knew something was amiss relative to lead in water and its health impacts for DC residents, because the employee later indicated to US EPA R3 that during April 2002, she had tried to get geographic data on elevated blood lead levels of children from the CDC-funded DC Lead Poisoning Prevention Program staff, and link it to information on the location of lead pipe. In response to her June 21, 2002 request for action, on July 24, 2002, US EPA R3 and DC WASA disingenuously stated that "testing has shown lead levels to be below Federal action levels" and "water quality testing . . . has consistently supported the position that our . . . lead and copper levels are below the action level." This, despite the now undisputed fact that both agencies knew about the forthcoming lead action level exceedance at least 5 days earlier (if not months and months earlier).

In the July 24th, 2002 response, US EPA R3 told the DC DOH water quality division that DC WASA had addressed "your concerns about the health effects of lead levels in the District's drinking water supplies." Clearly, the episode represents a lost opportunity by the agencies to address substantive lead in water health effects for DC children, nearly 20 months before the frenzied activities by the CDC and DC DOH in response to the *Washington Post* story in early 2004. It is quite likely that the DC DOH water quality division employee did not get cooperation from the CDC-funded childhood lead program in early 2002 when she tried to draw links between elevated blood lead in DC and occurrence of lead service lines. At a minimum, in early 2002, the efforts of the DC DOH water quality employee represented a chance for the agencies to "connect the dots" and address the spike in childhood lead poisoning that was occurring throughout DC due to contaminated water at that time.[14 23]

Fourth, public testimony and the CDC's "Talking Points" memo that accompanied the release of the CDC MMWR, stated clearly that the CDC became involved in the DC Lead Crisis on February 16, 2004. In fact, three questions in the CDC "Talking Points" memo, directly or indirectly, addressed the question of when CDC first became involved in the DC Lead Issue, and why the CDC was not doing more. The facts indicate that the CDC's statement was not completely accurate. Putting aside the likelihood that some CDC staff and DC DOH Lead Poisoning Prevention program knew about possible water-lead problems in April 2002, the CDC had also funded the DC DOH's grossly dysfunctional DC Lead Poisoning Prevention Program for years, and was acutely aware of serious shortcomings in the DC DOH's management of data and its poor record keeping. For example, a few months after the publication of the CDC MMWR, some CDC employees were alerted to forgery of blood lead records at the DC DOH, and to the fact that thousands of blood lead test data from 2003 were missing.41 Perhaps because of the enormous public health implications of the news for DC residents, as well as serious questions that would be raised about the integrity of the CDC MMWR that relied on this incomplete data, the CDC did not report the information about the data forgery and the missing blood lead data to appropriate authorities.[41] The agency's inaction suggests both complicity with DC DOH and duplicity in the CDC's actual commitment to protecting public health. Once again, had the CDC MMWR acknowledged even a single case of childhood lead poisoning from water, it is reasonable to assume that an investigation into DC DOH's failing lead poisoning prevention program would have revealed serious deficiencies under CDC's oversight.

Fifth, if the CDC's DC investigation had concluded that lead contaminated water could cause childhood lead poisoning, this could potentially interfere with a game-changing legal case of national importance that offered the possibility of billions of dollars from former lead-pigment makers for lead paint remediation. A landmark lawsuit against lead paint companies, initiated in Rhode Island in 1999, seemed to be heading towards a historic settlement which could require the defendants to pay billions in funds to rid Rhode Island homes of lead paint hazards and ultimately might create similar programs nationwide.[42] To date, the CDC has not produced documents that I have requested about Dr. Brown's involvement in this lawsuit; however, in 2007 Rhode Island apparently did consider that Dr. Brown serve as a "Special Master" to oversee spending the funds from the lawsuit, a proposal which the defendants protested.[43]

Indeed, an October 2002 article about Dr. Brown's recent research on lead in Rhode Island, stated that "She <Brown> added that the study may aid plaintiffs waging legal battles against lead paint manufacturers, mentioning one case in Rhode Island that recently resulted in a hung jury."[44]

To my knowledge, lead in water was never raised as a potential lead source in the Rhode Island lawsuit. However, if the DC Lead Crisis were shown to have caused demonstrable harm, it could have provided another significant argument for the former lead paint defendants, weakened the Rhode Island lawsuit, and jeopardized the potential procurement of billions of dollars nationally for lead paint remediation. Indeed, Lead and Copper Rule monitoring results and a recent article in the journal *Environmental Health Perspectives* (EHP) have revealed chronic problems with lead in the tap water of Providence, Rhode Island, and I am aware of relatively high lead in water of other Rhode Island cities.[45]

As for opportunities, they were also significant, for those interested in generating new funding sources to mitigate lead paint. First, any public relations coup about the supposed lack of harm from water, provided a high profile platform that CDC could (and did) use to drive home its belief that even in the midst of the largest lead in water contamination event in modern history, the only significant health concern in DC was lead paint. Two events, removal of the language from the US EPA website about the dangers of 40 ppb lead in water, and Dr. Brown's removal of the statement "Elevated levels of lead in the water are a public health concern" from the CDC MMWR, were separated at most by 3 days in late March 2004.

Secondly, the CDC's handling of the DC Lead Crisis not only protected lead paint advocates' drive for a Rhode Island legal settlement, but it was also used to create new opportunities for funding for lead paint from the water industry. For starters, the DC DOH lead program obtained millions of dollars of funding from DC WASA in early 2004 for blood lead tests, environmental assessments and software to track lead poisoning. National funding aspirations were also significant and could be cultivated. As revealed in a recent EHP article, one of Dr. Guidotti's colleagues and 2007 paper co-authors made a presentation at the 2009 American Public Health Association conference, about a Portland, Oregon program, in which water utilities could pay for lead paint remediation, in exchange for not having to fully optimize corrosion control to minimize lead in water concentrations according to federal regulations. The EHP article stated:[45]

> "Portland instead spends $500,000 annually on a public education campaign and lead paint abatement program. 'This approach was a win-win for community public health, reducing lead exposure across the community and across media of exposure, especially for children,' says David Leland, manager of the Oregon Department of Human Services Drinking Water Program . . . . 'Look at the hierarchy of concern for lead,' says Leland. 'Number one was the lead from gasoline in the air, before it was banned. Now it's paint,' he says."
>
> ". . . Jim Elder, who headed the EPA drinking water program from 1991 to 1995 <stated> 'Portland's choice between optimum corrosion control and public education is a "covert form of cap and trade' . . ."

Finally, funding for lead paint programs were to be cut by 25% in draft federal budgets, as revealed in a *Washington Post* article just days after the MMWR was released.[46] A few weeks later, on April 29, 2004, the CDC MMWR was used to update the President of the United States on what the CDC had done lately in relation to "Protecting Health Care Consumers," and also provided an opportunity to reiterate the high exposure risk from lead paint relative to lead in water. An ATSDR and CDC e-mail with the subject "CDC Topics for Secretary Thompson to Discuss with President Bush," mentioned that in relation to the DC Lead Crisis, CDC had helped:

> ". . . address pressing consumer questions about the lead exposure. Scientists found that . . . there was no evidence that it caused an increase in the number of children in the District with blood lead levels >= 10 ug/dL (our level of concern for individual children). Support to the district continues with development of a comprehensive assessment of lead sources in children's environments, including lead paint and leaded house dust."

Chairman MILLER. Thank you, Dr. Edwards.

We will now begin our first round of questions. I now recognize myself for five minutes.

I am struck by how many people seem not to understand that there is a reason that parents tell their children the story of the little boy who called wolf. There really is a point to the story. It is important to protect your credibility because the day may come when you need to be believed. This seems to be the little agency

that cried that there was no public health concern, and there is a time that we need to reassure the public, to tell the public that there is nothing to worry about, to damp down hysteria, to use a word from the *Washington Times* story six years ago, but if the agencies responsible for determining public health do not have credibility, they will not be able to do that credibly.

This subcommittee before Dr. Broun's service studied the preparations for a dirty bomb attack a couple of years ago. And one of the things that we needed to be prepared to do in the case of a dirty bomb was to tell the public not just what they had to worry about but what they didn't have to worry about, that their children were okay, that they could occupy certain areas within our largest cities, and they needed to be able to do that credibly. The public needed to believe them, and we need to protect the credibility of our government agencies responsible for determining if there is an environmental health hazard if they are to play that important role of damping down hysteria when the time comes when there may be panic and there may be hysteria.

Dr. Edwards, CDC has I think just today issued a new report, analysis, study in the MMWR looking again at the 2004, 2003 data. Have you had a chance to look at that?

Dr. EDWARDS. Yes, I have been sent a copy of that.

Chairman MILLER. And do you have—what is your reaction to that? I am tempted to say do you have an opinion satisfactory to yourself, but I am not a lawyer anymore.

Dr. EDWARDS. Deception, smoke-and-mirror gimmicks, perverted science, this is what the CDC embraces. There is nothing in that report that clearly indicates the harm that was done to D.C.'s children, as CDC knows, as it sits there today occurred, and the new report shows absolutely nothing of relevance other than the sorry set of data that they used for their assessment, and by correcting a single year of data, 2003, and leaving all the other years uncorrected, comes up with a comparison that is completely irrelevant. It took them eight months of effort to correct the data they relied on for 2003 alone. It would take therefore probably another 24 months of attempts to get good data for the earlier years which they need for their comparison.

Chairman MILLER. Ms. Bascetta, the GAO study appears pretty damning, the policies and procedures that ATSDR and NCEH, their procedures for initiating, developing, reviewing and clearing their public health products. How does ATSDR and CDC begin? Where do they start to fix this problem? They have new leadership at that agency. They will shortly have—at CDC in Dr. Frieden. They will shortly have new leadership at NCEH and ATSDR. Where do they begin to fix things?

Ms. BASCETTA. Obviously the concern today about the MMWR in particular which has always been viewed as an authoritative source of public health information is something that they must fix. We made two recommendations to ATSDR to develop a risk assessment process to better manage their public health products, and a second recommendation to revise their existing policies and procedures or to develop new guidance to provide documented direction for various levels of management, and roles and responsibilities in monitoring. One of the things we believe very strongly is that this

has to happen at the initiation of work and throughout the process, that it is too late to wait for review and clearance, that they need to bring the resources and the expertise to bear early in the process and that they need to manage their workload so that they can detect any problems early and correct them.

Chairman MILLER. Thank you.

My time is expired. I now recognize Dr. Broun for five minutes.

Mr. BROUN. Thank you, Mr. Chairman, and to the whole panel, the President's cancer panel recently released a report on the cancer risk for chemicals and other environmental hazards that was roundly criticized by the American Cancer Society for overestimating these threats. In a critique of the paper, Dr. Michael J. Thun, vice president emeritus, epidemiology and surveillance research at ACS stated, "Unfortunately, the perspective of the report is unbalanced by its implications that pollution is the major cause of cancer," and by its dismissal of cancer prevention efforts aimed at the major known causes of cancer—tobacco, obesity, alcohol, infections, hormones, sunlight as "focused narrowly." Then it went on to state, "That report is more provocative when it restates hypotheses as if they are facts, for example, its conclusion that the true burden of environmentally, i.e., pollution-induced cancer has been grossly underestimated does not represent scientific consensus. Rather it reflects one side of a scientific debate that has continued for almost 30 years."

Before we get into other matters, and since we have such an esteemed panel here today, would you please briefly comment on how the President's panel addressed the risk of environmental cancer versus other causes? The whole panel. Who wants to take it first? Mr. Lester, I see you reaching for the button.

Mr. LESTER. Well, I don't think the report says that the environment is the major source of cancer. What I think it says is that while there are many uncertainties about what we know and don't know about various exposures and various causes, we have a great deal of information about the relationship between these exposures and the toxicity of these chemicals and the susceptibility of the population, and I think the report says that we should take action and we should take steps to reduce exposures to the extent that we can, that we are not doing enough of that. I think Dr. Wargo mentioned that there seems to be this burden of having to rely on certainty that a chemical is causing a particular health problem and that if we do that we are just continuing to allow the population to be exposed and for the varying rates of different kinds of health problems to continue to rise as we are seeing in the last five to 10 years.

So I think that the message from that report is really that we should take steps that we can to reduce exposures because there is a lot that we can do along those lines.

Mr. BROUN. Anyone else? Dr. Wargo.

Dr. WARGO. Yes, I have had a chance to explore that question in a number of different contexts. One was in my experiences on a VA case where a very complicated mixture of chemicals was released and dozens of those compounds are recognized to be carcinogens. Also, I worked with several National Academy of Science panels that looked at this question with respect to pesticides, and you

probably know that there are a number of pesticides, the last I looked, more than 100, that are allowed to be used that are carcinogenic in laboratory studies. There are obvious problems in relying on animal studies alone but given the long latency period between exposure and the onset of many kinds of tumors, it makes it extremely difficult to prove that a chemical or a mixture induced cancer.

Now, I approach this question in a different way, and I think that the President's panel was suggesting a similar route, that it makes good sense to be precautionary and preventative where you can. It makes common sense to figure out where your exposure to carcinogens in the environment are most extreme and to reduce those. And in fact, when I think about how my wife and I raised my family, we couldn't prove that any chemicals that were positive in carcinogenicity tests were threatening our children but it was just prudent to avoid exposure. So I really agree with the panel's recommendations and I think that much more attention needs to be focused on managing environmental contamination as a way of reducing our burden of exposure to carcinogens.

Mr. BROUN. While I agree more research should be done to better understand environmental causes of cancer, I hope that it will not be a distraction from greater causes. Dr. Graham Colditz of Washington University School of Medicine St. Louis said, "The report's overemphasis on environmental toxins could actually cause more harm than good when it comes to the fight against cancer. Maybe up to four percent of cancers in the Western world are caused by contaminants and pollution yet we are chasing new unknown causes rather than focusing on acting on what we know." Things like this report are making it harder to move the Nation to a healthier lifestyle and I am very concerned about that as a physician.

My time is up, and I yield back.

Chairman MILLER. It is.

Mrs. Dahlkemper for five minutes.

Mrs. DAHLKEMPER. Thank you, Mr. Chairman, and thank the witnesses here today.

Dr. Edwards, the main message from the 2004 MMWR and the statements made by federal and city officials was that since blood levels above 10 micrograms per deciliter for children under six didn't show elevated numbers, everything was fine. My understanding is that blood levels between five and 10 micrograms per deciliter can have serious health and developmental effects and consequences for young children. So do you know why this message wasn't more clearly delivered in the District, and can you just comment on that?

Dr. EDWARDS. Actually that message was delivered in the CDC MMWR, that there is no safe level of lead and that there was a small increase, or there might have been a small increase in blood lead that was observed, but unfortunately, the way it was interpreted by the coauthors of the CDC MMWR who testified to Congress and the D.C. council and in the press was that because the increase was below the level of concern, that by definition the health effects were also below the level of concern. So it is unfortunate their subsequent sworn testimony did not look at that issue

in more detail but the reality is, as we showed in our paper, that the blood level of hundreds, if not thousands of D.C. children was raised above levels of concern, was raised above levels that constitute lead poisoning.

Mrs. DAHLKEMPER. What was the sampling number on that?

Dr. EDWARDS. It depends on which part of the study. There was one part of the study which was of 201 residents supposedly from the worst case homes, the homes where it wasn't revealed that 75 percent of the people had been drinking bottled water for weeks to months to a year beforehand. That only had perhaps a dozen children of whom none were drinking the tap water. There was another study where there were tens of thousands of data collected under the routine surveillance program and that was subject to a lot of flaws that are detailed in my testimony and in the House report.

Mrs. DAHLKEMPER. Thank you.

Mr. Lester, can you tell me, you have been working with ATSDR-related issues for two decades now, how have you found ATSDR reacting to your criticism and what has been your experience over those two decades you have worked with them?

Mr. LESTER. Well, when we first started they came to us seeking a route to reach the communities that they work with and to try to find a way to solve the concerns and the issues that had been raised. So for a year or so they were very responsive and conscientious and caring about how they could better work and involve communities in their work. But as things went on, as time went on, it became clear that they could not continue to develop those relationships. I think a lot of it goes back to the fact that they just don't value what community people know. I think that there are problems with the way they perceive information that people provide to them, and so they do not continue—they did not continue to work with communities or to listen to communities or pay attention to what communities want.

Mrs. DAHLKEMPER. Have there been any recent examples of this in the last two, three years?

Mr. LESTER. Yes, yes. I mean, over the years I think I mentioned in my testimony they became very slick at changing the language and adopting the language of what people want and appearing to respond to what people are concerned about, but they actually didn't—nothing has changed over the 20 years, in short. I mean, they are just doing many of the same things today that they did 20 years ago and it is very frustrating to continue to raise these issues with them and them to continue to do what they do.

Mrs. DAHLKEMPER. Ms. Bascetta, without policies and procedures in place, can we have faith in the quality of the work being done by the ATSDR?

Ms. BASCETTA. It certainly lowers our comfort level without those policies and procedures. The flip side is that having those policies and procedures is necessary but not sufficient to guarantee high product quality, uniform and consistent product quality because other factors, you know, could come into play. But certainly having policies and procedures is a necessary first step.

Mrs. DAHLKEMPER. Thank you. My time is just about up. I yield back.

Chairman MILLER. Thank you.

Mr. Rothman for five minutes.

Mr. ROTHMAN. Thank you, Mr. Chairman.

I am going to focus most of my questions, if not all of them, on Dr. Wargo with regards to the island of Vieques in Puerto Rico. Firstly, thank you for your work all these years in identifying and highlighting the significant and very disturbing health issues of the people of Vieques. I am told that in your book you refer approvingly or accept the Puerto Rican health officials' statements that residents of Vieques have a 25 percent higher infant mortality rate, 30 percent higher rate of cancer, 95 percent higher rate of cirrhosis of the liver, and a 381 percent higher rate of hypertension as well as a 41 percent higher rate of diabetes than those on the main island of Puerto Rico just eight miles away. And yet ATSDR saw no connection between those anomalies, if you will, and the dropping of 100 million pounds of explosives and contaminants including TNT, lead, mercury, PCBs and other pretty horrific poisons.

As you know, based on the prompting of many people including myself, in May of 2009 ATSDR's Dr. Frumkin was before us and agreed in response to a question of mine to officially for the first time, as far as I know, reopen the investigation on the health consequences of all those 50-plus years of bombing the island of Vieques. They say they put together an independent peer-review panel. I submitted two names recommended by the mayor of Vieques, two scientists. They just announced, they sent me a letter that I just received that they are going to put one of them on the panel but that all of the others still have no connection to ATSDR.

There is also—and I am sorry we only have five minutes for this. There was a heart disease study done back in 1999, I think, so that of course would be a peer review and a tissue sample study, would it not? In any event, do you think that from what you know, and I know you were out there in October at the CDC, do you think that this new panel will give a satisfactory review and determination about the connection, if any, between these health anomalies of the residents of Vieques and the 52 years of bombing on that island?

Dr. WARGO. No. I think that there are some serious fundamental deficits in the science and the quality of data that is available to the agency, and I also think that in fairness to the agency, if you took their total budget that is allocated toward public health assessments per year, and out of a budget of roughly $75 million per year, probably $10 million of that is allocated to public health assessments. So, say you are running ATSDR and you are responsible for doing health assessments or additional cleanup assessments on hundreds of different Superfund sites, that translates into tens of thousands of dollars only per year, to conduct an epidemiological study, to understand the cardiovascular effects——

Mr. ROTHMAN. Forgive me, Doctor. I have 58 seconds left. Can you provide me, would you be willing to provide me with a list of recommendations on what this new panel needs to do so I can submit it to ATSDR and request/demand that they adopt your recommendations so that you can be confident and I can be confident and the people of Vieques can be confident that this new review will be worth the paper is written on?

Dr. WARGO. Absolutely. I would be delighted to do that, and I just want to say one other thing about the islanders, 9,300 people that live there and suffered through 60 years of military activity and bombing, it is incredibly important to think of this group of people as a highly stressed people. When the Navy went in and took their land away, they basically destroyed their jobs, they moved them from their houses. This has been an island under serious social and economic stress for a long time, and we all know that under those conditions you have background medical problems and illnesses that the exposures are sitting on top of. So I think that much more attention by the ATSDR has to be placed on the idea of susceptibility, you know, who are the susceptible people on that island. They are the young, they are the youngest. They are the fetuses in pregnant women. They are also the elderly. These are the population subgroups that I think deserve the greatest degree of attention, and those with other background illnesses that the chemical exposures are piling on top of.

Mr. ROTHMAN. May I have—I will wait for the second round unless the chairman——

Chairman MILLER. We do have time for a second round.

Mr. ROTHMAN. Very good. Thank you, Chairman.

Chairman MILLER. Because every member kind of stuck to the five minutes, we do have time for a second round.

Dr. Edwards, the MMWR is not peer reviewed, and in fairness, not everything can be peer reviewed. I think even the critics who have suggested there should be further peer reviews that there is a sampling at least, not that everything be peer reviewed, but you certainly qualify as a peer and have looked more closely at the MMWR analysis than just about anybody, and you were also very critical of today's publication. Have you compared the fundamental findings of that 2004 MMWR to the publication today and particularly the reliance on the cross-sectional study that found no correlation between the highest, the elevated water lead levels and blood lead levels?

Dr. EDWARDS. Well, the thing I most remember about the new publication, and I have just seen it, you know, this morning, is that they are now claiming that their conclusion all along was that children living in homes with lead pipes had much higher blood lead than children living in homes without lead pipe, and implying that the public's conclusions were the results of misreading the earlier publication, and that is absolutely false. If you look at their quote where they talk about that in the new publication, it leaves out a sentence before it in the original MMWR that specifically says that the children living in the homes with lead pipes have high blood lead because of lead paint and other sources, not water. So they left that out. They are trying to rewrite history in the most blatant way I can imagine.

Chairman MILLER. And with respect—I know you have already touched on this, well, more than touched on it, you discussed it at some length, but again, what flaws did you see in the cross-sectional study for the 2004?

Dr. EDWARDS. You mean the study of the——

Chairman MILLER. Comparison of water lead level and blood lead level.

Dr. EDWARDS. Within the 300 PPB study?

Chairman MILLER. Right.

Dr. EDWARDS. Oh. Well, first and foremost, not mentioning the water filter use, even though the authors discussed that they should put that in the publication and they purposely decided not to mention it, the fact that there was this sampling gap and that those residents were not the worst case in the city but in fact was the group of residents in the city least likely to show harm from the high lead in water. So it was completely mischaracterizing what they did.

Chairman MILLER. Ms. Bascetta, the GAO report did emphasize, I just touched on, peer review. Do you know how often ATSDR now does conduct peer review and how often do you think it should conduct peer review?

Ms. BASCETTA. For their largest category of studies, out of 282 they only chose to do peer review twice. All of their health studies, but that is a very small proportion of their work, are peer reviewed. And as for what our suggestion would be, it is hard to answer that question without knowing more about the specific circumstances in which the peer review might be warranted but they do have criteria for where they think that a higher level of review is warranted, either from internal peer review or externally, and I would suggest that they take a look at those criteria and try to figure out in what percentage of cases they need to apply that more consistently across all their products.

Chairman MILLER. Dr. Edwards, back to the D.C. water, there was one child who did have elevated blood lead levels and they decided to exclude him from the study because they thought he had not been living there long enough. Do you have a sense of how long it takes exposure to affect the blood lead level and was it scientifically valid to exclude that child and do you have any information that they excluded children from the study who had not lived there long but—did not live in that house for very long but did not have high blood level either—blood lead level?

Dr. EDWARDS. Yes. At the levels of lead and water, the highest lead in water levels in D.C. at that time, 24,000, 48,000 parts per billion lead in water. These are nine times hazardous waste levels of lead in the water. Drinking a single glass of water at that level could elevate your blood lead over CDC's level of concern and cause lead poisoning. There is no doubt about it. So drinking a single glass of D.C. tap water at that time, if you were one of the unlucky ones to get that very, very high does of lead, that is all it would have required, one glass of water.

Chairman MILLER. So if the child had been living in a house for a couple months, they should not have been excluded from the study. That seems a fairly obvious——

Dr. EDWARDS. That was part of my allegations to CDC, why is it you are deleting from your study your known evidence about children that did have high blood lead, and the reason is, is because they could not allow it to be perceived that even a single child had been harmed, not one.

Chairman MILLER. I know that I praised everyone on the Committee for sticking to the five minutes and now I have exceeded slightly myself.

Dr. Edwards, none of us particularly like criticism but you have been very critical of NCEH and ATSDR's work in this area, CDC's work in this area. How have they taken your criticism? Have they regarded it as helpful and constructive or perhaps less welcoming of it?

Dr. EDWARDS. Well, they have been very unwelcoming, to say the least, but worse than what is constituted the scientific misconduct, possible scientific misconduct in the CDC and MMWR is that they refused for years to correct the public record. They saw this being misused not only in D.C. but all around the country and around the world and they refused to correct the record.

Chairman MILLER. Thank you.

Dr. Broun is now recognized for six minutes and 25 seconds.

Mr. BROUN. Thank you, Mr. Chairman.

After hearing you all's testimony, I think that the American public should be very concerned about any product that ATSDR puts out. Under the Superfund Amendments and Reauthorization Act, it exempted ATSDR from peer review. Can you tell me why we should not repeal that exemption? I see no reason that they should be exempted from peer review, just as Dr. Edwards was just talking about, these exemptions, exempting folks from the study and how the study was done. I am a medical doctor, a practicing physician, and some members of this committee who are more true research scientists, don't call me scientific but I am an applied scientist and I am just appalled at the products that ATSDR is putting out, frankly. Why shouldn't we—is there any reason to not remove this exemption on peer review? Let us start with Dr. Edwards and then Dr. Wargo.

Dr. EDWARDS. Well, I can't really speak authoritatively to that issue. What I can say in the case of the CDC MMWR, that the lead author from the CDC gave all her coauthors less than three hours to review the publication and determine whether they wanted to be coauthor or not. So not only is it not being peer reviewed in some cases, the coauthors are not even being given a chance to give input to the publication, and when they gave input, in many instances it was ignored, and I also showed that CDC violated its own clearance policies time and time again related to this publication. So it would be helpful if they started following their own rules to guard against release of misguided information before we started talking about additional rules which might very well be useful.

Mr. BROUN. So your answer is you think that we should remove the exemption from peer review there?

Dr. EDWARDS. I don't feel I can answer the question.

Dr. WARGO. I couldn't agree with you more. I think that that exemption has created very serious problems of credibility for the agency and I have also participated in panels working with the Environmental Protection Agency on their science advisory panel and their science review board and I know that those reviews can be conducted in an open, a transparent and a highly scientific and highly critical forum efficiently, and that is the key. You don't want to have the public health assessments held up for six months or a year to go through a peer review process. But if you have a standing group of experts in an area that know the literature, that are

recognized to be the best in their field, this can happen quite efficiently. I see no reason to maintain that exemption.

Mr. BROUN. Dr. Wargo, do you think this can be done in an expeditious manner or, as Dr. Edwards was talking about, the coauthors offered just hours but that seems to be a bit hasty to me, but can we do this expeditiously and still have peer review?

Dr. WARGO. I believe you can. I believe you can, and I think that having, say, standing panels of experts that are on call to conduct peer reviews in ways that would not prolong the agency's deliberations before they release a document, especially when you have a community that might be being exposed and at risk, you want that opportunity to intervene quickly. So I see it happen in the scientific community all the time.

Mr. BROUN. Thank you very much. I am not going to use my whole six minutes and 28 seconds, so I yield back.

Chairman MILLER. I think Dr. Broun is just trying to make the chairman look bad.

Mr. Rothman for five minutes.

Mr. ROTHMAN. That would be impossible, Mr. Chairman.

Dr. Wargo, we received—my office received after a request, some written assurances from ATSDR that they were aware of the limitations of health care access on Vieques as they were aware of the many health problems of the people of Vieques, and they said that, paraphrasing, while they could not provide the care themselves, they have committed to work with public health and health care partners to seek improvement and access to health care. Do you know of any evidence of their activities in that regard?

Dr. WARGO. No, I do not, and I fully agree that there are problems with providing medical care to the islanders. To get on and off that island commonly takes either a plane ticket, which is expensive, to get to San Juan or most of the islanders will get to the main island by taking a two-hour ferry. So if you have an emergency situation, it is just not sustainable.

Mr. ROTHMAN. And I don't believe there is a hospital on the island. I am not even sure, is there a clinic on the island?

Dr. WARGO. There is a clinic on the island.

Mr. ROTHMAN. Okay.

Dr. WARGO. But that community needs its own state-of-the-art hospital.

Mr. ROTHMAN. One would imagine that the moral responsibility of the people of the United States who were the beneficiaries of the 50-plus years of research, the bombing and use of our weaponry to protect our country, one would argue, I argue, that we have a moral responsibility to take care of the residents of that island, the 10,000 or less who suffered the consequences of in essence protecting us by allowing us to test our munitions.

Vieques was designated a federal Superfund site. Am I correct, Dr. Wargo?

Dr. WARGO. Yes, that is correct.

Mr. ROTHMAN. Is it ATSDR's role to say in its report that even if they don't find a connection between the poisons dropped or contaminants dropped on their island over 52 years and these health care—health status anomalies, that is the right way to describe these higher rates of diseases and bad physical conditions, even if

they don't find a connection, is it their job to recommend that these people be taken care of or is that by the U.S. government in some way or must that come from someplace else?

Dr. WARGO. Well, I read the provision in the statute that I cited earlier, and it is very clearing that provision that they do have a responsibility, that they have a responsibility to suggest opportunities for exposure reduction, and if they understand that there are adverse health outcomes, they have an obligation as well to consider what might be done in order to treat illnesses.

Mr. ROTHMAN. Is that only if the illnesses were related to exposure?

Dr. WARGO. Well, that is not clear in the code, and it strikes me that again if you have got a population that is stressed, that has a high background incidence of the illnesses that you just reviewed, and they are being exposed to chemicals that are well known——

Mr. ROTHMAN. But they would have to come to that—they would have to make that finding. They would have to make that connection.

Dr. WARGO. They would but, you know, knowing what I know about that island, you would be pretty hard pressed to reach a conclusion that those islanders were not exposed to those chemicals.

Mr. ROTHMAN. I agree with you, and ATSDR in a recent letter to us said that they believe that further investigation is warranted and that they will support Puerto Rican health officials and public health agencies to pursue that further investigation. Again, I would ask kindly and respectfully if you could provide my office as soon as possible with your list of recommendations that we will pass on immediately to ATSDR so that we can get a fair and medically credible, scientifically credible conclusion or examination completed as soon as possible by ATSDR.

Dr. WARGO. May I respond just very briefly?

Mr. ROTHMAN. Yes.

Dr. WARGO. It strikes me that the agency should be thinking about the problem in a very different way. They should be thinking about it as an opportunity to understand how to reduce exposures, not six months down the road, not five years down the road, but tomorrow, and there are opportunities to do that.

Mr. ROTHMAN. To reduce exposure on Vieques or in other places?

Dr. WARGO. On Vieques, but the same principle I think should apply to all Superfund sites and all communities that live adjacent to them.

Mr. ROTHMAN. Would you include that in your list of recommendations?

Dr. WARGO. Absolutely.

Mr. ROTHMAN. I thank the chairman.

Chairman MILLER. Thank you, and the Chair thanks Mr. Rothman for exceeding his time.

Mr. ROTHMAN. You are welcome.

Chairman MILLER. And we will include in the record Dr. Wargo's response.

We will now take a short break between panels. I thank all of you for appearing today and we will be back in a minute with Dr. Ikeda.

[Recess.]

Panel II

Chairman MILLER. I will introduce our second panel, which consists of one witness, Dr. Robin Ikeda. Dr. Ikeda serves as the Deputy Director for the Office of Noncommunicable Diseases, Injury and Environmental Health, and as the Acting Director for the National Center for Injury Prevention and Control at CDC. She has an undergraduate degree from Stanford, an MD from Cornell and an MPH, master of public health, degree from Emery. As our witness should know from having been here earlier, you will have five minutes for your spoken testimony. Your written testimony will be included in its entirety in the record for the hearing. When you have completed your spoken testimony, we will begin with questions and each member will have five minutes, and likely we will only have one round. I am sure you are disappointed.

It is the practice of the Subcommittee to take testimony under oath, as you saw earlier. Do you have any objection to taking an oath? The witness spoke the word "no." You also have the right to be represented by counsel. Do you have personal counsel here? Okay. If you will now please stand and raise your right hand? Do you swear to tell the truth and nothing but the truth? Okay. Dr. Ikeda has taken the oath. Dr. Ikeda, you are now recognized for five minutes for your spoken testimony.

STATEMENT OF ROBIN M. IKEDA, MD, MPH, DEPUTY DIRECTOR, OFFICE OF NONCOMMUNICABLE DISEASES, INJURY AND ENVIRONMENTAL HEALTH, AND ACTING DIRECTOR FOR THE NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL (NCIPC), CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

Dr. IKEDA. Good morning, Chairman Miller, Ranking Member Broun and other distinguished members of the Subcommittee. On behalf of Dr. Thomas Frieden, Director of the Centers for Disease Control and Prevention, CDC, and Administrator of the Agency for Toxic Substances and Disease Registry, ATSDR, I would like to thank you for the opportunity to present this testimony.

I am Captain Robin Ikeda, a physician and a member of the United States Public Health Service Commission Corps. Since February 2010, I have served as the CDC Deputy Director for Noncommunicable Disease. In this position, I provide guidance and leadership to the four noncommunicable disease centers at CDC including the National Center for Environmental Health and ATSDR. I have worked at CDC for nearly two decades and have served as Associate Director for Science at both the Epidemiology Program Office and at the National Center for Injury Prevention and Control.

Today I will focus on several areas of interest to the Subcommittee: improvements underway within NCEH and ATSDR, the National Conversation, CDC's work on elevated lead in Washington, D.C., drinking water, and the fresh look that ATSDR is taking on the island of Vieques in the Commonwealth of Puerto Rico.

CDC/ATSDR's senior leadership understands the need to improve ATSDR's ability to address concerns of communities related to potential exposures to hazardous substances. A team from the Government Accountability Office, GAO, recently reviewed

ATSDR's processes related to preparation and review of scientific manuscripts. We appreciate the GAO recommendations to improve ATSDR's procedures. In particular, ATSDR is working to strengthen both our priority setting and project management to make them more explicit and consistent across the agency. Staff roles and responsibilities from project inception to publication of findings must also be clearly defined and understood.

On a larger scale, NCEH, ATSDR along with many others launched the National Conversation in June 2009. Individuals from dozens of organizations are represented on the National Conversation six work groups. This two-year project will identify strategies to better protect the public from harmful chemical exposures. The National Conversation is currently at the midpoint in the process. Recommendations from the project's leadership council are expected this winter.

Moving to more specific areas, I will touch on our efforts to address lead in the District of Columbia drinking water. As you have heard, between 2000 and 2003, the District of Columbia detected a very high lead concentration in its drinking water. Available surveillance data were analyzed and in April 2004 CDC reported that lead in tap water contributed to a small increase in blood lead levels in D.C. among those living in homes with lead service lines. Several concerns have been raised about this report. A critical issue has been the missing blood lead data from 2003 and whether this compromised our analysis. Given these concerns, we took steps to obtain the data that we should have had for the 2003 analysis. We conducted a complete reanalysis and invited outside experts to review our work. Today I can report to you that our more comprehensive analysis did not fundamentally change our findings from 2004. These results were released on our website yesterday and will be announced in CDC's MMWR—that's the Morbidity and Mortality Weekly Report—today.

My final topic is ATSDR's work on the island of Vieques. Between 1999 and 2006, ATSDR evaluated the extent of exposures to hazardous substances and potential health effects. As part of this work, ATSDR used available data collected from a variety of sources. In general, these reports found that residents of Vieques had likely been exposed to contaminants. However, the levels of exposure were sufficiently low that the available scientific methods at that time could not establish a link to negative health effects.

In 2009, ATSDR pledged to take a fresh look at the island of Vieques. This has involved both a thorough review of its previous work on the island and any new scientific data. In August 2009, ATSDR leadership and staff visited the island, and during November convened a face-to-face consultation with independent scientists including individuals from Puerto Rico and from academic institutions on the mainland. ATSDR is in the final stages of completing a draft report. This document will be externally peer reviewed and then shared with this Committee and the public for comment.

NCEH/ATSDR works to address environmental public health concerns including those raised by communities. Although we have assembled a strong record of accomplishment, we continually seek to strengthen our ability to prevent harmful exposures and to protect the public. I am committed to applying my 19 years of experi-

ence at CDC, particularly my service as Associate Director for Science, to guide this ongoing improvement in our work. I look forward to working with the new Director of NCEH/ATSDR and Dr. Frieden to protect the public from dangerous environmental exposures.

Thank you, Mr. Chairman and members of the Subcommittee, for this opportunity to testify before you today.

[Statement of Dr. Ikeda follows:]

PREPARED STATEMENT OF ROBIN M. IKEDA

Introduction

Good morning Chairman Miller, Ranking Member Broun, and other distinguished members of the Subcommittee.

On behalf of Dr. Thomas Frieden, Director of the Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR), I would like to thank you for the opportunity to present this testimony.

I am Captain Robin Ikeda, a physician board-certified in both internal medicine and preventive medicine, as well as a member of the U.S. Public Health Service Commissioned Corps. Since February 2010, I have served as CDC Deputy Director for Noncommunicable Diseases, Injury, and Environmental Health. I am responsible for providing guidance and leadership to the four noncommunicable disease centers at CDC, including the National Center for Environmental Health (NCEH) and ATSDR. I have had the privilege of serving at CDC for nearly two decades, during which I have held key leadership positions including as Associate Director for Science in CDC's Epidemiology Program Office, and later in the same role at the National Center for Injury Prevention and Control. I began my CDC career as a member of the Epidemic Intelligence Service, assigned to the New York State Department of Health.

This experience provides a solid foundation for the responsibilities I have in my current position, particularly during this important time for ATSDR and NCEH, when we are actively searching for a new director to lead our environmental health programs. We are committed to finding a director who will assure and facilitate excellence at NCEH/ATSDR in achieving our mission.

Today I will focus my remarks on several areas in which the Subcommittee has expressed interest: changes underway within NCEH and ATSDR to improve the ways in which we protect the health of the public; CDC's work related to lead poisoning prevention, including that related to elevated lead in Washington, D.C. drinking water; and the fresh look that ATSDR is taking to evaluate potential health effects of exposures to hazardous substances on the Island of Vieques in the Commonwealth of Puerto Rico.

ATSDR Improvements

ATSDR is a small agency with a large mission. CDC/ATSDR's senior leadership, and Dr. Frieden in particular, understand the need to improve ATSDR's ability to address concerns of communities related to potential exposures to hazardous substances.

Recently, a team from the Government Accountability Office (GAO) completed a review of ATSDR's management processes related to preparation of scientific documents, and provided us with a draft report, *Agency for Toxic Substances and Disease Registry: Policies and Procedures for Public Health Product Preparation Should be Strengthened (GAO–10–449)*. We appreciate GAO drawing attention to areas where ATSDR can improve the documentation and functioning of our processes and controls. ATSDR has undertaken several efforts to formalize and improve its processes in fulfilling its public health mission. Several improvements are underway. Some of these changes are in response to the report, and others were initiated prior to our receipt of the draft report.

- ATSDR is working to ensure that scientific principles and approaches are consistently applied across all of our divisions—and that all documents that are prepared for public dissemination receive an appropriate level of review and clearance.
- ATSDR has moved away from paper-based tracking and record keeping systems to computer or electronic based systems. This ensures review and clearance by the appropriate chain-of-command, and precise documentation of the

process. ATSDR is working to greatly improve project tracking, to ensure projects stay on track, are completed in a timely fashion, and receive scientific and management review and input on a consistent basis.

- As recommended by GAO, ATSDR is working to strengthen its project management and priority-setting processes, to make them more explicit and consistent across the Agency. It is important, given the scope of ATSDR's mission, that we have a sound system for handling and triaging requests and that management and staff roles and responsibilities are clearly defined and understood from project inception to publication of findings.

In addition to these improvements in processes for preparation of scientific documents, ATSDR is actively reviewing other ways to further strengthen its scientific approach. These include:

- Reviewing areas where ATSDR work has been particularly effective, and the needs of federal, state, and community partners, in order to identify a clear set of priorities that emphasize the activities that are achievable and best meet the needs of our partners.
- Adjusting the scope or volume of ATSDR's scientific activities to ensure consistently high quality.
- Leveraging both NCEH and ATSDR programmatic and scientific strengths to improve environmental public health practice.

National Conversation on Public Health and Chemical Exposures

Many agencies and organizations—governmental and nongovernmental, 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.

In June of 2009, with the collaboration of ATSDR and NCEH, other government agencies, national experts and members of the public, the National Conversation on Public Health and Chemical Exposures was launched.[1] The National Conversation is a two year project that aims to identify strategies that many stakeholders, including ATSDR, can take to better protect the public from harmful chemical exposures. The National Conversation currently is at the mid-point in the process.

Through the National Conversation, public health professionals and others who contribute the experience and perspectives of government, communities, business, NGOs, and academic institutions, are engaging in a collaborative effort to recommend measures based on consideration of the broad range of related programs and activities. Many knowledgeable individuals from dozens of organizations are represented on one of the National Conversation's six work groups or Leadership Council. The work groups are organized around key components of public health action on chemical exposures, including Monitoring, Scientific Understanding, Policies and Practices, Chemical Emergencies, Serving Communities, and Education and Communication, and each group is currently developing a report of prioritized recommendations. We anticipate that these recommendations will be provided to the project's Leadership Council within the next year.

Among the issues currently being discussed as part of the National Conversation are several that relate directly to current CDC/ATSDR programs and activities, including:

- Building state biomonitoring capacity;
- Enhancing ATSDR's community-based environmental health activities; and
- Advancing ATSDR's efforts to characterize risks from exposure to multiple chemicals.

NCEH Work Related to Lead Poisoning Prevention, Lead in Washington, D.C., Drinking Water.

Substantial improvements have been made in reducing lead in the environment: during 1999–2004, 1.4% of children in the United States aged 1–5 years had blood lead levels above 10 ug/dL, compared with 8.6% of children during 1988–1991.[2] These improvements are the result of population-wide prevention strategies to re-

[1] *www.atsdr.cdc.gov/nationalconversation*

[2] Jones, Robert L., David M. Homa, Pamela A. Meyer, Debra J. Brody, Kathleen L. Caldwell, James L. Pirkle, and Mary Jean Brown. Trends in Blood Lead Levels and Blood Lead Testing Among U.S. Children Aged 1 to 5 Years, 1988–2004: Pediatrics, March 2, 2009, 123(3); e376–385. *http://pediatrics.aappublications.org/cgi/content/abstract/123/3/e376*

duce the incidence of lead poisoning. Collaborative public health efforts by CDC, the Environmental Protection Agency, the Department of Housing and Urban Development and others contributed to this dramatic reduction.

However, lead paint hazards in residences and public buildings, and lead in water, consumer products, and as a result of take-home exposure by parents who work with lead, continue to contribute to children's blood lead levels.

Since 1990 CDC has designed and implemented programs that identify the children most likely to have elevated blood lead levels and helped ensure that they receive timely and appropriate care; identify the houses most likely to have lead hazards and ensure that the lead hazards are controlled or eliminated before more children are exposed; provide information to health care providers, educators, and advocates to support lead poisoning prevention; and provide information to parents to empower them to protect their children from lead exposure. CDC also supports 40 state and local health departments through funding and technical assistance to eliminate elevated blood lead levels in children.

Between 2000 and 2003, the District of Columbia (D.C.) detected very high lead concentrations in its drinking water. Upon learning of this in February, 2004, CDC immediately began working with the D.C. Department of Health to ensure that the public was alerted to this exposure and that alternative sources of drinking water were made available. Within six weeks, CDC analyzed all available surveillance data, and, in April 2004, reported in the CDC publication, the Morbidity and Mortality Weekly Report (MMWR)[3], that between 2000 and 2003, lead in tap water contributed to a small increase in blood lead (BPb) levels in D.C. among those living in homes with lead water service lines. The report also advised that there is no safe level of exposure to lead and all sources of lead exposure should be eliminated.

Concerns have been raised over whether the MMWR report accurately characterized the impact of lead in water on blood lead levels. We take those concerns seriously. Over the past 8 months, we have taken a number of additional steps to improve our understanding of the impact of elevated lead levels in tap water on the levels of lead in the blood of D.C. residents. Today I can report to you that, as a result of a more comprehensive analysis, we have concluded that CDC's initial reports did not understate the magnitude of the problem.[4]

Since the initial analyses attracted much interest, I would like to provide a little more detail about our reanalysis here. CDC conducted a more intensive data recovery and reanalysis because data reported in the 2004 MMWR did not include a substantial number of test results from blood specimens collected in 2003. Scientists outside CDC, lead poisoning prevention advocates, and Members of Congress have raised concerns that the missing test results might have resulted in an underestimation of the effect that elevated drinking water lead levels had on blood lead levels. To evaluate this potential bias, CDC recently collected all known 2003 blood lead test results and compared them to the subset of tests included in the MMWR article. This reanalysis was peer reviewed by experts from outside of CDC.

CDC received 2003 blood lead test results from D.C. on three occasions. In March 2004, CDC received 9,765 test results from surveillance data and included these in the analysis for the MMWR article. An additional 1,753 tests from 2003 surveillance data (that had not been received previously) were reported by July 2006. In the fall of 2009, CDC received 21,324 test results reported by the laboratories that ran tests for D.C. children. Of these tests, 7,701 had been reported previously as surveillance data, while 12,168 tests had not been previously reported to CDC. Of these, 1,455 were not included in analyses because they were either duplicates, not from 2003, or not from a D.C. address.

CDC found that the percent of 2003 blood lead tests that were elevated were actually lower when using all known 2003 blood lead tests compared to the subset of tests used previously in the 2004 MMWR article. The only variable that systemically predicted whether or not a test had been reported as part of the DC surveillance datasets was the reporting laboratory processing the test. Previously missing but now-available 2003 data did not cause an underestimation for 2003 of the association between elevated blood lead levels and lead water service lines.

Nonetheless, CDC recognizes the importance of better understanding the contribution of lead in water to blood lead in children. CDC recently completed an epidemiological study, and the preliminary results suggest a relationship between partial replacement of lead water service lines and elevated blood lead levels in children. That is, when public water service lines are replaced but the portion of the

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[3] Stokes L, Onwuche NC, Thomas P, et al., Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water—District of Columbia, 2004; MMWR Weekly, April 2, 2004, 53(12); 268–270.

[4] CDC's reanalysis is available at: *http://www.cdc.gov/nceh/lead/leadinwater/*

service lines belonging to the homeowner are not, the preliminary results suggest that blood lead levels increase, at least for some period of time. Due to the significance of the preliminary findings, even though publication of the study results was still pending, on January 5, 2010, CDC sent letters to lead program grantees (state and local departments of health) and water departments across the Country, and posted this information on our website.[5]

In the wake of the MMWR article we have learned a great deal about how we work with state and local governments to gather surveillance data, how we communicate our findings, and how we ensure appropriate response when questions are raised about the quality of our science. We are applying these lessons to our ongoing work in NCEH and ATSDR, and we have new organizational structures and leadership in place across CDC to help ensure that appropriate steps are taken.

ATSDR Evaluation of Potential Human Health Hazards on Vieques

In 1999 ATSDR received a petition from a resident of Vieques, who was concerned about potential health effects related to the Navy bombing range and other military training activities. ATSDR has worked extensively on the island to evaluate the extent of exposures to hazardous substances, and potential health effects. As part of this work, ATSDR used available data collected from the Commonwealth of Puerto Rico, the U.S. Environmental Protection Agency, the U.S. Navy, and published scientific reports, as well as gathering additional data to supplement areas where needed. ATSDR also convened expert scientific panels to gather more information on specific areas. From 2001 to 2006, ATSDR published four public health assessments, as well as reports on several specific topics of health concern to the community. In general, these reports found that residents of Vieques had likely been exposed to contaminants. However, the levels of exposure were sufficiently low that the available scientific methods could not establish a link to negative health effects. Notwithstanding, ATSDR could not say with certainty that the low level of exposure did not cause harmful effects in some people.

In 2009, ATSDR pledged to take a fresh look at the island of Vieques in response to members of Congress, who expressed concerns voiced by the community. ATSDR outlined an aggressive course of action to thoroughly review its previous work on the island and to gather any new scientific data that has become available. In August 2009, ATSDR leadership and staff visited the island and met with representatives of EPA, the Puerto Rico Environmental Quality Board, the Puerto Rico Department of Health, and the Puerto Rico Cancer Registry to determine what additional information was available. We also met with elected officials, health officials, and members of the community on Vieques to better understand community concerns related to health and the environment.

Since then, ATSDR has convened a face-to-face scientific consultation with independent scientists who have conducted research work related to health and environmental issues on Vieques. The consultation included scientists from Puerto Rico as well as from academic institutions on the mainland, and focused on the strengths and weaknesses of many environmental health studies conducted in Vieques. ATSDR is currently in the final stages of completing a draft report—*A Fresh Look at Environmental, Biological, and Health Data from the Island of Vieques, Puerto Rico*—which will be submitted for external peer review. Once the peer review and clearance processes have been completed, ATSDR will release the document for public comment.

Conclusion

NCEH and ATSDR work to address environmental public health concerns, including the needs and concerns raised by communities. Although we have assembled a strong record of accomplishment—protecting health near hazardous waste sites, advancing science through our health studies and the work of the environmental health laboratory, and educating health professionals and the public—NCEH and ATSDR constantly seek to strengthen our ability to prevent harmful exposures and protect the public.

For example, ATSDR reviews and updates health assessments based upon significant additional data that it obtains, and based on advancements in scientific knowledge. At Camp Lejeune, North Carolina, ATSDR has been gathering data, refining methods, and amending findings as additional information has come to light. I appreciate the Committee Members' interest in ATSDR's work at Camp Lejeune, and support in responding to the concerns of the service men and women who served

[5] *http://www.cdc.gov/nceh/lead/waterlines.htm*

there. We look forward to working with you in the future as ATSDR continues to work at Camp Lejeune and at other sites across the Country.

ATSDR also seeks to maximize the effectiveness of our internal processes and appreciate the recommendations from GAO for improving processes at ATSDR.

I am committed to applying my 19 years of experience at CDC, and in particular my service as Associate Director for Science in different parts of the Agency, to guide and contribute to this ongoing improvement in our work, and look forward to working with the new Director of NCEH/ATSDR to achieve the goal of protecting the public from dangerous environmental chemical exposures.

Thank you Mr. Chairman and Members of the Subcommittee for the opportunity to testify before you today.

Chairman MILLER. Thank you, Dr. Ikeda. We will now have a round of questioning, and the Chair recognizes himself for five minutes.

Dr. Ikeda, there has been some assertion that the MMWR from 2004 was misinterpreted, was widely misinterpreted as saying that there really was not a public health concern. That was not the intent, it shouldn't have been read that way. But it does appear to have been widely reported in the press that that was the takeaway, the lesson, and it appears that that was in fact from the documents that you all had provided or that we have obtained that seems to be the intended message. That there was a talking point, talking points for Dr. Brown, main message, there is no indication that D.C. residents have blood lead levels above the CDC levels of concern of 10 micrograms per deciliter for children six months to 15 years old and 25 micrograms per deciliter for adults as a result of lead in the water. There was an e-mail exchange between Dr. Falk, who was then the head of ATSDR/NCEH, and Dr. Brown referring to the MMWR. Dr. Falk said, "Have you had many calls? How is it going?" She wrote back, "Today has been the first day in over a month that there wasn't a story on lead in water in the Washington Post and also the first that I haven't been interviewed by at least one news outlet. I guess that means it worked."

What steps should ATSDR and NCEH and CDC take in the future, or do you think it was incumbent upon those agencies to correct this impression? Did they do as they should have, and how do you go forward from here?

Dr. IKEDA. One of the reasons that we published the MMWR today, this is a notice to readers that points people in the direction of the reanalysis, was to correct the record, was to let people know that we understood that our comments in the MMWR from 2004 were ambiguous and open to interpretation, so we wanted to make sure that people understood the principal message that we intended from 2004. Certainly we know that no lead level is safe and that we are very concerned about addressing and preventing, controlling, and eliminating lead exposure from any source.

In terms of I think the larger question that you were asking about how ATSDR can move forward from here, we have heard a number of comments today about the concerns raised about scientific quality at ATSDR, procedural issues at ATSDR, and we are working to correct those. There are a number of improvements that are in place already and others that we are contemplating and thinking about in terms of moving forward. Dr. Frieden is very committed to ensuring the highest quality of science at ATSDR. I know that you and he have had conversations about that. And it is my responsibility as Deputy Director to make sure that that

commitment is carried through. So I look forward to working with him and our new director to ensure that we improve the overall processes, procedures and scientific quality at ATSDR.

Chairman MILLER. With respect to the D.C. lead issue and the 2004 MMWR, what is published today does not specifically retract or correct the weaknesses of the cross-sectional study, which was the most single cited part of the study. You heard Dr. Edwards' testimony today that it had a very fundamental flaw, that it is hard to imagine it was not intentional, that it left the impression that children drinking the water did not have elevated blood lead levels—that is not easy to say—when in fact they weren't, the vast majority of the children, perhaps all the children weren't drinking the water at all. Have you corrected that part of the record?

Dr. IKEDA. And again, we hope that our statement today and that the notice to readers in the MMWR will indicate to folks that we realize that statements in that original MMWR were ambiguous and open to interpretation. The cross-sectional study has not been repeated so I can't speak to whether there is any ability to redo that study or not. Certainly that study had limitations as well. We heard already today about the limited numbers, the possibility of other confounding factors influencing the results, etc.

Chairman MILLER. My time is expired. Dr. Broun for five minutes.

Mr. BROUN. Thank you, Mr. Chairman.

Dr. Ikeda, in the case of formaldehyde levels in FEMA trailers, EPA conducted sampling after limited consultation with ATSDR. The sampling was deemed to be insufficient to characterize long-term exposure. In the case of D.C. lead in water, the agency received insufficient data from the D.C. health department, Department of Health, that was also counterintuitive. How does the Agency now ensure that it receives appropriate samples and the data to adequately characterize exposure and risk?

Dr. IKEDA. In addition to the improvements that I mentioned earlier that are specific to ATSDR, there are a number of organizational CDC improvements that are also ongoing. Certainly our efforts to build state and local capacity and to strengthen our relationships and how we work with state and local health departments and labs would assist in this effort. You may know that CDC underwent an organizational improvement over the past several months and we now have a new office for state, local, tribal, and territorial support which is designed to help us strengthen those relationships and make sure that we provide the appropriate levels of technical assistance to states and locals and laboratories and also to address some of the accountability issues that have been a problem in the past.

Mr. BROUN. Doctor, what does ATSDR have if sampling data is limited for particular review? How challenging is this in terms of communicating results and how do you propose ATSDR address this issue?

Dr. IKEDA. I think there are a couple different things in that question. Often in science we have limited information and, you know, we joke in science that more studies are needed because that is always true. We always feel like we need more information. We never have perfect understanding. And science is very dynamic,

that it is always changing, there is always new information. So there is that part of it. We can always try and get more information, more samples. But the other piece of it is the communication piece, so how do we, when we have limited information, how do we share findings and recommendations, how do we even craft findings and recommendations when the data are limited, and that really is an art and we have to make sure that our communication messages are clear and that we document and let folks know that it is limited in whatever way.

Mr. BROUN. Doctor, is caveating the limitations in reports your only option that you have on sampling data?

Dr. IKEDA. I am sorry. I am not sure I——

Mr. BROUN. Is caveating the limitations in the report of the sampling data, is that your only option of trying to make sure that the particular review is appropriate?

Dr. IKEDA. I am sorry if I am not answering the question. Forgive me. I think we would try and make efforts to achieve the appropriate samples or the full sample size that we would want. I guess I am assuming that we are talking in a world where these samples don't exist, that we don't have more of them. And there are other communication venues that we could use to make sure that people understand that we are making these recommendations based on limited information.

Mr. BROUN. I want to go back to the previous panel where we were talking about the exemption for peer review as well as not only the methodology but the results of the reviews. Would CDC welcome a peer review process that is mandated and not exempted as it is today, and would you welcome a review of the findings beyond the methodology, just what the conclusions would be from that peer review as well as a review of the findings from the data samples that you get?

Dr. IKEDA. Peer review is a pillar of good science and certainly we welcome peer review in many different forms at CDC. As someone who oversaw peer review for other centers at CDC, I recognize the value of transparent peer review. I think you heard some of the concerns raised about peer review here, that again we need to balance the rigor of peer review and the time that it takes to conduct good peer review with the need to get information out quickly, particularly in emergent settings. So yes, in general peer review is—we support peer review wholeheartedly. I think it is just trying to balance when it is appropriate, whether it is for all documents, and the timeliness with which we can then move out with recommendations.

Mr. BROUN. Thank you, Doctor. If I may take my extra minute, Mr. Chairman, I have got one more quick question.

As a physician, and I know that you are a physician also, we look at data, we look at results, and what I was taught in medical school five years later was—what I was taught in medical school as being absolute fact, five years later we were being taught exactly the opposite. When you have this expeditious process, do you all have any kind of process in place or mechanism in place to come back and re-review what was done in such a hurried-up manner so that the appropriate findings, if they were indeed found in the original review, are still valid or if there is another set of conclu-

sions that may be kind of contradictory to the original findings? Is there a process or is there not one to go back and do that?

Dr. IKEDA. I think it depends on the type of product. Certainly things that CDC puts out that are listed as interim recommendations, for example, in an H1N1-type situation where again they are trying to get recommendations out in an expeditious way and yet they realize that the science on which it is based may not be complete. So for things like that, it is clearly labeled, you know, this is interim with the understanding that this is preliminary based on the best information that we have now but we know we need to get it out quickly. For those types of documents, there is a process because it is labeled interim to begin with and so there is a process by which it is reviewed if and when other additional data become available. For other documents, I think it is less clear. It is part of the general scientific process as you were describing where information is always changing, new information is always at hand, and the findings and conclusions and results and recommendations may change over time.

Mr. BROUN. Thank you, Doctor, and I appreciate your letting me have a few extra minutes, Mr. Chairman. Thank you, and I yield back.

Chairman MILLER. And the Chair thanks Dr. Broun for exceeding his time, although he didn't exceed it quite that much.

The Chair now recognizes Mr. Rothman.

Mr. ROTHMAN. I thank the chairman, and let me—I was remiss in not thanking you earlier, Mr. Chairman, for holding this hearing. It is extremely important.

Dr. Ikeda, thank you for being here. I have a lot of questions. I am going to try to ask them quickly and I hope you can give me as concise answers as possible. Do you know—I got a letter from Dr. Frieden saying that he had pursuant to my request and the mayor of Vieques's request decided to accept at least one of the two scientists that the mayor of Vieques had requested be a part of the study, although he did say that they have already established or identified their peer review panel and this scientist would be an adjunct reviewer of the report whose comments would be carefully considered. Do you know the name of the scientist that was chosen?

Dr. IKEDA. No.

Mr. ROTHMAN. Okay. If you can get that to us as soon as possible, that would be great.

You said in your testimony that the draft was expected, I am paraphrasing, soon, reasonably shortly. Do you have some kind of a better date estimate than that?

Dr. IKEDA. I don't have a specific date estimate. I do know that the draft report is being prepared now to be delivered to the peer reviewers, so the panel of seven peer reviewers will then review, provide their comments, come back to CDC to incorporate those comments, consider those comments, so those are the steps that will be taking place.

Mr. ROTHMAN. Thank you. I mentioned earlier, I don't know if you were here, that I thought that the United States had a moral obligation to the people of Vieques to take care of them because it seems obvious that there is a connection between the dropping of

several hundred million pounds of contaminants on that island over 52 years has caused health problems to these people, and the people are suffering as a result. If one is to believe the findings of the Puerto Rican health authorities, there are unusually high levels of infant mortality, cancer, cirrhosis of the liver, hypertension and diabetes amongst other things going on. I sit on another committee in addition to this one called the Appropriations Committee and I am on the Defense, among others, subcommittee of Appropriations. Could you make sure or do I need to put this in writing that we get a recommendation whether there is a causal connection acknowledged in the final report between these high rates of illnesses in the people of Vieques and the dropping of these—and the creation of this federal Superfund site by the dropping of these poisons on the island for 52 years, whether or not they make a connection? Could you tell us how much it would cost to establish a sufficient medical facility on that island to take care of these people and how much it would cost? Let me just finish. And perhaps wearing that other hat of mine, I can then try to get the resources to establish that appropriate facility to take care of these people.

Dr. IKEDA. I don't know how much it would cost but I can certainly consult with colleagues and we can do our best to provide an estimate, but——

Mr. ROTHMAN. Can we make it a part of the report, though?

Dr. IKEDA. From the consultation in November, there was clear discussion about CDC's role in terms of assisting Puerto Rico health officials to make sure that clinical care was received by folks, and again——

Mr. ROTHMAN. In light of that—I have 27 seconds. Sorry. In light of that acknowledgment by CDC that you wanted to help the Puerto Rican health care officials, I am requesting that you put a dollar amount on what help is necessary to completely address the health care issues that are being suffered by the people of Vieques.

Dr. IKEDA. Thank you for the suggestion.

Mr. ROTHMAN. Thank you.

Chairman MILLER. Thank you.

We have been joined by the delegate from the District of Columbia, Eleanor Holmes Norton. I ask unanimous consent that Ms. Norton join the panel. Without objection.

And the Chair now recognizes Ms. Norton for five minutes.

Ms. NORTON. Chairman Miller, I certainly can't thank you enough, and I thank you and the ranking member for allowing me to question this witness and to join the panel, but I want to thank you, Mr. Chairman, especially for the enormously important follow-through you have done here with this investigation.

This matter was a matter of national concern. So what you do here, you do not only for the residents of the District of Columbia but for all of those who were roused by the notion that in all places, the Nation's capital, there was lead in the water. Some of these families of course came to see me in the Government Oversight and Reform Committee, which has jurisdiction over District of Columbia matters. There were a number of hearings in which we also were told that there was nothing to fear but fear itself. Those hearings were in 2004. There was panic, particularly among

young women with children and some of those who came to see me were pregnant, were told not to worry.

Therefore, Dr. Ikeda, I have got to be concerned now. That was then, this is now. In light of what we know now about what CDC reported to them, my concern is with the families that have now been identified. We know who has experienced lead in the water of five to 10 milligrams above what it should have been. We know that those who rushed to change their pipes, part of the pipes now have worse conditions involving that. What can CDC do now for these now-identified families? What specifically can you do? Do you intend to notify them? Do you intend to be in touch with them to and to examine them and their children for the health effects of this misinformation?

Dr. IKEDA. CDC works with local and state health department lead programs who in turn then work directly with families who have been exposed or who have been discovered to have high levels of lead and there are—the programs that are in place include contact with the individuals——

Ms. NORTON. Dr. Ikeda, I am going to have to ask you very specifically. I am not asking you about the CDC's programs. I am well aware of them. I am asking you whether in preparing your testimony now that you know what has occurred, what specific initiative you believe CDC should take in this situation now with respect to whatever it is you can do, what services you can provide, not what services are generally available. What is it that CDC can do? What will you be asking CDC staff to do, if anything?

Dr. IKEDA. I am sorry if I am misunderstanding your question. I would say that we work through the lead prevention programs to make sure that children and families are appropriately taken care of.

Ms. NORTON. You have been in touch with the District of Columbia?

Dr. IKEDA. Yes, our lead programming folks.

Ms. NORTON. Regarding this new information?

Dr. IKEDA. I don't know about regarding the new information. I do know that we posted and shared letter to—a dear-colleague-type letter letting them know that this information had been released on our website yesterday and that the MMWR notice to readers was being published today.

Ms. NORTON. Do you intend to meet with the mayor or with health officials in the District of Columbia?

Dr. IKEDA. I don't know.

Mr. NORTON. You don't know whether you intend to meet or have CDC staff meet with health officials or the mayor of the District of Columbia? You don't know that?

Dr. IKEDA. Offhand——

Ms. NORTON. You can't testify that you will do that?

Dr. IKEDA. No, I was responding to the question that I don't know, but I can certainly take the suggestion back to our——

Ms. NORTON. I wish you would take the suggestion. It seems to me all but obvious that CDC be in touch immediately with health officials in the District of Columbia to offer specific services to them and to the identified families. I would very much appreciate that.

Dr. IKEDA. I will.

Ms. NORTON. Thank you, Dr. Ikeda, and thank you very much, Mr. Chairman.

Chairman MILLER. Thank you.

We are at the end of our time. The President of Mexico is speaking to a joint session in just a short while. There is certainly—there has certainly been a problem with paralysis, intentional paralysis by analysis on environmental issues. This subcommittee, I have been very critical in the last Congress and the last Administration for the work at OIRA in insisting upon studies of studies before finding anything to present a public health risk, formaldehyde being perhaps the best example.

Mr. ROTHMAN. May I have 20 seconds, Mr. Chairman?

Chairman MILLER. Mr. Rothman is recognized for 20 seconds.

Mr. ROTHMAN. I wanted to clarify one thing, Dr. Ikeda. I believe that there is a connection between the bad health situation of the people of Vieques and what we did to the island, the United States did, for 52 years, and I believe that the proper study should reveal that, so I don't want my comments that there should be a health clinic regardless of the findings to be misinterpreted otherwise. I believe there is a connection. I believe a fair and scientifically valid study will prove that, and I hope that with the new procedures it will.

Thank you, Mr. Chairman.

Chairman MILLER. Thank you.

Formaldehyde, there were studies upon studies upon studies, studies of studies. All of that seemed to be urged by the Administration, by the formaldehyde industry and by allies in Congress. Our former colleague, Mark Souder, was best known in Congress for two positions. One was that sex was bad for you and the other was that formaldehyde was good for you. He apparently changed his position on sex but maybe not on formaldehyde. We don't want to get that point. We don't want to have paralysis by analysis but we do want to have sound science that has credibility, that does reach a conclusion but one that can be taken seriously.

I do hope that the new—I have, as you have pointed out, spoken to Dr. Frieden, and I trust that we will again. I hope that there is an effort to make this an agency that the professionals who work there can be proud of the work they do and that the Nation can rely upon the work they do. We need that.

So I want to thank all of our witnesses for testifying. The record will remain open for a couple of weeks, for two weeks for any additional statements from members. I know that Dr. Wargo was going to provide a response to a question from Mr. Rothman.

With that, the witnesses are now excused and the hearing is adjourned.

[Whereupon, at 10:56 a.m., the Subcommittee was adjourned.]

Appendix:

Additional Material for the Record

A PUBLIC HEALTH TRAGEDY: HOW FLAWED CDC DATA AND FAULTY ASSUMPTIONS ENDANGERED CHILDREN'S HEALTH IN THE NATION'S CAPITAL

Report by the Majority Staff of the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U.S. House of Representatives to Subcommittee Chairman Brad Miller

May 20, 2010

A PUBLIC HEALTH TRAGEDY: HOW FLAWED CDC DATA AND FAULTY ASSUMPTIONS ENDANGERED CHILDREN'S HEALTH IN THE NATION'S CAPITAL

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STAFF FINDINGS

The staff findings represent the essential elements of what could be proven based on the records provided to the Subcommittee and the information gathered in dozens of interviews with both former and current officials from the Centers for Disease Control and Prevention (CDC), the Public Health Service (PHS), and the District of Columbia. A fuller accounting of the results of the staff's work can be found in the Summary and body of the report.

In the Subcommittee's attempt to fully investigate many of the allegations surrounding the publication of the March 30, 2004 *Morbidity and Mortality Weekly Report Dispatch (MMWR)* and the CDC's overall response to the DC lead-in-water crisis, it has been very difficult to obtain all relevant records regarding the issue from either the CDC or the District of Columbia government, and there are key documents that have been referred to by persons interviewed that have never been located. In other instances, records obtained by the Subcommittee from non-CDC sources completely contradict allegations made by CDC officials. Some assertions made by CDC staff remain completely unsubstantiated by documentation or by outside participants who should have knowledge of the events.

Despite the gaps in some of the Subcommittee's information, it is clear that the CDC's March 30, 2004 *MMWR* was marred by many problems that have yet to be corrected. Among the Subcommittee's primary findings:

- **CDC Has Yet to Inform Public Health Community of Its Faulty Analysis.** Since 2004, lead experts, including some at CDC, have done significant research that negates most of the conclusions of the 2004 *MMWR* article about the lack of a correlation between exposure to elevated water lead levels [WLLs] and the public's health. These include determining that elevated WLLs can cause lead poisoning in children and did so in the District of Columbia; that the substitution of chloramine for chlorine as a water disinfectant causes lead corrosion and elevated WLLs and BLLs; and that "partial" lead line replacements can elevate, instead of reduce, WLLs and result in increased BLLs. CDC has failed its public health responsibilities by refusing to withdraw its 2004 *MMWR* article or to alert the public health community at large of this new information.

- **CDC Has Failed to Publish Its Own Subsequent Research Showing that Elevated WLLs Increase BLLs.** In 2007, CDC researchers presented a paper at a public health conference showing that elevated WLLs can cause lead poisoning in children and did so in the District of Columbia; that the substitution of chloramine for chlorine as a water disinfectant causes lead corrosion and elevated WLLs and BLLs; and that "partial" lead line replacements can elevate, instead of reduce, WLLs with an accompanying four-fold risk for elevated BLLs. CDC has only informed DC officials of these results recently and has failed to inform public health and water utility officials elsewhere of these results. These findings are important since many cities and states across the country have engaged in changing disinfectants and partial lead line replacements. The DC government alone spent nearly $100 million replacing lead service lines as a response to

the DC lead-in-water crisis before the program was halted because of concerns it was actually increasing, at least in the near term, not decreasing the water lead levels.

Because the *MMWR* is not a peer-reviewed publication, but is heavily relied on by public health offices, CDC should publish its key findings expeditiously in the *MMWR* as it does other public health alerts.

- **CDC Failed to Include Key Data When It Published the Results of a "Cross-Sectional Study" in the *MMWR*.** The cross-sectional study looked at BLL test results for residents of homes with over 300 parts per billion (ppb) of lead in their drinking water, and did not find a *single* person with an elevated blood lead level. It was the most-cited part of the *MMWR* and used as evidence that elevated WLLs did not affect BLLs. But the study failed to mention that many residents had stopped drinking their tap water months earlier, although three co-authors suggested raising this issue in the *MMWR*.

- **CDC Failed to Include Residences with WLLs between 100 and 300 ppbs in Its Cross-Sectional Study Even Though It had Evidence that the BLLs of Children in Those Homes Would Actually Be Higher than Those in Homes with WLLs over 300 ppb.** CDC staff knew that a higher proportion of children in homes with WLLs between 100 and 300 ppbs had tested with BLLs $\geq 10\ \mu g/dL$ than in homes with WLL greater than 300 ppb. None of the authors of the study can explain why they did not expand the study to include these homes.

- **CDC Cannot Produce the Raw Data Used in the Cross-Sectional Study.** Both CDC and the District government claim they have no records containing the raw scientific data to substantiate the basis for this study. The only raw data available, a single spreadsheet provided to Dr. Marc Edwards in a FOIA request in 2006, points to grave problems in the scientific integrity of this study, including individuals who were "tested" *after* the *MMWR* article was published and the fact that more than half of those surveyed said they drank bottled water, a key detail never mentioned in the *MMWR* article. In addition, according to this spreadsheet only 13 individuals in the study drank tap water exclusively and did not use a water filter or drink bottled water. This key fact was also omitted from the *MMWR* article.

- **The *MMWR* Eliminated One Child with an Elevated BLL.** Dr. Lynette Stokes, the first author of the MMWR article, a former CDC official and chief of the Bureau of Hazardous and Toxic Substances at the D.C. Department of Health, who oversaw the DC lead program, admitted in an interview that one child who lived in a home with 300 ppb of lead in the water and no other known source of lead in the child's home, was identified in February 2004 as having an elevated BLL. Dr. Stokes said she excluded this child from the cross-sectional study because the child had only lived in the house a short time. Excluding this child permitted CDC to conclude that even among homes with the highest water lead levels not a *single* person was found with an elevated blood lead level. No records concerning this case can be located, or have been produced by either the District or the CDC.

- **In Its Hurry to Release "Good News," CDC Ignored Decades of Its Own Research and That of the Scientific Community When It Claimed That Elevated Water Lead Levels in the District of Columbia Did Not Significantly Impact the Blood Lead Levels of Children.** Humans have known since at least the time of the Roman Empire that ingestion of lead in water leads to lead poisoning and negative cognitive and health impacts particularly in children. CDC publications have warned of the threat posed by lead-contaminated water, and numerous peer-reviewed studies over the years have documented increases in blood lead levels in children consuming water with high lead levels. When CDC's 2004 cross-sectional study concluded that there was no such correlation, it should not have been published without a thorough peer review. Such a review would have resulted in the cancellation of that publication because of the major short-comings of the study.

- **CDC Failed to Provide Reliable Public Health Guidance When It Published an *Emergency* Dispatch Based on Known Missing Data.** Before publishing the *MMWR Dispatch,* Dr. Mary Jean Brown, the principal author of the longitudinal study who is also the chief of the CDC's Childhood Lead Poisoning Prevention Branch (CLPPB), knew that thousands of blood lead level test results were missing, and that the District's Department of Health had had major problems with entering this data into its computer system. She chose not to inform her editors, superiors, co-authors or the public about these problems. As a result, the *MMWR* article included incomplete blood lead level test data for the years 2002 and 2003. The Subcommittee's investigation has found that the number of DC children with elevated blood lead levels in 2002 and 2003 was at least three times greater than the CDC claimed in 2004.

- **In its Public Messaging about Health Effects of Blood Lead Levels, CDC Officials Focused on Levels Greater than 10 μg/dL.** The public statements of CDC after the issuance of the *MMWR Dispatch* focused on its conclusion that there was no increase in children with blood lead levels (BLLs) over 10 μg/dL. However, there was an increase in children with blood lead levels over 5 μg/dL, which CDC acknowledged but did not consider significant. On February 23, 2004, CDC's own Advisory Committee on Childhood Lead Poisoning Prevention issued a review of the evidence of health effects of BLLs under 10 μg/dL in children and concluded that lower BLLs had a negative impact, even in children with BLLs less than 5 μg/dL. CDC chose not to provide this critical information to public health officials and District residents. The crisis in Washington D.C. turned on whether large numbers of children with blood lead levels greater than 10 μg/dL would be found or not, even though CDC officials were well aware significant harm could occur to the development of young children even at much lower levels.

INTRODUCTION AND EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention (CDC), a division of the U.S. Department of Health and Human Services (HHS), is the nation's premier public health agency. Since its establishment in 1946, the CDC has played a leading role in eradicating smallpox, identifying the cause of Legionnaires' disease and investigating the first known cases of acquired immunodeficiency syndrome (AIDS).[1] The "CDC protects the health of Americans on many levels and in many arenas," the agency states. "We conduct surveillance on a wide range of health threats—from infectious diseases to bioterrorism to environmental hazards. When diseases break out around the globe, CDC responds at a moment's notice, lending its expertise and resources to conduct outbreak investigations and provide technical assistance."[2]

The Lead Contamination Control Act of 1988, an amendment to the Safe Drinking Water Act, authorized the Centers for Disease Control and Prevention (CDC) to initiate program efforts to eliminate childhood lead poisoning in the United States.[3] A major aspect of that program was to provide blood lead level screening grants to state and local jurisdictions. In 2000, a federal interagency work group was established to develop recommendations to eliminate childhood lead poisoning as a major public health problem in the United States by 2010. The work group produced a "coordinated federal program" to eliminate childhood lead poisoning. Its focus was on eliminating the hazards of lead paint.[4] This focus would have significant implications for the federal response to the lead-in-water crisis in the District of Columbia.

Public Health Implications of Exposure to Lead

The fact that lead in water can cause poisoning of humans has been known for centuries, and the adverse health effects of lead poisoning, which include death, insanity, nervous system damage and sterility, have been known since the second century BCE.[5] For decades, the CDC has warned of the dangers, especially to children, of elevated levels of lead in drinking water. Numerous peer-reviewed studies done in the 1980s documented the increases in blood lead levels (BLL) in young children who were consuming lead-contaminated water in their formulas and prepared foods.[6] In 1989, Dr. Mary Jean Brown, currently head of CDC's childhood lead poisoning prevention branch,

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[1] "Historical Perspectives History of CDC," *Morbidity and Mortality Weekly Report* (*MMWR*), Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, June 28, 1996, accessed at: http://www.cdc.gov/mmwr/preview/mmwrhtml/00042732.htm.

[2] "State of CDC 2008: Partnering for a Healthy World," Centers for Disease Control and Prevention, p. 4, accessed at: http://www.cdc.gov/about/stateofcdc/pdf/SOCDC2008.pdf.

[3] P.L. 100-572,

[4] President's Task Force on Environmental Health Risks and Safety Risks to Children, "Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards," February 2000, p.1 accessed at: http://www.cdc.gov/nceh/lead/about/fedstrategy2000.pdf

[5] Major, RH, *Classic Descriptions of Disease.* 3rd ed. Springfield, Illinois: Charles C. Thomas Publishing, 1945.

[6] See, *e.g.*, Ryn, J.E.; Ziegler, E.E., Nelson, S.E., Formon, S.J., "Dietary intake of lead and blood lead concentration in early infancy," *American Journal of Disabled Children,* 137, 886-91 (1983); Bonnefoy., X, Huel, G., Gueguen, R., "Variation of the Blood Lead Level as a Result of Lead Contamination of the Subjects Drinking Water," *Water Res.* 19, 1299-1303 (1985; Sherlock, J.C., Quinn, M.J., "Relationships between blood lead concentrations and dietary lead intake in infants: the Glasgow duplicate diet study 1979-1980," *Food Additives and. Contaminants.* 3, 167-176 (1986).

co-authored an article in the *Journal of Environmental Health* that traced the lead poisoning of a child in Massachusetts to drinking water exposures. "Lead poisoning as a result of drinking water carried through lead service lines has been well-documented in the literature," the paper stated. It concluded: "The case presented here indicates a strong correlation between pre-treatment blood levels and lead in drinking water."[7]

The BLL in children that CDC has used to mandate action has dropped from 40 μg/dL [40 micrograms of lead per deciliter of blood] in 1970 to 10 μg/dL in 1991. In the publication announcing that change, CDC warned of the danger of lead in drinking water, stating that it was "probably absorbed more completely than lead in food", and that for babies consuming formula made with hot tap water the "lead exposures from water are unusually high."[8]

In 1991, the Environmental Protection Agency (EPA) set an action level for lead in drinking water of 15 parts per billion (ppb). Both of these limits are still in place today, despite the fact that lead experts have known since the 1980s that BLLs less than 10 μg/dL also are linked to decreased IQ and cognition in children from 1-5 years of age.[9] In a study funded by the National Institute of Environmental Health Sciences of the National Institutes of Health, children with BLLs less than 10 μg/dL scored an average of 11.1 points lower on the Stanford-Binet IQ test.[10] Although it was expected that CDC would reduce its action level as a result of this study, that never occurred. However, in February of 2004, a working group of the advisory committee for CDC's Childhood Lead Poisoning Program reviewed the literature on the cognitive effects of BLLs < 10 μg/dL and found numerous negative impacts on children that did not become weaker at lower mean BLLs.[11] Dr. David Jacobs, an expert in lead poisoning, told a Senate committee in 2007 that the CDC "level of concern" was neither "safe" nor "normal."[12]

In the 1980s, EPA began developing its Integrated Exposure Uptake Biokinetic (IEUBK) model, which indicated that the BLLs of infants drinking formula containing lead in water would be expected to rise by as much as 11 ug/dL for each increase of 100 ppb of lead in water.[13]

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[7] E. Cosgrove, M.J. Brown, et. al., "Childhood Lead Poisoning: Case Study Traces Source to Drinking Water," *Journal of Environmental Health*, Volume 52, Number 1, July/August 1989, pp. 346-349.

[8] "Preventing Lead Poisoning in Young Children: 1991," U.S. Department of Health and Human Services, Centers for Disease Control, Oct. 1, 1991, p. 15, accessed at http://wonder.cdc.gov/wonder/Prevguid/p0000029/p0000029.asp

[9] Levin R., Brown, MJ. *et al*., "Lead Exposures in U.S. Children, 2008: Implications for Prevention," *Environmental Health Perspectives,* October 2008, p. 1285

[10] AP, "Study: Lead Affects Child IQ," April 30, 2001. The study was subsequently published in the *New England Journal of Medicine (NEJM).* See, Canfield, Henderson, Cory-Slechta, Cox, Jusko and Lanphear, "Intellectual Impairment in Children with Blood Lead Concentrations below 10 μg per Deciliter," *NEJM*, April 17, 2003.

[11] CDC/NCEH, "A Review of Evidence of Health Effects of Blood Lead Levels <10 μg/dL in Children Reported by a Work Group of the Advisory Committee on Childhood Lead Poisoning Prevention," Feb. 23, 2004.

[12] "Statement of David E. Jacobs" before the Environment and Public Works Committee, Oct. 18, 2007.

[13] Memorandum from Paul White, Chief, Quantitative Risk Methods Group, Washington Division, National Center for Environmental Assessment, Office of Research and Development, Environmental Protection Agency to David A. Bussard, Director, Washington Division, National Center for Environmental Assessment, Office of Research and Development, Environmental Protection Agency, "SUBJECT: Risks of elevated blood lead for infants drinking formula prepared with tap water," March 3, 2004; and White, Van Leeuwen et al., "The Conceptual Structure of the Integrated Exposure Uptake Biokinetic Model for Lead in Children," *Environmental Health Perspectives,* December 1998, pp. 1513-30, accessed at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1533456/pdf/envhper00541-0248.pdf

Origins of the Lead-in-Water Crisis in the District of Columbia

In 1998, EPA published its "Stage 1 Disinfection Byproduct Rule," which mandated that water treatment systems reduce the production of carcinogenic disinfection byproducts that resulted from the use of chlorine.[14] The Army Corps of Engineers, which control the Washington Aqueduct used by the District of Columbia's Water and Sewer Authority (WASA), began to use chloramine in November of 2000.[15] This change increased lead corrosion inside the D.C. drinking water system and resulted in elevated water lead levels (WLLs).[16] WASA did not notify the public until 2003, but the notices were unclear and announced meetings to "discuss and solicit public comments on WASA's Safe Drinking Water Act projects."[17] As a result, thousands of unwitting D.C. residents and their children were exposed for two years to harmful levels of lead from the water they were drinking and using for cooking and infant formulas.

Public Knowledge of Excessive Lead in Water

On Saturday, January 31, 2004, a front-page story in *The Washington Post* told the public for the first time that water tests conducted the previous summer by WASA found that thousands of D.C. homes – two-thirds of those tested – had tap water lead levels above the EPA limit of 15 ppb. Approximately 2,300 of the homes tested had results over 50 ppb, and 157 were higher than 300 ppb.[18]

The District fell into a crisis mode as the media revealed that WASA and EPA officials had been aware of the problem since 2002 but never informed the public.[19] Residents inundated WASA's water hotline with calls and overwhelmed water testing laboratories. District officials called for public meetings and established an inter-agency task force to investigate.[20] There were questions about what D.C. officials knew, when they knew it and whether they took the issue seriously. At a Congressional hearing, EPA officials described the levels of lead contamination as the worst they had ever seen and threatened to take over the system.

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[14] "Disinfectants and Disinfection Byproducts Notice of Availability," 63 *Fed. Reg.* 15673-692, March 31, 1998.
[15] Edwards, M., Dudi, A., "Role of chlorine and chloramines in corrosion of lead-bearing plumbing materials," *Journal of American Water Works Association* 96, 69-81 (2004).
[16] "Changes in Lead Levels during Annual Switch to Free Chlorine, Lead in DC Drinking Water," undated, Environmental Protection Agency, accessed at: http://www.epa.gov/dclead/chlorine.htm
[17] "Water in D.C. Exceeds EPA Lead Limit: Random Tests Last Summer Found High Levels in 4,000 Homes throughout City," *Washington Post,* Jan. 31, 2004, A1. See also, "Audit of Elevated Levels of Lead in the District's Drinking Water," Office of the Inspector District of Columbia, pp. 39-45; "Summary of Investigation Reported to the Board of Directors of the District of Columbia Water and Sewer Authority," WASA, July 16, 2004, pp. 7-8 and 77-91.
[18] 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.
[19] EPA had initially said that WASA's actions had followed "the letter of the law," but later changed its mind. "Response to Lead Blasted on Hill; EPA Threatens to Step In, Oversee D.C. Water System," *Washington Post*, March 7, 2004, C1. In June of 2004, EPA filed an administrative order finding numerous failures with WASA's response to the lead contamination. "Administrative Order for Compliance on Consent, Docket No SDWA-03-2004-0259DS," USEPA Region III, June 2004.
[20] "D.C. to Create WASA Task Force; Water Agency Accused of Not Revealing Data on High Lead Levels," *Washington Post,* B1, Feb. 5, 2004.

Even then the city's reaction was slow and inadequate. The D.C. Department of Health did not issue an advisory to warn pregnant women and children under six to stop drinking unfiltered tap water and have their blood tested until a month after the story broke and described it only as a "cautionary" measure until they determined what was causing the elevated WLLs.[21]

In an attempt to respond to the public outcry and to get a quick answer about the potential human health impact, Dr. Daniel Lucey, the District's new interim medical director, sought the assistance of CDC two weeks after the news of the lead-in-water crisis first broke. The CDC responded within a week by providing expert technical assistance and sending Dr. Brown, the head of its childhood lead poisoning prevention branch. On March 10, 2004, the Surgeon General also dispatched U.S. Public Health Service (PHS) officers to help locate affected residents and test their blood.[22]

CDC to Washington, D.C.: There is No Public Health Crisis

Based on this effort, on March 30, 2004, the CDC published an emergency "dispatch" in its Mo*rtality and Morbidity Weekly Report (MMWR)* titled: "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water — District of Columbia, 2004" that summarized the results of "preliminary investigations."[23] The purpose of the unusually rapid publication was to let the public know that CDC – "working as quickly as we could" and "under some constraints" – had not found any evidence of a public health crisis.[24] This conclusion was counter to all previous peer-reviewed research on the impact of the ingestion of elevated WLLs on children.

In fact, according to CDC, based on a longitudinal study of the four-year period from 2000-2003, elevated BLLs ≥10 μg/dL in the District's children had actually declined from 9.8 percent to 7.6 percent for children living in homes with lead service lines. This trend, however, did not hold true for children with BLLs between 5 and 10 μg/dL. CDC conveniently ignored all the scientific evidence and its own advisory group in not warning D.C. residents that these children could also be severely and negatively affected.

The results of a separate study, known as the "cross-sectional study," and included in the *MMWR,* were even more compelling to the press and the general public. This study targeted homes in the District with water lead levels at or above 300 ppb to see if there was a correlation with elevated BLLs among residents in those homes. Surprisingly, not a single child or adult was found with a BLL above the action level. The *MMWR Dispatch* thus concluded, although

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[21] "District to Issue Warning on Lead; Health Advisory on Water to Target Pregnant Women, Small Children," *Washington Post,* Feb. 25, 2004; "D.C. Assailed for 25-Day Delay in Acting; Former Health Directors, Others Chide City, Saying Warnings Were Long Overdue," *Washington Post,* Feb. 26, 2004.

[22] Subcommittee staff interview of Dr. Tim Cote, Sept. 8, 2009.

[23] "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, 2004," *MMWR Dispatch,* Vol. 53, March 30, 2004, available here: http://www.cdc.gov/mmwr/pdf/wk/mm53d330.pdf. Three days later it was re-published in the regular *MMWR Weekly.* "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, 2004," *MMWR Weekly*, Vol. 53, No. 12, April 2, 2004, available here: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm.

[24] "High Lead Levels Found in D.C. Kids; Numbers Rose during Water Crisis," quoting Dr. Mary Jean Brown, *Washington Post,* Jan. 27, 2009, Met 2 edition.

with many qualifications, that the CDC's longitudinal analysis of blood tests of the city's children "suggest[ed]" that excessive lead in water might increase blood lead levels slightly but not raise it to harmful levels, which it inexplicably defined as ≥10 μg/dL – once again in opposition to the conclusions of its own advisory group. The report stated unequivocally that "although lead in tap water contributed to a small increase in BLLs in DC, no children were identified with BLLs ≥10 μg/dL, even in homes with the highest water lead levels." (emphasis added)[25] In other words, not a single child in the entire District required follow-up action because of lead in their drinking water.

For D.C. residents, that was CDC's take-away message. It was clearly spelled out in the "talking points" written by Dr. Mary Jean Brown, the MMWR's primary author and the head of the CDC's childhood lead poisoning prevention branch:

> **Main message: There is no indication that DC residents have blood lead levels above the CDC levels of concern of 10 micrograms per deciliter for children 6 months – 15 years old and 25 micrograms per deciliter for adults as a result of lead in water** (emphasis in original).[26]

There were many problems with both the longitudinal and cross-sectional studies. For children living in homes with lead service lines, the decrease in children testing over10 μg/dL was less than the national decline. And there was no decrease from 2000 to 2003 of children with BLLs ≥ 5 μg/dL with lead service lines, who would also be affected negatively by lead exposure. Nor was anyone able to tell Subcommittee staff why only residents of homes with WLLs of 300 ppb were chosen for the cross-sectional study when much lower WLLs were known to be harmful. Most importantly, the cross-sectional study did not include any information about whether the residents were actually drinking tap water or not.

There were other problems. There was a mysterious drop of almost 6,000 in the number of children tested in 2003 compared to 2000, and no one could explain the discrepancy. Long-standing data entry problems in the District's lead program made reliance on its data highly questionable.

Some of the co-authors were surprised by the results of the studies, particularly the cross-sectional study, and described them as "counter-intuitive." That, however, did not stop CDC from issuing its emergency *Dispatch* before determining how such "counter-intuitive" results were obtained. And it was the results of that study that caught everyone's attention, not the fact that those studied might not have been actually drinking the water. The public message was that if children drinking water with 300 ppb of lead weren't affected, everyone else could relax.

When asked why the results of these "preliminary investigations" were not held up until they could be verified, Dr. Brown stated that there was pressure from the city, EPA and CDC to get something out quickly on the public health effects of elevated WLLs.[27]

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[25] *MMWR Dispatch,: supra,* p. 2.
[26] Dr. Mary Jean Brown's "Talking Points / Q's and A's – D.C. Lead Issues (3/30/04)."
[27] Subcommittee staff interview of Mary Jean Brown, July 22, 2009.

Dr. Bruce Lanphear, one of the leading experts on lead poisoning of children, later described the report as "a quick and sloppy study to address public health concerns." If the article had been "submitted to a journal to 'prove' that lead in water wasn't an important source, it would have been rejected."[28]

But for public health officials, CDC's "main message" of no harm brought a rapid end to the public's concern about the elevated drinking WLLs. Many local and federal officials and the residents of DC breathed a collective sigh of relief. As reported in the *Washington Post*, "In other words, lead in water seems likely to raise children's blood lead levels past 5 micrograms but not past 10 micrograms." The issue soon faded from the headlines. Two days after publication of the *MMWR Dispatch*, Dr. Brown reported to Dr. Falk, that for the first day in over a month there wasn't a story on lead in water in the *Washington Post.* "I guess that means it worked!"[29]

Three months later, District health officials were telling the public that lead paint was actually the cause of all unsafe blood lead levels in their children. According to those officials, "every single one" of the homes where children had elevated blood levels that the Health Department had assessed between February and May of 2004 had "increased amounts of lead paint in the home, lead in the soil and lead in other areas of the home." That conclusion was reiterated in Congressional testimony[30] and in a fact sheet the department issued. The message to the public, as recalled by a local environmentalist, was that city and WASA officials said that concerns about the impact of lead in drinking water were "a scare and that there wasn't any health impact at all – there weren't any cases found of health impact." EPA issued a fact sheet based on the report that stated unequivocally: "Residents with high lead levels in their tap water did not have elevated blood lead levels."[31]

The *MMWR's* impact went far beyond the District of Columbia. Despite the years of research indicating that for fetuses and very young children, particularly those drinking formula constituted with tap water, there is no safe lead level, and despite evidence that BLLs under 10 μg/dL also d permanent damage, CDC's work was used in other cities with elevated water lead levels to dampen citizen concerns about the public health risk of consuming lead-contaminated water.[32]

The CDC Study Begins to Unravel

Dr. Marc Edwards, an award-winning professor of civil engineering at Virginia Tech who had been studying corrosion in water utility systems for several years, could not believe

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[28] Rebecca Renner, "Lead on Tap: An alarming return of lead in drinking water is being ignored by the EPA and municipal officials," *salon.com*, Nov. 27, 2006, accessed at http://ww.salon.com/news/feature/2006/11/27/lead

[29] E-mail entitled "RE: MMWR Vol. 53/No. 12" from Mary Jean Brown to Henry Falk, April 1, 2004.

[30] Testimony of Jerry N. Johnson, WASA general manager, before the House Committee on Government Reform, May 21, 2004.

[31] "High Lead Levels Found in D.C. Kids; Numbers Rose during Water Crisis," *Washington Post*, Jan. 27, 2009, Met 2 Edition.

[32] There were also elevated WLLs in Maine, Rhode Island, Connecticut, Boston and Portland, Oregon. Renner, "Lead on Tap," *supra.*

CDC's conclusion that elevated WLLs did not have harmful health effects. He looked at the home risk assessments that D.C. DOH had done in early 2004 where children with elevated BLLs lived. In 2006, he told the local public radio station that some of the city's assessments pointed to water as the key source of lead in the home, and that the message that very high levels of lead in water did not cause "measurable public harm" was false.[33]

In early 2007, researchers at Duke University, who had studied a similar lead-in-water spike in a North Carolina town and the resulting lead poisoning of a child after the switch by the water system from chlorine to chloramine, warned that lead poisoning programs needed to be aware of the potential increase in children's BLLs because of the use of chloramines and to take preventive steps in advance.[34] Very little attention was paid in the District to this research.

But in 2009, Virginia Tech's Edwards released another analysis of the blood lead level tests done on District children from 2000 to 2004, which came to a shockingly different conclusion from that in the 2004 *MMWR* and reopened the debate. Dr. Edwards reviewed thousands of BLL test results , for children under six from the Children's National Medical Center (CNMC), one of the largest service providers for children in the District. He determined that for the most vulnerable population of children -- those under 1.3 years – the incidence of elevated blood levels over 10μg/dL "abruptly" increased by 9.6 times in the second half of 2001 over the first half of the year. However, when he attempted to compare the CNMC data, which should have been a subset of the larger dataset used in 2004 by CDC, he found an error rate in the data of over 50 percent and could not analyze the full data set.[35]

Dr. Edwards also found correlations between BLLs and WLLs for children older than 30 months who lived in neighborhoods at high risk for having lead water lines. He concluded that the experience in Washington, D.C., was consistent with the "decades of research linking elevated WLLs to higher BLL and EBL [elevated blood level]."[36]

CDC Finally Finds a Negative Health Impact, but Refuses to Publish It

Four days after the 2006 radio report on Dr. Edwards' review of D.C.'s risk assessment reports, CDC announced that it would conduct a new study to determine whether its original finding was correct. Dr. Brown, the primary author of the original study, said she had not known about the home assessments done by the D.C. DOH. CDC would reanalyze the data and look at the assessments with the new study to be complete in "several months."[37]

The new study has never been published, but a preliminary abstract released at the annual meeting of the American Public Health Association in 2007 indicated that the conclusions in the

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[33] WAMU 88.5FM, "Transcript of "Questions over Harm Caused by Lead in the Water," Sept. 21, 2006, accessed at http://wamu.org/news/06/09/lead_questions.php

[34] Miranda, Kim, Hull, Paul and Galeano, "Changes in Blood Lead Levels Associated with Use of Chloramines in Water Treatment Systems," *Environmental Health Perspectives,* February 2007, pp. 221-25.

[35] Edwards, Triantafyllidou and Best, "Elevated Blood Lead in Young Children due to Lead-Contaminated Drinking Water: Washington, DC, 2001-2004," *Environmental Science Technology,* March 1, 2009, pp. 1618-23.

[36] *Ibid.*

[37] WAMU 88.5FM, Transcript of "CDC Lead Study," Sept. 25, 2006, accessed at http://wamu.org/news/06/09/lead_questions.php

new research matched those of Dr. Edwards. The abstract stated that CDC had found that children with BLLs over 5 or 10 μg/dL were "significantly more likely" to have lived in a home with a lead service line, even after adjusting for the "confounders," such as the age of the housing unit with its presumed lead-based paint.[38]

None of the results of CDC's new work was provided to the EPA, the District of Columbia, WASA or the public. No new "emergency dispatch" was published in the *MMWR,* and many public health experts continue to rely on the discredited 2004 article when dealing with elevated WLLs.

The Subcommittee's Investigation

Since March 2009, the Subcommittee staff has been investigating these serious questions about the reliability, accuracy and scientific integrity of the 2004 *MMWR* and the process used by the CDC to produce it. Numerous interviews by Subcommittee staff of CDC and District personnel and the listed authors on the study made it clear that the data reporting by the District was seriously flawed, with large amounts of data apparently never entered into the system. As a result, the Subcommittee obtained the raw test results for 2002 and 2003 from the laboratories that performed the tests.

From that data, Subcommittee staff determined that the number of children with elevated BLLs in 2002-03 was at least ***three times*** greater than reported by the CDC in the *MMWR*. Specifically, the CDC found a little over 300 children with elevated BLLs in 2002 and 2003. In reality, based on the actual lab reports obtained by Subcommittee, ***nearly 1,000 District children had elevated BLLs during that same time frame***.

The responsibility for collecting and maintaining accurate BLL test data is with the local or state agency tasked – in this case, the District of Columbia. Subcommittee staff found massive problems, both technological and human, with the District's efforts to maintain this database. A computer system put in place in 1999 at the behest of CDC never worked properly, requiring a laborious and error-prone manual entry process. CDC was well aware of these problems. In 2002, the CDC data manager ran the District's 2001 annual submission and found so many errors that the data could not be loaded.[39] To compound the problems, the data entry employees responsible for taking lab results and putting them manually into the District's system were laid off in 2003, causing massive delays in entering BLL test results. There were allegations of forgery of reports and test results that were never entered or thrown away before entry. A properly functioning computer system was not installed until after the CDC report was published.

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[38] "Association between Lead Poisoning among Children less than Six Yeard Old and Lead Service Pipes in Washington DC," APHA, Abstract # 166176, Nov. 7, 2007, accessed at http://apha.confex.com/apha/135am/techprogram/paper_166176.htm Nonetheless, Dr. Tee Guidotti, then WASA's public health consultant, told the WASA board in both 2007 and 2008 that "the lead in DC water did not appear to be associated with elevated BLL on a population or on an individual basis." Minutes of the Ad-hoc Committee on Drinking Water Quality, WASA Board of Directors, June 30, 2008. See also, Minutes of Meeting of WASA Board of Directors, July 26, 2007.

[39] E-mail from Jaime Raymond [nee Schoonover] to Obiora Offor, entitled: "Subject: DC's 2001 Submission," February 18, 2003.

The Subcommittee also asked for the original data used in CDC's cross-sectional study. Neither the District nor CDC could produce it. Furthermore, even the single spreadsheet provided by the District to Dr. Edwards pointed to grave problems in the scientific integrity of this study. For example, it listed individuals who appeared to have been tested *after* the *MMWR* was published.

All of these problems made it clear that any reliance by CDC on the 2003 data from the District's reporting system and the hastily collected BLL tests for the cross-sectional study as the basis for an emergency *"Dispatch"* advising parents and public health officials that the children of the District were in no danger from drinking lead-laced water was highly questionable. When new data came out in 2006, 2007 and 2009 which contradicted the CDC's initial work, CDC should have withdrawn the 2004 report and done a more thorough study based on accurate data. It never did so.

It is inexplicable that the CDC – the nation's premier public health agency – promoted as credible a report that countered every single piece of research that outside scientists, the agency and its own advisory committee had previously issued on the dangers of elevated lead levels in drinking water and the permanent damage to children from blood lead levels less than 10 μg/dL. CDC's actions in publishing – and continuing to stand by – the *MMWR* article made the problem go away for the agency and the politicians, but not for the parents and the children throughout the nation who will suffer life-time consequences from this misguided document.

A PUBLIC HEALTH TRAGEDY: HOW FLAWED CDC DATA AND FAULTY ASSUMPTIONS ENDANGERED CHILDREN'S HEALTH IN THE NATION'S CAPITAL

1. CDC Lead Programs and the Known Effects of Lead in Water

The Lead Contamination Control Act of 1988, an amendment to the Safe Drinking Water Act, authorized the Centers for Disease Control and Prevention (CDC) to initiate program efforts to eliminate childhood lead poisoning in the United States.[40] In 2000, after significant funding increases had been proposed for the program, a federal interagency work group was established to develop recommendations to eliminate childhood lead poisoning as a major public health problem in the United States by 2010. The work group produced a "coordinated federal program" to eliminate childhood lead poisoning by focusing on eliminating the hazards of lead paint.[41] This focus would have significant implications for the federal response to the lead-in-water crisis in the District of Columbia (D.C.) as eliminating lead paint, not lead-contaminated water, was the primary goal of public health officials.

The CDC provides grants for blood lead screening programs to many local and state lead programs. In 2003, the CDC awarded $31.7 million to 42 state and local health departments to develop and implement comprehensive lead poisoning prevention efforts of which $500,000 went to the District.[42] Over the years, the CDC has provided the District with more than $12 million in lead grants.[43] At the time of the lead-in-water crisis, the Bureau of Hazardous Materials and Toxic Substances in the District's Department of Health (D.C. DOH) ran the Childhood Lead Poisoning Prevention Program (CLPPP) which collected blood lead level (BLL) test data for children under six years old, did follow-up home risk assessments where children with high BLLs lived, and provided general public education on lead poisoning. In 2004, Dr. Lynette Stokes, a former CDC official, was the Chief of the Bureau of Hazardous Materials and Toxic Substances. The CDC's Lead Poisoning Prevention Branch (LPPB) was (and still is) headed by Dr. Mary Jean Brown.

As part of their agreements with the CDC, the recipients of these grants were required to provide summary data on the total number of BLL tests they conducted and the number of elevated BLLs in quarterly reports provided to the CDC's LPPB. They were also required to submit copies of their annual surveillance testing "raw data" by the end of April of the following year.

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[40] "Lead Contamination Control Act of 1988," Public Law 100-572, October 31, 1988, accessed at: http://www.epa.gov/history/topics/sdwa/06.htm.

[41] President's Task Force on Environmental Health Risks and Safety Risks to Children, "Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards," February 2000, p.1 accessed at: http://www.cdc.gov/nceh/lead/about/fedstrategy2000.pdf

[42] "Cooperative Agreement Funding," Childhood Lead Poisoning Prevention Branch, Centers for Disease Control and Prevention, available here: http://www.cdc.gov/nceh/lead/funding.htm#CooperativeAgreement

[43] History of CDC lead grant funding to the District of Columbia from 1992-to-2009 provided in a spreadsheet e-mailed to the Subcommittee from the CDC on July 2, 2009.

Public Health Implications of Exposure to Lead

The fact that lead in water can cause poisoning of humans has been known for centuries, and the adverse health effects of lead poisoning, which include death, insanity, nervous system damage and sterility, have been known since the second century BCE.[44] During the Roman Empire, lead plumbing systems supplying water to cities around Rome are believed to have caused widespread lead poisonings.[45] In 1893, the *Washington Post* ran a story warning of the health hazards of lead exposures from lead-based pipes being placed in the city to carry public drinking water. The newspaper called the installation of lead pipes "a menace to the health of the people."[46] An article in the 1923 edition of the *American Journal of Public Health* noted that in 1901 physicians in New Hampshire were well aware of "lead poisoning from drinking water."[47] In 1936, an article in the same journal said: "In some instances the occurrence of lead poisoning from water has been so extensive as to be spoken of as an epidemic."[48]

Children are especially susceptible to ingesting large amounts of lead from drinking water. They drink more water per pound of body weight per day than adults do and absorb it more easily. The greatest potential for harm from lead is in the immature brain where loss of IQ is sustained from lead exposure. In addition, children with elevated BLLs develop attention deficits, language problems, reading difficulties and other learning problems.[49]

In the 1980s, EPA also had developed its Integrated Exposure Uptake Biokinetic (IEUBK) model to predict the impact of lead exposures on the BLLs in infants and young children. That model indicated that the BLLs of infants drinking formula containing lead in water would be expected to rise by as much as 11 ug/dL for each increase of 100 ppb of lead in water.[50] A National Academy of Sciences report on lead exposures in children in 1993 said: "Lead in tap water-consumed in the home, offices, other worksites, and public buildings-can be a particularly important source of lead exposure of young children, pregnant women, and other

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[44] Major, RH, *Classic Descriptions of Disease,* 3rd ed. Springfield, Illinois: Charles C. Thomas Publishing, 1945.
[45] Jack Lewis, "Lead Poisoning: A Historical Perspective," *EPA Journal*, Environmental Protection Agency, May 1985, accessed at: http://www.epa.gov/history/topics/perspect/lead.htm.
[46] "Lead Pipes Unsatisfactory: Looking for a Good Sanitary Pipe For Supplying Water," *The Washington Post*, June 9, 1893.
[47] "Charles D. Howard, "Lead in Drinking Water," *American Journal of Public Health*, Volume 13, Issue 3, March 1, 1923.
[48] G. N. Quam and Arthur Klein, "Lead Pipes as a Source of Lead in Drinking Water," American *Journal of Public Health*, Volume 26, August 1936.
[49] "Testimony of Dr. Jerome A. Paulson before the City Council of Washington, D.C. on the matter of Lead in Drinking Water," Feb. 4, 2004, p. 3, accessed at: http://www.gwu.edu/~macche/presentations/02-04-04_Testimony_Lead_In_Drinking_Water.pdf
[50] Memorandum from Paul White, Chief, Quantitative Risk Methods Group, Washington Division, National Center for Environmental Assessment, Office of Research and Development, Environmental Protection Agency to David A. Bussard, Director, Washington Division, National Center for Environmental Assessment, Office of Research and Development, Environmental Protection Agency, "SUBJECT: Risks of elevated blood lead for infants drinking formula prepared with tap water," March 3, 2004; and White, Van Leeuwen et al., "The Conceptual Structure of the Integrated Exposure Uptake Biokinetic Model for Lead in Children," *Environmental Health Perspectives,* December 1998, pp. 1513-30, accessed at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1533456/pdf/envhper00541-0248.pdf

people."[51] In the mid-1980s elevated water lead levels in the Palisades neighborhood of Washington, D.C. were believed to have led to elevated blood lead levels in some children.[52]

For decades, the CDC has warned of the dangers, especially to children, of elevated levels of lead in drinking water. In 1997, in a public health assessment of contamination resulting from various chemicals, volatile organics and lead at Camp LeJeune, the Agency for Toxic Substances and Disease Registry (ATSDR), an office within CDC, stated that

> [P]eople drinking water containing lead at levels above 50 ppb [parts per billion] could absorb enough lead to experience long-term health consequences. Moreover, people highly sensitive to the effects of lead, particularly children, infants and fetuses, could experience irreversible adverse health effects such as decreased IQ and compromised mental development. . . .
>
> It is the total body burden of lead that is related to the risk of adverse health effects. Because the body accumulates lead over a lifetime and releases it slowly, even small doses of lead over time can cause lead poisoning. Further, relatively low blood lead levels can cause adverse health effects, some of which, like decreased IQ or mild behavioral disorders, may not produce noticeable signs or symptoms.[53]

Numerous peer-reviewed studies done in the 1980s documented the increases in blood lead levels (BLL) in young children who were consuming lead-contaminated water in their formulas and prepared foods.[54] In 1989, Dr. Mary Jean Brown, currently head of CDC's childhood lead poisoning prevention branch, co-authored an article in the *Journal of Environmental Health* that traced the lead poisoning of a child in Massachusetts to drinking water exposures. "Lead poisoning as a result of drinking water carried through lead service lines has been well-documented in the literature," the paper stated. As the "only identified source of lead" was solder from newly installed water pipes, the paper concluded: "The case presented here indicates a strong correlation between pre-treatment blood levels and lead in drinking water."[55]

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[51] "Measuring Lead Exposure in Infants, Children, and Other Sensitive Populations," Committee on Measuring Lead in Critical Populations, National Research Council, National Academy of Sciences, 1993.

[52] Margaret Engel, "City Officials Say Lead in Water Poses Problem in Palisades Section of NW," *The Washington Post*, November 3, 1986, p. D1.

[53] ATSDR, "Public Health Assessment," U.S. Marine Corps Camp LeJeune Military Reservation, Camp LeJeune, Onslow County, North Carolina, CERCLIS No. NC6170022580, January 1997, pp. 16-17, citing ATSDR, "Case studies in environmental medicine: lead toxicity," 1992, and CDC, "Preventing Lead Poisoning, in Young Children," October 1991.

[54] See, *e.g.*, Ryn, J.E.; Ziegler, E.E., Nelson, S.E., Formon, S.J., "Dietary intake of lead and blood lead concentration in early infancy," *American Journal of Disabled Children,* 137, 886-91 (1983); Bonnefoy., X, Huel, G., Gueguen, R., "Variation of the Blood Lead Level as a Result of Lead Contamination of the Subjects Drinking Water," *Water Res.* 19, 1299-1303 (1985; Sherlock, J.C., Quinn, M.J., "Relationships between blood lead concentrations and dietary lead intake in infants: the Glasgow duplicate diet study 1979-1980," *Food Additives and. Contaminants.* 3, 167-176 (1986).

[55] E. Cosgrove, M.J. Brown, et. al., "Childhood Lead Poisoning: Case Study Traces Source to Drinking Water," *Journal of Environmental Health*, Volume 52, Number 1, July/August 1989, pp. 346-349.

The BLL in children that CDC has set to mandate action has dropped from 40 μg/dL [40 micrograms of lead per deciliter of blood] in 1970 to 10 μg/dL in 1991. In the publication announcing that change, CDC made the following statement about the danger of lead in drinking water:

> Lead in drinking water is probably absorbed more completely than lead in food. Adults absorb 35-50% of the lead they drink, and the absorption rate for children may be greater than 60% [citation omitted]. In general, lead in drinking water is not the predominant source for poisoned children. In some circumstances, however, lead exposures from water are unusually high . . . . Several babies have been poisoned when hot tap water, which was then boiled (resulting in concentrating the lead), was used to make baby formula.[56]

In 1991, the Environmental Protection Agency (EPA) set an action level for lead in drinking water of 15 parts per billion (ppb). Both of these limits are still in place today.

Are the Action Levels "Safe"?

Public health experts have known since the 1980s that BLLs lower than CDC's action level of 10 μg/dL are linked to decreased IQ and cognition in children from 1-5 years of age.[57] In a study funded by the National Institute of Environmental Health Sciences of the National Institutes of Health, children with BLLs less than 10 μg/dL scored an average of 11.1 points lower on the Stanford-Binet IQ test. "There is no safe level of blood lead," Dr. Bruce Lanphear, one of the researchers and a childhood lead expert, declared, a conclusion that has been espoused by the CDC and other national and international health organizations.[58] It was expected that CDC would reduce its action level as a result of this study, but that never occurred.

CDC did, however, task a working group of its Advisory Committee on Childhood Lead Poisoning Prevention to review the evidence of health effects of blood lead levels less than 10 μg/dL in children. Their report, which was issued in February of 2004 – just as the CDC was beginning work in the District of Columbia to determine the health effects on children because of elevated lead levels in drinking water – stated that both longitudinal and cross-sectional studies had consistently found a relationship between lowered cognitive functions and BLLs less than 10 μg/dL.[59]

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[56] "Preventing Lead Poisoning in Young Children: 1991," U.S. Department of Health and Human Services, Centers for Disease Control, Oct. 1, 1991, p. 15, accessed at http://wonder.cdc.gov/wonder/Prevguid/p0000029/p0000029.asp

[57] Levin R., Brown, MJ. *et al.*, "Lead Exposures in U.S. Children, 2008: Implications for Prevention," *Environmental Health Perspectives,* October 2008, p. 1285

[58] AP, "Study: Lead Affects Child IQ," April 30, 2001. The study was subsequently published in the *New England Journal of Medicine (NEJM).* See, Canfield, Henderson, Cory-Slechta, Cox, Jusko and Lanphear, "Intellectual Impairment in Children with Blood Lead Concentrations below 10 μg per Deciliter," *NEJM*, April 17, 2003.

[59] CDC/NCEH, "A Review of Evidence of Health Effects of Blood Lead Levels <10 μg/dL in Children Reported by a Work Group of the Advisory Committee on Childhood Lead Poisoning Prevention," Feb. 23, 2004, accessed at: http://www.cdc.gov/nceh/lead/ACCLPP/meetingMinutes/lessThan10MtgMAR04.pdf

As. Dr. David Jacobs testified before the Senate Environment and Public Works Committee in 2007,

> Importantly, the CDC level of concern was not established to be a "safe" or "normal" level, although some have used it in this fashion. As early as 1991, CDC reported that adverse health effects could be seen at blood lead levels below 10 μg/dL [footnote omitted]. More recent evidence from multiple studies, reviewed by CDC itself, has confirmed the 1991 CDC Statement that no safe level of lead exposure has been found [footnote omitted].[60]

Dr. Jacobs further stated instead of using the nation's children as "detectors of lead problems" and to "avoid the perception that a blood lead level of 10 μg/dL or 5 μg/dL is 'normal' or 'safe,' CDC and other medical authorities might consider labeling blood lead levels between 2 and 10 μg/dL what they really are: 'above average.'"[61]

2. Origins of the Lead-in-Water Crisis in the District of Columbia

In 1998, EPA published its "Stage 1 Disinfection Byproduct Rule, which mandated that water treatment systems to reduce the production of disinfection byproducts that resulted from the use of chlorine. Those byproducts, known as trihalomethanes, were recognized carcinogens.[62] The Army Corps of Engineers, which control the Washington Aqueduct used by the District of Columbia's Water and Sewer Authority (WASA) began to use chloramine, a compound composed of chlorine and ammonia, in November of 2000.[63] This change increased lead corrosion inside the D.C. drinking water system and resulted in elevated water lead levels (WLLs)..[64] By late 2001, WASA knew that the levels of lead in the District's drinking water were above EPA's limit. One reporter later described it as one of the worst lead contaminations of city water on record.[65] WASA notified EPA in August of 2002. Although WASA was also required to notify customers of the elevated WLLs within 60 days, it did not do so until 2003. Subsequent investigations found that WASA's notices lacked both clarity and a sense of urgency. Advertisements for public meetings did not reveal the lead problem, but stated the meetings would "discuss and solicit public comments on WASA's Safe Drinking Water Act projects." [66] As a result, thousands of unwitting D.C. residents and their children were exposed

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[60] "Written Statement of David E. Jacobs, Ph.D., CIH," U.S. Senate Environment and Public Works Committee, Oct. 18, 2007, p. 12.

[61] Jacobs Statement, *supra,* p. 13.

[62] "Disinfectants and Disinfection Byproducts Notice of Availability," 63 *Fed. Reg.* 15673-692, March 31, 1998.

[63] Edwards, M., Dudi, A., "Role of chlorine and chloramines in corrosion of lead-bearing plumbing materials," *Journal of American Water Works Association* 96, 69-81 (2004).

[64] "Changes in Lead Levels during Annual Switch to Free Chlorine, Lead in DC Drinking Water," undated, Environmental Protection Agency, accessed at: http://www.epa.gov/dclead/chlorine.htm

[65] Rebecca Renner, "Health agency covered up lead harm," *salon.com,* April 10, 2009, accessed at http://www.salon.com/env/feature/2009/04/10/cdc_lead_report

[66] "Water in D.C. Exceeds EPA Lead Limit: Random Tests Last Summer Found High Levels in 4,000 Homes throughout City," *Washington Post,* Jan. 31, 2004, A1. See also, "Audit of Elevated Levels of Lead in the District's Drinking Water," Office of the Inspector District of Columbia, pp. 39-45; "Summary of Investigation Reported to the Board of Directors of the District of Columbia Water and Sewer Authority," WASA, July 16, 2004, pp. 7-8 and 77-91.

for two years to harmful levels of lead from the water they were drinking and using for cooking and infant formulas.

Public Knowledge of Excessive Lead in Water

On Saturday, January 31, 2004, a front-page story in *The Washington Post* told the public for the first time that water tests conducted the previous summer by WASA found that thousands of DC homes – two-thirds of those tested – had tap water lead levels above the EPA limit of 15 ppb. Approximately 2,300 of the homes tested had results over 50 ppb, and 157 were higher than 300 ppb.[67]

The District fell into a crisis mode as the media revealed that WASA and EPA officials had been aware of the problem since 2002 but never informed the public.[68] Residents inundated WASA's water hotline with calls and overwhelmed water testing laboratories. District officials called for public meetings and established an inter-agency task force to investigate.[69] High lead levels were found in the fountains at nine District schools.[70] The District Health Department's director was ousted after it was found that he did not respond to a call for help in December of 2003 from WASA because lead in water was a WASA, not a city, problem. A few days later, it was determined that District health officials actually had known about the lead problem since October of 2002 and even assisted WASA in drafting an education brochure, but did not believe it was a "major" health concern.[71] At a Congressional hearing, EPA officials described the levels of lead contamination as the worst they had ever seen and threatened to take over the system.[72] Earlier statements that the contamination was confined to houses with lead service lines were questioned when it was found that houses with copper service lines also had elevated WLLs. But WASA often didn't know the actual composition of the service lines.[73] WASA's directives to about where to expect lead, how to flush it away and when not to drink the water often were based on false assumptions and had to be withdrawn.[74]

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[67] 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.

[68] EPA had initially said that WASA's actions had followed "the letter of the law, but later changed its mind. "Response to Lead Blasted on Hill; EPA Threatens to Step In, Oversee D.C. Water System," *Washington Post*, March 7, 2004, C1. In June of 2004, EPA filed an administrative order finding numerous failures with WASA's response to the lead contamination. "Administrative Order for Compliance on Consent, Docket No SDWA-03-2004-0259DS," USEPA Region III, June 2004.

[69] "D.C. to Create WASA Task Force; Water Agency Accused of Not Revealing Data on High Lead Levels," *Washington Post,* B1, Feb. 5, 2004.

[70] "High Lead Levels Found in Water at 9 D.C. Schools; Untested Fountains, Sinks Still in Use," *Washington Post,* Feb. 25, 2004, B1.

[71] "D.C. to Oust Health Chief over Response to Lead Problems," *Washington Post*, March 26, 2004, B8 "D.C. Knew of Lead Problems in 2002; Timing of E-mails Contradicts Claims," *Washington Post*, March 29, 2004, A1

[72] EPA had initially said that WASA's actions had followed "the letter of the law, but later changed its mind. "Response to Lead Blasted on Hill; EPA Threatens to Step In, Oversee D.C. Water System," *Washington Post,i March 7, 2004,* C1. In June of 2004, EPA filed an administrative order finding numerous failures with WASA's response to the lead contamination. "Administrative Order for Compliance on Consent, Docket No. SWDA-03-2004-259DS," USEPA Region III, June 2004.

[73] "Homes with Copper Lines not Immune to High Lead," *Washington Pos,t* March 13, 2004, B1.

[74] "WASA Backpedaling Prompts Confusion; D.C. Agency Changed Advice on Flushing Taps, Replacig Pipes, Health Risks," *Washington Post*, March 14, 2004, A16.

There also was evidence that city health officials – who had decided in 2002 that lead in water was not really a serious problem – had not really changed their views. The Department of Health did not issue an advisory warning pregnant women and children under six to stop drinking unfiltered tap water and have their blood tested until a month after the story broke. Even then, they described it as a "cautionary" measure until they determined what was causing the elevated WLLs.[75]

In an attempt to respond to the public outcry and to get a quick answer about the potential human health impact, Dr. Daniel Lucey, the District's new interim medical director, sought the assistance of CDC, the federal agency which issued the grants for childhood blood lead screening and provided public education, two weeks after the news of the lead-in-water crisis first broke.[76] CDC Director Julie Gerberding quickly directed top staff members to "help Dan. He is the new Acting DC health director. He is terrific!!!"[77] The CDC responded within a week by providing expert technical assistance and sending Dr. Brown, the head of its childhood lead poisoning prevention branch. On March 10, 2004, the Surgeon General also dispatched U.S. Public Health Service (PHS) officers to help locate affected residents and test their blood.[78]

Problems with the District's Lead Tracking System

Both the quarterly reports and the raw surveillance data submissions from the D.C. CLPPP to the CDC would play important roles in the scientific integrity issues that arose regarding the credibility of the underlying raw data used in the March 30, 2004 *Morbidity and Mortality Weekly Report* (MMWR) *Dispatch* to evaluate the public health impact of lead in water in Washington, D.C. The conduct by D.C. offices is not the focus of this report, but it is impossible to fully appreciate the data integrity problems associated with the CDC's lead analysis at the time of the 2004 lead-in-water public health crisis without an appreciation of the source of the data used by CDC. Further, an appreciation of how much was and is known by CDC officials regarding problems with the management of data by city offices helps clarify questions about those officials commitment to transparency and integrity.

Prior to 1999, the District's lead program maintained a manual system to track lead test data results and individual childhood lead case files. In 1999, the D.C. CLPPP implemented a CDC-developed, software program that the CDC provided free of charge to state and local CLPPPs to track medical and environmental activities and to maintain BLL test data. The software, called STELLAR (Systematic Tracking of Elevated Lead Levels & Remediation), was meant to replace the functions of a paper tracking system with a computerized one, provide easier and quicker access to data and automate routine program tasks.[79] The laboratories that reported BLL test

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[75] "District to Issue Warning on Lead; Health Advisory on Water to Target Pregnant Women, Small Children," *Washington Post,* Feb. 25, 2004; "D.C. Assailed for 25-Day Delay in Acting; Former Health Directors, Others Chide City, Saying Warnings Were Long Overdue," *Washington Post,* Feb. 26, 2004.

[76] E-mail from Daniel Lucey to Julie Gerberding entitled "A washingtonpost.com article on lead in the DC water from Dan Lucey," Feb. 16, 2004.

[77] E-mail entitled "FW: A washingtonpost.com article on lead in the DC water from Dan Lucey," from Julie Gerberding to Henry Falk, Patrick Meehan, Richard Jackson and Tom Sinks, Feb. 16, 2004.

[78] Subcommittee staff interview of Dr. Tim Cote, Sept. 8, 2009.

[79] "STELLAR: Systematic Tracking of Elevated Lead Levels & Remediation" & Remediation" web-page, Childhood Lead Poisoning Prevention Program (CLPPP), The National Center for Environmental Health (NCEH),

data results to D.C. would simply send the data on a computer disk that could be easily uploaded to STELLAR and be retrieved by D.C. CLPPP staff. Accuracy would be improved because of the elimination of the manual entry of laboratory results by data entry clerks.

However, the STELLAR database had problems from the start in both the District and in other jurisdictions.[80] In 1999, the District database crashed, and it is unclear if all the data was ever recovered. "I was looking back over my notes about your 99 data submission and noticed our discussion about trying to identify how much data you recovered after your crash," wrote Wendy Blumenthal, then the head of CDC's lead database reporting program, to Obiora Offor, database manager of the D.C. lead program.[81]

The electronic data often could not be uploaded into STELLAR, so the data entry clerks in the D.C. CLPPP office had to manually input the data from paper copies. As before, the process was time consuming and prone to human errors. In addition, in 2002 the District began to lay off the estimated one dozen data entry clerks then working in the D.C. CLPPP office, leading to a significant data entry backlog. By May 2002, Offor realized that the lead program's data entry of test results was far behind. The target was to enter 22,000 BLL test records into STELLAR in FY2002. But in the first seven months, from October 1, 2001 through May 2, 2002, only 4,856 test results had been entered.[82]

In the 2002 timeframe, Offor wrote several undated memos to Christine Onwuche, the D.C. lead program manager, highlighting his concerns about the STELLAR database and the ability of the D.C. lead program to accurately and efficiently track its childhood lead cases. He requested a new computer system to help eliminate these issues. By May, only two data entry clerks were entering BLL test results into STELLAR. In a memo that month, labeled "Data Concern," Offor pleaded with some of the lead program's investigators to volunteer to enter blood lead test results into the lead database. Offor and four other lead program employees volunteered to meet a quota each week entering a specific number of blood test results into STELLAR. Offor pledged to enter 150 BLL tests himself each week, and the other volunteers committed to entering 600 BLL test results. "While I see this as a temporary solution to this data problem," wrote Offor, "I look forward to the approval of the funding for the new web-based system to [sic] that will eliminate the need to seek so many people to enter data."[83] Offor proposed that the District scrap STELLAR and acquire a new lead tracking database by Welligent LLC called LeadTrax "to facilitate data sharing, improve communication and enable

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Centers for Disease Control and Prevention (CDC), Page last updated: June 1, 2009, accessed at: http://www.cdc.gov/nceh/lead/data/stellar.htm.

[80] Barry Brooks, the CDC's health advisor to the District of Columbia and the CDC project manager for CDC's lead grants to D.C. told the Subcommittee staff that STELLAR was never intended to be a surveillance system, but was a case management system. Subcommittee staff interview with Barry Brooks, July 14, 2009.

[81] E-mail from Wendy J. Blumenthal to Obiora Offor, cc'd to Jaime Schoonover, entitled "DC data," Oct. 10, 2001.

[82] Undated Memo titled "Data Concern" written by Obiora Offor, the database manager in the D.C. Childhood Lead Poisoning Prevention Program (CLPPP). The memo appears to be from May 2002. Mr. Offor says he sent the memo to Ms. Christine Onwuche, the CLPPP program manager.

[83] Undated Memo titled "Data Concern" written by Obiora Offor, the database manager in the D.C. Childhood Lead Poisoning Prevention Program (CLPPP). The memo appears to be from May 2002. Mr. Offor says he sent the memo to Ms. Christine Onwuche, the CLPPP program manager.

us to better serve the citizens of the District of Columbia."[84] According to Offor, by the end of 2002, all the data entry clerks had been laid off.[85]

There were also major accuracy problems in the data that was entered. In February 2003, the CDC's new LPPB data manager, Jaime Raymond, told Offor that she had run D.C.'s 2001 annual submission and found "there were so many errors, that you hit the >10% error, so I was not able to load any of your data."[86] By 2003, critical problems with data collection still paralyzed the D.C. lead program. In August 2003, Offor faxed a letter to Bobby Dixon of the Laboratory Corporation of America (LABCORP), one of seven laboratories reporting blood lead level screening data to CLPPP, asking for all lead screening data processed between September 1st 2002 and July 31st, 2003.[87] The reason was that "on close examination of the District Lead database, it was discovered that not all lead result [sic] were . . . entered into the database." (emphasis added)[88]

CDC's Knowledge of Data Gaps and Inconsistent Reports

In November of 2003, Barry Brooks, the CDC's new project manager in charge of the CDC lead grant funding for the District's (as well as several other states') CLPPP program, visited the D.C. CLPPP offices for the first time. His trip report said that he became aware during that visit that the D.C. CLPPP was "manually entering" data into STELLAR because of technical issues uploading the electronic data from the laboratories into the database.[89]

However, according to Subcommittee staff interviews with CDC officials, including Brooks, Dr. Brown, and Raymond, the CDC's lead program database manager, none of them were aware of the D.C. CLPPP's STELLAR blood lead test data "backlog." Dr. Brown said she was aware that there was a "lag" of several weeks in the labs reporting their BLL test data to the D.C. lead program, but that she was not aware of the backlog in entering data.[90]

According to Offor, because there was a growing backlog of BLL test results that had not been entered into STELLAR in 2003, every month the D.C. CLPPP program staff was adding

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[84] Undated Memo titled "Request For A New Database" written by Obiora Offor, the database manager in the D.C. Childhood Lead Poisoning Prevention Program (CLPPP). The memo appears to be from May 2002. Mr. Offor says he sent the memo to Ms. Christine Onwuche, the CLPPP program manager.

[85] Subcommittee staff interview with Obiora Offor, Sept. 1, 2009.

[86] E-mail from Jaime Raymond [nee Schoonover] to Obiora Offor, entitled: "Subject: DC's 2001 Submission," February 18, 2003.

[87] In 2003 the following laboratories were reporting blood lead level test results to the DC Department of Health: 1) The Laboratory Corporation of America (LABCORP), Herndon, Virginia; 2) Quest Diagnostics, Chantilly, Virginia; 3) Quest Diagnostics, Baltimore, Maryland; 4) Children's National Medical Center; Washington, D.C.; 5) DC Public Health Laboratory, Washington, D.C.; 6) MedTox Laboratories, St. Paul, Minnesota; 7) Mayo Labs, Rochester, Minnesota.

[88] "Data Request" faxed from Mr. Obiora Offor, Computer Specialist, Government of the District of Columbia, Department of Health, Childhood Lead Poisoning Screening & Education Program to the Laboratory Corporation of America (LABCORP), August 5, 2003.

[89] Subcommittee staff interviews of Barry Brooks, July 13, 2009 and October 22, 2009; also see "Draft Timeline of CDC Activities related to Lead in Water in the District of Columbia," prepared by Barry Brooks and Mary Jean Brown, June 1, 2009, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

[90] Subcommittee staff interview with Mary Jean Brown, October 22, 2009.

the number of BLL test results received, but *not* yet entered into STELLAR, into monthly "Performance Measures Reports" used internally by the D.C. lead program. The report for September 2003, for example, showed that the D.C. CLPPP had 5,324 blood lead test results that had *not* been entered into STELLAR.[91] Offor said these monthly reports were provided to both Onwuche and Dr. Stokes on a routine basis, and he assumed that Onwuche was providing them to the CDC. But in October 2009, when the Subcommittee showed Dr. Brown and Brooks copies of this September 2003 report during separate interviews with them, both said they had never seen these reports before and were unfamiliar with them.[92]

The LeadTrax database was finally installed in April 2004, a month after the *MMWR* article was published. But the problems regarding the "data entry" issues in the D.C. CLPPP program played a key role in undermining the scientific integrity of the raw data the *MMWR* relied upon to base its analysis of the D.C. lead-in-water crisis and the article's ultimate conclusions. Based on the subsequent research done by Dr. Marc Edwards, as well as work done by the Subcommittee staff, it is clear that the data used in the longitudinal study published in the March 2004 *MMWR* was significantly incomplete, inaccurate and undermined any reliable conclusions about the health effects of elevated WLLs that were made in that report.

Data Problems: A Blood Lead Level Test "Data Gap"

Barry Brooks told the Subcommittee that when the lead-in-water crisis broke publicly in January 2004, he immediately went to look at the District's quarterly reports to get a quick handle on what their elevated blood lead tests showed.[93]

According to the CDC, in 2001, 16,042 children in D.C. under six years old were screened for elevated BLLs; 156 had elevated BLLs. In 2002, 15,755 children were screened; 122 had elevated BLLs.[94] When Brooks looked at the D.C. lead program's quarterly reports for 2003 that were filed with CDC, he claims, they showed that approximately 15,000 D.C. children had been screened for lead in 2003, roughly the same as the year before, although he does not recall the exact numbers with elevated BLLs.[95]

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[91] "Performance Measures Report," Childhood Lead Poisoning, Screening, and Education Program (CLPSEP), Bureau of Hazardous Materials and Toxic Substances (BHMTS), District of Columbia Department of Health (DCDOH), Environmental Health Administration, September 30th FY 2003.

[92] Subcommittee staff interview with Dr. Mary Jean Brown, October 22, 2009; Subcommittee staff interview with Mr. Barry Brooks, October 22, 2009.

[93] The quarterly reports are short 2-page summary documents that provide a snapshot of the numbers of blood lead tests conducted, children identified with elevated BLLs and related statistical information. The "raw data" in the blood lead screening test results received from the laboratories actually performing the blood lead tests include information related to each actual blood lead screening test result, not simply summarized statistical data. The CDC requires that it is provided with a copy of this raw surveillance data by all of its lead grant recipients annually.

[94] "Number of Children Tested and Confirmed EBLLs by State, Year, and BLL Group, Children < 72 Months Old," Childhood Lead Poisoning Data, Statistics, and Surveillance, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), available here: http://www.cdc.gov/nceh/lead/data/State_Confirmed_byYear_1997_to_2006.xls

[95] The Subcommittee staff conducted three interviews with Barry Brooks, the CDC's health advisor to the District of Columbia and the CDC's project manager in charge of the CDC lead grants to DC. The first interview with Mr. Brooks via telephone was conducted on March 23, 2009 the other two interviews were conducted in the Subcommittee offices in Washington, D.C. and occurred on July 13, 2009 and October 22, 2009. Brooks reiterated

However, on Feb 28, 2004, as part of the CDC's review, the D.C. lead program's raw surveillance data maintained in STELLAR for the years from 1998 through 2003 was brought to the CDC in Atlanta for analysis.[96] This data – the source for the longitudinal study in the *MMWR* article – included records for the screening of only 9,229 children in 2003, an astounding drop of 6,526 children from the previous year.[97] The dramatic decline was unprecedented and unexplained. It should have raised red flags at CDC about the completeness and reliability of the District's data for use in the *MMWR* report. It did not.

Allegations of Forgery

What is even more astounding was the unquestioned use of this data based on the knowledge that CDC had about the problems with the District's data prior to the *MMWR's* publication. Not only was D.C. having trouble with its blood lead database and significant backlogs in entering test results into the database, but CDC also received an allegation of forgery of the administrative quarterly reports submitted by the District. According to Brooks, in February or March of 2004, he telephoned the D.C. CLPPP program and asked about the 6,500 discrepancy in the numbers between the 2003 quarterly reports submitted to CDC and the "raw data" in the STELLAR database.

Brooks claims that during that telephone call, a CLPPP program official admitted to "forging" the quarterly CDC reports. According to Brooks, the official claimed they did this because of the huge disparity between the screening numbers for 2003 as compared to those provided from D.C. to the CDC in previous years.[98] Although Brooks claims that the CDC had three separate copies of the allegedly "forged" quarterly reports, the CDC has been unable to locate any of them for the Subcommittee and claims they were all lost during an office move. In addition, none of the 2003 quarterly reports obtained by the Subcommittee from the District of Columbia government support the allegations of forgery made by Brooks and repeated by Dr. Brown. It is unclear when Dr. Brown learned of this claim of "forgery." In staff interviews, she suggested she knew before the MMWR was published, but an "official" internal CDC chronology prepared by Brown and Brooks for senior CDC officials indicates that she was told by Brooks in the first week of April-right after the MMWR was released.[99]

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this description of what he found in February 2004 when he reviewed DC's 2003 quarterly reports submitted to CDC during each of these interviews.

[96] "Draft Timeline of CDC Activities related to Lead in Water in the District of Columbia," included in "Office of the Director Briefing Memo: Lead in Water," Monday, June 1, 2009, 1:00 – 2:00 p.m., Roybal Campus, Bldg. 21, Conference Room 12302, For Internal Discussion Only, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC). The dataset included nearly 85,000 blood lead test results which were used for the longitudinal analysis in the *MMWR* article.

[97] "Number of Children Tested and Confirmed EBLLs by State, Year, and BLL Group, Children < 72 Months Old," Childhood Lead Poisoning Data, Statistics, and Surveillance, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), available here: http://www.cdc.gov/nceh/lead/data/State_Confirmed_byYear_1997_to_2006.xls

[98] In interviews with the Subcommittee, the D.C. official Brooks named adamantly denies these assertions and says such a suggestion was not made. This official could point to some documents in their attorney's possession that seemed to confirm their story.

[99] The Subcommittee has not been provided with any records by CDC to indicate exactly when Barry Brooks informed Dr. Brown about the allegations of "forgery." The CDC apparently has no contemporaneous e-mails,

Furthermore, Brooks claimed that in March 2004 he was told by the same D.C. official that Quest Diagnostics laboratory, one of the seven labs that provided blood lead data to D.C. in 2003, claimed that it had stopped reporting *all* BLLs to D.C. in 2003 and *only* reported elevated results. Dr. Brown confirmed that she was aware of this claim that a lab had not reported all of its results and said she sent an e-mail (no email has ever been provided by CDC or D.C. to confirm this communication) to Dr. Stokes in D.C. asking that the lab be contacted for a full reporting.[100] Both Brooks and Dr. Brown told Subcommittee staff they believed this was a cause of the 2003 "missing" blood lead level test data. Yet, that official has denied that Quest labs ever said any such thing, or that he suggested this to Brooks. The information provided to the Subcommittee from Quest labs, as well as additional information provided by the D.C. government, also contradicts the recollection of events or causes for the drop in 2003 BLL test data from both Brooks and Dr. Brown.

3. CDC's Involvement in the District's Lead-in-Water Crisis and the *MMWR Dispatch*

Offices of the CDC learned of problems with lead in D.C.'s water even before the Washington Post story broke. According to Dr. Brown, the Environmental Protection Agency (EPA) contacted Dr. Tom Sinks, deputy director at CDC's Agency for Toxic Substances and Disease Registry (ATSDR) sometime in late 2003 or early 2004 and reported that WASA was out of compliance with the lead and copper water rules.[101] Dr. Brown began working with the District's lead office and EPA's water office in early February 2004. Some kind of human testing program may have already been under consideration because CDC had asked for the addresses of persons whose water had elevated lead levels, but there is no evidence of urgency in either Brown's efforts or CDC's response.[102]

Very quickly, CDC's involvement escalated. February 10, 2004, was the first day of Dr. Daniel Lucey's three-month contract to be the District's interim chief medical officer. Dr. Lucey was an infectious disease specialist with no experience in dealing with lead poisoning, no staff or budget and only a temporary office left vacant by an employee on leave. Within three days of

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memorandums or other records about this alleged incident. But the Brooks/Brown timeline prepared for senior CDC officials conveniently says Brooks informed Brown of the allegations of "forgery" in the "First week of April 2004," days after the publication of the MMWR article. Regardless of the specific day Dr. Brown became away of the alleged "forgery" she acknowledged to Subcommittee staff that she did not share this information with any other CDC officials, including her superiors, for more than *four years*. In July 2008 she finally informed former NCEH/ATSDR director Dr. Howard Frumkin about these allegations in preparing him for an interview with science reporter Rebecca Renner. Dr. Frumkin in turn failed to inform Renner about this issue until March 2009, eight months after she interviewed him about the "missing" blood lead level test results. Dr. Mark Bashor, the Associate Director for Science (ADS) at NCEH/ATSDR, did not learn about these allegations until March 2009 as well. "I never heard a whisper about it from Mary Jean Brown," Bashor told Subcommittee staff. "I was the ADS for god's sake. It takes a lot to get me mad," said Bashor. "I was totally ticked off."

[100] Subcommittee staff interview of Dr. Brown, July 22, 2009.

[101] Subcommittee staff interview of Dr. Brown, July 22, 2009.

[102] E-mail from Dan Lucey to Julie Gerberding entitled "A washingtonpost.com article on lead in the DC water from Dan Lucey," Feb. 16, 2004 .

coming on the job, he was told by Mr. James Buford, then the head of the District's Department of Health (DOH) that he was to be "the face of lead in DC."[103]

In an e-mail to himself dated February 16, 2004, Dr. Lucey recorded the frustration of the public resulting from the lack of reliable information and skepticism about the ability of the District's task force to address the problem as expressed in a *Washington Post* editorial:

> To this day, the public has no idea of the number of District homes that have lead levels in their water that exceed the federal limit of 15 parts per billion. We know that more than 4,000 homes fall into the category based on WASA tests last summer, but we know that only because of media reports two weeks ago . . . But there are . . . as estimated 23,000 lead service lines in the city. The extent to which homes connected to those lines have lead contamination is unknown and will remain unanswered until WASA completes a survey. The first letter targeted to those estimated 23,000 homes or locations likely to have lead lines, we learned yesterday, may be mailed out by WASA sometime next week. This is coming roughly seven months after WASA first learned that lead exceeded federal limits in thousands of District homes. Little wonder WASA had so many anxious and outraged customers on its hands. (emphasis added)[104]

The same day, he forwarded the editorial in an e-mail to Dr. Julie Gerberding, then CDC's director, seeking the agency's expertise and assistance in responding to the D.C. lead-in-water crisis. He informed Dr. Gerberding that a series of public community meetings would begin the next day and asked to talk to a "content expert" and a "risk assessor for lead." He also referred to the previous request from the CDC for the addresses of persons whose water may have elevated levels of lead as District officials had expressed concern about confidentiality.[105]

Dr. Gerberding quickly responded and commandeered top CDC staff to help. She forwarded the e-mail to Dr. Henry Falk, then the director of CDC's National Center for Environmental Health (NCEH) and assistant administrator for ATSDR; Tom Sinks, his deputy; Dr. Patrick Meehan, the NCEH deputy director; and Richard Jackson, one of her senior advisors "Please help Dan," she wrote. "He is the new Acting DC health director. He is terrific!!!"[106] Dr. Sinks reported back to Dr. Gerberding that Dr. Brown had been working with the D.C. lead office and EPA's water office for a week, but that he would have her contact Dr. Lucey.[107] "Thanks Tom!" Dr. Gerberding replied. "Dan is just a few days on the job and getting hit with

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[103] Subcommittee staff interview of Dr. Dan Lucey, Nov. 4, 2009. Buford was fired because of his poor performance responding to the DC lead crisis before the *MMWR* was released at the end of March 2004. See: Avram Goldstein, "D.C. to Oust Health Chief Over Response to Lead Problem," *The Washington Post*, March 26, 2004, B8.

[104] E-mail from Dan Lucey to Dan Lucey entitled "A washingtonpost.com article on lead. . . " from Dan Lucey to Dan Lucey, quoting from an editorial entitled "In Deep Water", *Washington Post,* Feb. 14, 2004, A28, Feb. 16, 2004

[105] E-mail from Dan Lucey to Julie Gerberding entitled "A washingtonpost.com article on lead in the DC water from Dan Lucey" from Dan Lucey to Julie Gerberding. Feb. 16, 2004. Dr. Lucey and Dr. Gerberding had conducted their medical internships and residencies together at the University of California in San Francisco in the early 1980s.

[106] E-mail from Julie Gerberding to Henry Falk, Patrick Meehan ,Tom Sinks and Richard Jackson entitled "FW: A washingtonpost.com article on lead . . .", Feb. 16, 2004.

[107] E-mail from Tom Sinks to Julie Gerberding, entitled "Re: A washingtonpost.com article on lead . . .", Feb. 16, 2004.

this mess."[108] Dr. Sinks contacted Dr. Brown and – in an e-mail marked of "high" importance – asked her to get in touch with Dr. Lucey "to see what his needs are," and then provide a one-pager to Dr. Gerberding about their activities.[109]

The next day, Dr. Lucey had a conference call with Dr. Brown, Dr. Falk and Dr. Meehan. "I was asking for help," Dr. Lucey recalled. "The CDC said they were glad to help in any way they could."[110] Dr. Brown offered to come to Washington and arrived on February 24.[111] Dr. Lucey said that, because of their expertise, Dr. Stokes and Dr. Brown became the lead experts he relied upon most often in developing a response to the D.C. lead crisis.

Two days later, on February 26, the District's Department of Health (D.C. DOH), under Dr. Lucey's signature and with the assistance of the CDC, sent a letter to the 23,000 residences that were believed to have lead service lines. It warned them of potential hazards from elevated water lead levels (WLLs), and stated that "Children under six years and women who are pregnant or breastfeeding should not drink unfiltered water, or use it to prepare infant formula or concentrated juice, in any of these 23,000 residences until the concerns regarding the lead levels in the water have been resolved."[112]

CDC's Studies: The Longitudinal and Cross-Sectional Studies

Two parallel, but separate, data review and collection efforts were quickly spawned after the CDC became involved in the D.C. lead issue. Both became part of the March 2004 *MMWR*. The first involved looking at the District's historic BLL test data to identify specific trends and anomalies regarding the increases or decreases of elevated BLLs among the city's children. This longitudinal study was led by Dr. Brown. The other effort involved going to the homes with the highest known WLLs and taking BLL samples from those residents in an attempt to correlate the public health impact from exposure to elevated WLLs in the city's drinking water supply. This effort was designed and led by Dr. Tim Cote of the U.S. Public Health Service and was included in the *MMWR* report as the cross-sectional study.

The Longitudinal Study

The longitudinal study was based on public health surveillance data maintained by the D.C. CLPPP. Public health surveillance data can serve as a useful means to identify public health trends over time and to detect potential health perils to the public.[113] Surveillance data, by

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[108] E-mail from Julie Gerberding to Tom Sinks entitled "Re: A washingtonpost.com article on lead . . . " Feb. 16, 2004.

[109] E-mail from Tom Sinks to Mary Jean Brown, Tina Forrester and Christopher DeRosa entitled "Dr. Gerberding was contacted directly about the Pb situation in DC by Dan Lucey,".Feb.17, 2004.

[110] E-mail from Henry Falk to Tom Sinks entitled "Re: Dr. Gerberding was contacted directly about the Pb situation in DC by Dan Lucey," Feb. 17, 2004; Subcommittee staff interview of Dr. Lucey, Nov. 4, 2009.

[111] Subcommittee staff interview of Dr. Dan Lucey, *supra.*

[112] "Dear Resident" letter, signed by Dr. Daniel R. Lucey, M.D., Interim Chief Medical Officer, Office of the Director, Department of Health, Government of the District of Columbia, available here: http://www.dcwatch.com/wasa/040226.htm.

[113] "Welcome to Child Blood Lead Surveillance (CLBS) Orientation," Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), available here: http://www.cdc.gov/nceh/lead/training/surveillance/index.html. The CDC defines public health surveillance data as

definition, is "not perfect," as CDC officials repeatedly told the Subcommittee staff. But, as discussed above, the District's data had such significant omissions and errors that reliance upon it was very questionable. At the time of *MMWR,* it was well-known that there was an unexplained drop of more than 6,500 in the number of children tested in 2003 compared to 2002. Flaws, errors or omissions in public health surveillance data may put the public at risk by failing to identify known health dangers or underestimating the extent of the potential danger. Those shortcomings must be pointed out in any study that purports to provide advice on public health. The authors of the MMWR had a scientific obligation and public health responsibility to clearly identify those shortcomings, but they never did. Six years after the publication of the MMWR they have still not informed the public of the article's many data integrity flaws or their faulty conclusions.

Both Brooks and Dr. Brown made a variety of claims to the Subcommittee staff about why the data for more than 6,500 children was missing, and why CDC continued to use data that was – at a minimum – incomplete. Dr. Brown, the head of the CDC's lead branch and primary author of the *MMWR,* had several explanations. She assumed – based on her previous experience – that any "missing" blood lead tests were non-elevated screening tests not reported by the labs.[114] She claimed that the 2003 data provided for use in the *MMWR* did not include the last quarter as there was often a lag between tests being submitted and labs reporting back. She also claimed that the "Quest Labs" non-reporting story explained some of the gap. Finally, she indicated that whether she had the data or not wouldn't make a difference in the final results. No effort was made to confirm any of these problems by Dr. Brown. She simply assumed away the reasons for the missing 6,500 tests.[115]

In short, Dr. Brown's reasons for ignoring the data gap was questionable. While Dr. Brown did not apprise any of the *MMWR* editors, her co-authors, other CDC officials, or the public of the critical data integrity questions that swirled around the 2003 BLL test data used in the *MMWR*, some of her co-authors were likely to have known of the problems. The lead author of the *MMWR* article was Dr. Lynette Stokes, head of the D.C.CLPPP. Another co-author with direct knowledge of problems was Christine Onwuche, the CLPPP manager.

In training materials, CDC directed state and local public health officials to acknowledge known limitations or potential flaws in public health data. A CDC on-line guide on child BLL surveillance states, "The key to interpreting data is to know the limitations of the data and to keep the limitations in mind when describing the findings. Inaccuracies in the data may preclude more sophisticated analyses," the guide, developed under the leadership of Dr. Brown, states. "Erratically collected or incomplete data cannot be corrected by complex analytic techniques," it warns.[116] The CDC, however, failed to follow its own advice and never offered any warnings

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follows: "Ongoing, systematic collection, analysis, and interpretation of health-related data essential to the planning, implementation, and evaluation of public health practice, closely integrated with the timely dissemination of these data to those responsible for prevention and control." See CLBS Orientation, Module 1 – Child Blood Lead Surveillance, Surveillance in Public Health section, prepared by Dr. Pamela Meyer.

[114] Subcommittee staff interview of Mary Jean Brown, July 22, 2009.

[115] Subcommittee staff interview of Mary Jean Brown, July 22, 2009.

[116] "Welcome to Child Blood Lead Surveillance (CLBS) Orientation," Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), Module 4 – Analysis, Interpretation and Use of CBLS Data, Data Interpretations and Limitations section, available here: http://www.cdc.gov/nceh/lead/training/surveillance/Module05/Analysis-Limitations.html.

about the known flaws in the data used to compile the *MMWR* report or attempted to correct them before publication.

CDC'S Cross-Sectional Study: Another Flawed Effort

Fifteen years before she oversaw the publication of the *MMWR* article, Dr. Brown was a co-author of an article in the *Journal of Environmental Health* that traced the lead poisoning of a child in Massachusetts to drinking water exposures. "Lead poisoning as a result of drinking water carried through lead service lines has been well-documented in the literature," her article published in 1989 said. "A case of childhood lead poisoning is presented in which the only identified source of lead was lead solder from newly installed water pipes." The paper concluded: "The case presented here indicates a strong correlation between pre-treatment blood levels and lead in drinking water."[117]

The cross-sectional study was the most significant portion of the *MMWR* article because it allegedly did not find a correlation between homes that had WLLs ≥300 ppb – the "worst"cases – and elevated BLLs of those residents. The study was small, including only 201 residents, just 17 of whom were children under the age of six years old. This is the element of the *MMWR* that was the most widely cited by the media and local, state and federal health officials. They relied on it to claim that in the D.C. lead-in-water crisis there is no evidence that even these highest WLLs led to human harm. Even though the study lacks statistical power given its small size, the persuasive power of looking at the worst of the worst cases and failing to find a single instance of a person with lead above the level of concern cannot be understated.

In the talking points that Dr. Brown prepared for the release of the *MMWR Dispatch*, she wrote that "all [the participants in the cross-sectional study] had BLLs below the CDC levels of concern of 10 micrograms per deciliter for children 6 months – 15 years old and 25 micrograms per deciliter for adults."[118] The Subcommittee, however, has identified serious questions with the integrity of the data used in this study.

The study was designed by Dr. Tim Cote, a Public Health Service officer. The explanation offered to Subcommittee staff for choosing homes with 300 ppb or greater of lead in water has been that public health investigators were looking for the "worst case" examples to see what impact, if any, the most extreme levels of lead in water may have had on the blood lead levels of residents drinking the water. Dr. Cote said, "We needed to conduct a rapid assessment." As a result, they focused on the "worst case" homes.[119] The D.C. Water and Sewer Authority (WASA) provided a list of 179 homes that fit the criteria.[120]

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[117] E. Cosgrove, M.J. Brown, et. al., "Childhood Lead Poisoning: Case Study Traces Source to Drinking Water," *Journal of Environmental Health*, Volume 52, Number 1, July/August 1989, pp. 346-349.

[118] "Talking Points / Q's and A's – D.C. Lead Issues (3/30/04)", prepared by Mary Jean Brown.

[119] Subcommittee staff interview of Dr. Tim Cote, September 8, 2009.

[120] E-mail from Gregory Hope, Chief, D.C. Water Quality Control Branch, to Nkechi (Christine) Onwuche and Obiora Offor, cc'd to Lynette Stokes and Jerusalem Bekele, entitled "Updated Lead Replacement Monitoring Data," "Attachments: Combined WASA Lead Monitoring Data Above 300.xls; Partial Lead Replacement GE 300.xls," Feb. 11, 2004.

However, Dr. Brown by mid-March 2004 already had information indicating that the highest BLL results were not found in homes with WLLs over 300 ppb, but in homes with WLLs from 16 to 300 ppb in both the first and second draws of water. This data was included in a series of tables attached to an e-mail sent to Dr. Lucey by Dr. Brown on March 12, 2004, more than two weeks before the *MMWR's* release.[121] In that e-mail, Dr. Brown told Dr. Lucey the "good news" that BLLs in the District were decreasing, even though they were higher in homes with lead service lines. Without evidence or home risk assessments, Dr. Brown claimed that these results were "confounded by age of housing and presumably lead contaminated house dust and soil in these same homes."[122] But she did not mention the findings in the attached charts for the 852 homes with WLLs of 15 ppb and above, a significantly larger number than the 179 homes that had WLLs over 300 ppb. Those homes had a much higher percentage of children with elevated BLLs than the homes with WLLs over 300 ppb.

In fact, Table 10 in Dr. Brown's e-mail shows that while 34.1 percent of people tested in homes with WLLs between 201 and 300 ppb had elevated BLLs, only 8.1 percent of those in homes with WLLs above 300 ppb had elevated blood lead levels. Given the existence of this data, limiting the cross-sectional study to only those homes with WLLs of 300 ppb or more seriously skewed the results of the study in favor of finding no violations of the CDC levels of concern.

Table 10: Frequency of Elevated Blood Lead Tests in 852 Home by Second Draw Water Lead Level

Blood Lead Levels	0-15 ppb	16-50 ppb	51-100 ppb	101-200 ppb	201-300 ppb	> 300 ppb	TOTAL
<10 µg/dL	577 85.7%	612 84.9%	324 78.8%	183 85.5%	60 65.9	34 91.9%	1,790 83.3%
≥ 10 µg/dL	97 14.4%	109 15.1%	87 21.2%	31 14.5%	31 34.1%	3 8.1%	358 16.7%

Source: Subcommittee on Investigations and Oversight, based on data provided in March 12, 2004 e-mail from Dr. Mary Jean Brown to Dr. Daniel Lucey.

The co-authors of the *MMWR* article interviewed by Subcommittee staff, including Dr. Brown, Dr. Lucey, Dr. Stokes and Dr. Cote all agreed that the fact the Cross-sectional study did not identify a single individual with an elevated BLL was "counterintuitive." "It doesn't make a lot of intuitive sense, does it," Dr. Cote said. But that was what the data showed, they argued. "We are interested in finding relationships," said Dr. Cote. "But we take the facts as they come."[123]

In fact, one resident in those homes was found to exceed the level of concern. In a radio interview on February 27, 2004 Dr. Stokes said: "One child had a 14 microgram per deciliter blood lead level from that 175 homes with addresses above 300 parts per billion."[124] That child

[121] E-mail from Mary Jean Brown to Dan Lucey, March 12, 2004, Tables 9 and 10.
[122] E-mail from Mary Jean Brown to Dan Lucey, March 12, 2004, Tables 9 and 10.
[123] Subcommittee staff interview of Dr. Tim Cote, Sept. 6, 2009.
[124] Lisa Nurnberger, "Lead Crisis in DC," Metro Connection, WAMU 88.5 American University Radio, Feb. 27, 2004, audio available here: http://wamu.org/programs/mc/04/02/27.php.

was dropped from the study, allowing the authors to make the false claim that "The findings in this report indicate that although lead in tap water contributed to a small increase in BLLs in DC, no children were identified with BLLs >10 μg/dL, even in homes with the highest water lead levels."[125]

When the Subcommittee first interviewed Dr. Stokes on May 1, 2009, and asked her about her statement, she said it must have been taken out of context, and that she must have been talking about a child exposed to lead paint.[126] However, when a Subcommittee staff member sat in on another interview of Dr. Stokes by D.C. Office of Inspector General (OIG) investigators in September 2009, her recollection changed dramatically. When asked about the radio interview, Dr. Stokes said that when D.C. investigators examined the home of the child, they found no signs of lead in the paint, dust or soil.[127] Although this was one of the 175 homes with a WLL of at least 300 ppb, Dr. Stokes said the child was excluded from the Cross-sectional study because the child had only lived in the home for a short time, a matter of "weeks or days." Lead, however, remains in the blood stream for a relatively short period of time, normally around 30 days.[128] It is therefore an indicator only of recent lead exposure. Even if a child had been in a home for a few weeks but had been drinking tap water with elevated levels of lead, the result could have been an elevated BLL. Dr. Stokes, who was hired in the D.C. Department of Health because of her lead expertise and is both an epidemiologist and toxicologist, said she was unfamiliar with how long lead stays in the bloodstream.[129]

Instead of following up on the one case that clearly showed a child living in a home with a WLL above 300 ppb, who also had an elevated BLL, Dr. Stokes simply excluded this child from the *MMWR* study. Several of Dr. Stokes' *MMWR* co-authors, including Dr. Brown, said they were unaware of anyone being dropped from the study.[130]

Not only was at least one participant excluded from the cross-sectional study by Dr. Stokes, some individuals were included despite the fact that they had either only lived in the targeted homes infrequently or had stopped drinking the water long before they had their blood tested. One of the few children included in the study appears to have been Charles Eason's grandson who only stayed at Mr. Eason's home on the weekends. Mr. Eason had been informed of his elevated WLLs in the fall of 2003. He had stopped consuming any tap water in November of 2003 and made sure his grandson only drank bottled water while at his home.[131]

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[125] *MMWR Dispatch, supra,* p. 2.
[126] Subcommittee staff interview of Dr. Lynette Stokes, May 1, 2009.
[127] Joint interview of Dr. Lynette Stokes by Subcommittee staff and DC Office of Inspector General, Sept. 10, 2009.
[128] "Toxicological Profile for Lead," Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), August 2007, available here: http://www.atsdr.cdc.gov/ToxProfiles/tp13.pdf. While the half-life of lead in blood is about 30 days, it remains in soft tissue for between 30 and 45 days and in bone for between 25-to-30 years.
[129] Joint interview of Dr. Lynette Stokes by Subcommittee staff and DC Office of Inspector General, Sept. 10, 2009.
[130] Public Health Service officials who visited DC homes with 300 ppb of lead in the water and collected blood lead samples for the Cross-sectional study say they did not exclude anyone from their survey regardless of how long they lived in these homes. See, *e.g.,* Subcommittee staff phone interview of Capt. Lydia Velazquez, U.S. Public Health Service, Oct. 20, 2009.
[131] Subcommittee staff telephone interview of Charles Eason, Sept. 15, 2009.

In the fall of 2003, as it did for thousands of other District residents with lead service lines, WASA provided Mr. Eason with a free sampling kit and requested that he sample his water and mail it back. In November, WASA sent him a letter stating that the EPA limit for WLLs was 15 ppb and that Eason's water measured 550 ppb. But the letter provided little additional information. Eason began using a filter on his tap water immediately and drinking bottled water. He kept trying to get fuller answers from WASA about his water but had little luck. A few weeks after the WASA letter arrived, Eason saw an announcement for a WASA community meeting at the Martin Luther King Branch Library on Dec. 17, 2003, which he attended[132] According to Eason, there was only one other D.C. resident at the meeting and several WASA officials.

One of the WASA officials at the meeting said that two-thirds of the D.C. homes WASA tested were above the EPA limit of 15 ppb. Eason was surprised that he had not heard this before and wondered if the public was aware of what he believed was an important public health issue. Eason called *The Washington Post* and spoke with Dave Nakamura, the reporter who broke the story on the D.C. lead-in-water crisis on Saturday, January 31, 2004.

Equally important to the credibility of the cross-sectional study was the fact that it did not adequately address whether the residents of the homes were actually drinking unfiltered tap water. The reality was that more than half of them acknowledged drinking bottled water, a fact omitted from the study. Still more were filtering their water. Based on the only data available from the field work (see discussion regarding this issue below), only 13 individuals in the study – from 11 separate residences' -- drank tap water exclusively and did not use a water filter or drink bottled water. This key fact was omitted from the *MMWR* article.[133]

At least three individuals involved in the cross-sectional study – two co-authors and one public health service officer acknowledged for his assistance in the article – raised concerns prior to the publication of the report that many of those included in the study may have been drinking filtered or bottled water prior to having their blood drawn. Obviously, this would undermine the study's conclusion that there was no correlation between elevated WLLs and elevated BLLs.

"Do we want to mention that many of D.C. residents (couldn't give you #'s though) have been drinking bottled water before any of this went public?" asked Lt. Cmdr. Christine Yu, a senior regulatory management and PHS officer at the Food and Drug Administration. "Or does

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[132] See letter to Mr. Donald S. Welsh, Regional Administrator, Environmental Protection Agency, Region III, Philadelphia, Pennsylvania from Jerry N. Johnson, General Manager, District of Columbia Water and Sewer Authority (DCWASA), Attachment #1, "DCWASA Community and Civic Lead Meetings," December 17, 2003, EPA Grant Meeting, Martin Luther King Branch Library, available here: http://www.epa.gov/dclead/WASA_Letter_3-17-04.pdf.

[133] The only raw data available on the MMWR's cross sectional study is a single spreadsheet obtained by Dr. Marc Edwards in a Freedom of Information Act (FOIA) request he submitted with the District of Columbia government. The Excel spreadsheet was sent to Dr. Edwards via e-mail from Tom Collier, the D.C. Department of Health FOIA Officer as an attachment on May 31, 2006. In formal requests by the Subcommittee to the D.C. government and various components of the Department of Health and Human Services, including the CDC, requesting all raw data used as a basis for the conclusions and findings in the MMWR's cross sectional study none of those agencies have found a single record responsive to the Subcommittee's request.

that just confound the data some more?" Yu's e-mail was cc'd to both Dr. Cote and Dr. Brown.[134]

Another Public Health Service officer, LCDR Anthony Walker, wrote to Mary Jean Brown and asked:

> "I am not sure if the bottled water consumption would skew the data, but it does present another peice [sic] that might confuse the reader."[135]

On March 23, 2004, PHS Capt. Mark Eberhardt also sent an e-mail to Dr. Brown raising similar concerns.

> "6) Do you want to point out that the water sample [sic] that were tested in many of the homes were done last year, but the blood lead measures were determined this month? Between these two time periods, some people stopped drinking water supplied by WASA; some people started using filters, and some people had the lead supply lines to their home replace[d] before blood lead levels were measured. *The point is that this may help to explain why currently no persons have blood lead levels above the levels of concern."* (emphasis added)[136]

There is no evidence that this obvious and critical concern was ever addressed by the authors prior to publication. The Subcommittee was never provided with a single e-mail response from Dr. Cote or Dr. Brown regarding how to handle this issue in the *MMWR*, nor did they remember anyone raising it when interviewed by staff.

Given the arbitrary selection of those homes with WLLs of over 300 ppb, the very small number of children under six in the study and the failure to determine whether any residents were actually drinking tap water at the time the blood tests were taken made the conclusions scientifically meaningless. It is inconceivable that trained scientists would produce such a study. and expect that it would stand up to any kind of critical review or attempt to use it to reach any sort of valid public health conclusion about the impact of elevated WLLs. Despite the factual and scientific problems with the study, some of the *MMWR* authors remained comforted by its conclusions. "People were relieved there weren't bodies in the street," Dr. Cote told Subcommittee staff.[137]

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[134] E-mail from Christine Yu to one dozen Public Health Service colleagues and cc'd to Dr. Tim Cote and Dr. Mary Jean Brown, entitled "Subject: RE: MMWR Lead contamination data analysis," Wed., March 24, 2004 1:17 AM.

[135] This e-mail was one of many undated e-mails placed into a word file and provided to the Subcommittee by the Centers for Disease Control and Prevention (CDC) regarding the "clearance" of the cross-sectional study in the MMWR article. The date is unknown because they appear to be deleted from the information provided by the CDC to the Subcommittee.

[136] E-mail from Mark Eberhardt to Mary Jean Brown, cc'd to Dr. Cote, "Subject: Comments regarding DC lead MMWR," March 23, 2004. Emblematic of the data integrity problems with the MMWR article is the fact that Eberhardt's name was spelled incorrectly (Eberhart) in the MMWR article which did not address his comments and he was cited as a Medical Doctor (MD), which he is not, according to a Subcommittee staff interview with Mark Eberhardt, September 16, 2009.

[137] Subcommittee staff interview of Dr. Cote, Sept. 8, 2009.

Rationale for the *MMWR* and its Consequences

What had started as an effort to offer support to the D.C. public health authorities had morphed into a push to get an article published. As Dr. Brown acknowledged, an article was desired by D.C. officials. Dr. Lucey told staff that he relied on the CDC staff to do public health work and when they told him they were not finding any evidence of a problem due to lead in water, he wanted them to get that out as quickly and authoritatively as possible. Lucey was not a lead expert and was managing the public health response of town hall meetings and blood testing clinics. He relied on Dr. Brown and Dr. Stokes to manage the public health inquiries.

The MMWR was published very rapidly, just six weeks after the first contact with Dr. Gerberding at the CDC. The two studies that form the basis of that article were neither peer reviewed nor subject to elaborate internal review by CDC staff. The article was drafted in a political atmosphere where CDC staff were responding to perceived pressure from the top of their agency—Dr. Gerberding wanted them to help Dr. Lucey—and perceived pressure within the District to calm panic about water quality and health. On top of this, there is an undoubted feeling in the CDC lead program that a fixation on lead in water could derail the progress the program had been making on lead in paint, an issue perceived as being much more dangerous to children across the country.[138]

4. CDC to Washington, D.C.: There is No Public Health Crisis

Based on this effort, on March 30, 2004, the CDC published an emergency "dispatch" in its Mo*rtality and Morbidity Weekly Report (MMWR)* titled: "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water — District of Columbia, 2004" that summarized the results of "preliminary investigations."[139] The purpose of the unusually rapid publication, according to a statement made in 2009 by Dr. Brown, its primary author, was to let the public know that CDC – "working as quickly as we could" and "under some constraints" – had not found any evidence of a public health crisis.[140] In fact, according to CDC, based on a longitudinal study of the four-year period from 2000-2003, elevated BLLs $\geq$10 μg/dL in the District's children had declined from 9.8 percent to 7.6 percent for children living in homes with lead service lines. This trend, however, did not hold true for children with BLLs $\geq$ 5 μg/dL.

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[138] Despite the well-documented history of the toxic effects of lead in water on human health and her own publications – and perhaps because of the focus of federal programs on eliminating the lead paint hazard – Dr. Brown seemed singularly focused on the hazards of lead paint and dust, even during the height of the District's lead-in-water crisis. On July 16, 2004, four months after the *MMWR* article was released, Brown wrote to Dr. Lynette Stokes, "Now that there is a better understanding of the public health impact of lead in the drinking water in the District, I hope we will be able to focus on the issue of lead-based paint hazards," she wrote. Memo from Mary Jean Brown to Lynette Stokes, entitled "Subject: Environmental Lead Hazards for Young Children Living in Washington DC," July 16, 2004.

[139] "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, 2004," *MMWR Dispatch,* Vol. 53, March 30, 2004, available here: http://www.cdc.gov/mmwr/pdf/wk/mm53d330.pdf. Three days later it was re-published in the regular *MMWR Weekly*. "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water --- District of Columbia, 2004," *MMWR Weekly*, Vol. 53, No. 12, April 2, 2004, available here: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5312a6.htm.

[140] "High Lead Levels Found in D.C. Kids; Numbers Rose during Water Crisis," quoting Dr. Mary Jean Brown, *Washington Post,* Jan. 27, 2009, Met 2 edition.

While the integrity of the underlying data and the methodology used in both studies in the *MMWR* were highly questionable, the public health message to the citizens of the District was very clear: there was no public health crisis. While full of the normal warnings about no safe level of lead, and the adverse impacts of lead on children and adults, the one English language sentence most likely to resonate with readers read:

> "The findings in this report indicate that although lead in tap water contributed to a small increase in BLLs in DC, no children were identified with BLLs >10 μg/dL, even in homes with the highest water lead levels."[141]

At the same time, her own agency's advisory committee was warning of the health effects of BLLs of less than 10 μg/dL on children, Dr. Brown's prepared talking points to be used in response to public, press, congressional and other potential inquiries after the release of the *MMWR Dispatch* said all was well:

> **Main message: There is no indication that DC residents have blood lead levels above the CDC levels of concern of 10 micrograms per deciliter for children 6 months – 15 years old and 25 micrograms per deciliter for adults as a result of lead in water** (emphasis in original).[142]

As if to reinforce the message of the article, most of the Public Health Service staff packed up and returned to their home agencies by mid-April. The crisis was officially over.

In the wake of the *MMWR* being published, Dr. Falk sent Dr. Brown an e-mail on April 1, 2004 with the *MMWR Dispatch* article attached. "Have you had many calls re this? How is it going?" Falk asked.[143] Dr. Brown's response implied a shared sense of relief that the public interest in the D.C. lead-in-water crisis had finally abated.

> "Today has been the first day in over a month that there wasn't a story on lead in water in the Washington Post and also the first that I haven't been interviewed by at least one news outlet. I guess that means it worked!"[144]

From January 31, 2004 through March 31, 2004, *The Washington Post* had published 66 individual stories revolving around the D.C. lead-in-water crisis. In an interview with Subcommittee staff, Brown explained her statement by suggesting that she was hoping that the *MMWR Dispatch* would serve as a single source of information for reporters and others

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[141] MMWR Dispatch, March 30, 2004, page 2.
[142] Dr. Mary Jean Brown's "Talking Points / Q's and A's – D.C. Lead Issues (3/30/04)."
[143] E-mail from Dr. Henry Falk to Mary Jean Brown, cc'd to Patrick J. Meehan, entitled "FW: MMWR Vol. 53 / No. 12," April 1, 2004, 4:01 pm.
[144] E-mail from Mary Jean Brown to Dr. Henry Falk entitled "RE: MMWR Vol. 53 / No. 12," April 1, 2004.

regarding the CDC's analysis and findings.[145] Dr. Falk suggested that his interpretation of Brown's response was the same.[146]

Indeed, the *MMWR* article was very effective in informing the public that the CDC didn't think there was a public health crisis. On April 6, 2004, a week after publication, a commentary titled: "EPA's lead heads," in *The Washington Times,* read, "The ongoing hysteria about lead in D.C.'s drinking water is much ado about nothing, according to a new report from the Centers for Disease Control and Prevention." Based on the *MMWR* article, the commentary continued: "No health effects whatsoever have been attributed to the lead in D.C.'s water. This is hardly a surprise since the already very low blood lead levels among D.C. residents overall have dropped steadily for years, according to the CDC." (emphasis added)[147]

The District of Columbia government was also quick to seize on the report's findings. On April 9, 2004, the D.C. Interagency Task Force on Lead in Drinking Water, chaired by D.C. Mayor Anthony Williams and Councilmember Carol Schwartz, issued their interim report, which was followed by a final report on April 22, 2004. Both reports cited the basic conclusions of the *MMWR Dispatch* that there was no problem.[148]

When asked why the results of these "preliminary investigations" were not held up until they could be verified, Dr. Brown stated, "The city certainly wanted a document out there. . . . EPA Region 3 wanted it; CDC wanted it. . . . Lots of people wanted to push it forward."[149] But, five years later, Dr. Brown told the Subcommittee staff that she didn't have "a lot of confidence" in the 300 ppb, cross-sectional study data. "There were lots of people not drinking the water," she said.[150]

Dr. Bruce Lanphear, one of the leading experts on lead poisoning of children, later described the report as "a quick and sloppy study to address public health concerns." If the article had been "submitted to a journal to 'prove' that lead in water wasn't an important source, it would have been rejected."[151]

According to Dr. Falk, Dr. Gerberding, CDC's director, proclaimed herself "very pleased" with the results.[152]

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[145] Subcommittee staff interview of Mary Jean Brown, July 22, 2009.
[146] Subcommittee staff interview of Dr. Henry Falk, Sept. 2, 2009.
[147] Steve Milloy, "EPA's lead heads," Special to *The Washington Times*, April 6, 2004, p. A14.
[148] "Final Report of the Interagency Task Force on Lead in Drinking Water and Recommendations of the Co-Chairs," Government of the District of Columbia, April 22, 2004, p. 10: Available here: http://www.dc.gov/mayor/news/2004/lead_task_force_report_4.23.04.pdf.
The interim report released on April 9, 2004, is available here: http://www.dc.gov/mayor/pdf/Task_Force_Report040904.pdf.
[149] Subcommittee staff interview of Mary Jean Brown, July 22, 2009.
[150] Subcommittee staff interview of Mary Jean Brown, July 22, 2009.
[151] Rebecca Renner, "Lead on Tap: An alarming return of lead in drinking water is being ignored by the EPA and municipal officials," *salon.com*, Nov. 27, 2006, accessed at http://ww.salon.com/news/feature/2006/11/27/lead
[152] Subcommittee staff interview of Henry Falk, Sep. 2, 2009.

The Broader Impact of the *MMWR*

In a March 21, 2004, e-mail exchange between Dr. Cote and Dr. Brown regarding draft comments on the *MMWR* paper, the two appear to realize the importance of the paper that they were about to publish and its broader public health implications. "Something happened to the water [in D.C.], and this could happen elsewhere," wrote Brown, "so the recommendation for caution is important." "Hey, I'm all for caution," Dr. Cote wrote. "I agree that this paper will be important for many municipalities outside DC," he wrote.[153]

In fact, at the same time that CDC officials were completing their work on the *MMWR* article, Pitt County health workers in Greenville, North Carolina, detected elevated BLLs in two young children at the same time the local water utility discovered elevated WLLs in several of the city's homes, including the homes of those children. As in the District, the cause of the high WLLs was also attributed to the addition of chloramines into the city's drinking water supply. By November 2004, the Greenville water utility mailed notices to 27,000 customers warning them that the city had exceeded the EPA's standards for lead levels in water.[154]

But county health officials did not connect the elevated WLLs and the lead poisoned children because they had never seen a case of lead poisoning attributed to elevated WLLs before. In addition, Dr. John Morrow, the Pitt County health director, said in a phone interview with Subcommittee staff that he had read the CDC's *MMWR* article and spoken briefly with Dr. Brown via telephone about the article and therefore kept looking for non-water sources of lead exposures in Greenville.[155] It was not until March 2005 – a year after the children's elevated BLLs were discovered – that the North Carolina health workers finally made a connection between the elevated BLLs and elevated WLLs. Dr. Edwards blames that year-long delay on the *MMWR*'s influence on local and state public health workers.

On May 8, 2004, writing in *The Seattle Times*, William O. Robertson, medical director of the Washington Poison Center, cited the CDC's *MMWR* in his efforts to downplay fears about lead-in-water issues that had emerged in some of Seattle's schools.[156] On July 16, 2004, a story in *The Seattle Times* regarding elevated WLLs in Seattle's schools again cited the CDC's *MMWR* article. "Parents should not be overly concerned about lead in Seattle schools' drinking water because it is unlikely any child has been harmed," the paper wrote. It quoted Dr. Brown cautioning parents from thinking their children were brain-damaged because they drank from the school's water fountains. The conclusions of the *MMWR*'s cross-sectional study was prominently

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[153] E-mail from Tm Cote to Mary Jean Brown, cc'd to Daniel R. Lucey, "Subject: RE: MMWR draft2 comments," Sunday, March 21, 2004, 11:51 pm.

[154] See for instance: Pat Stith, Catherine Clabby and David Raynor, "Silence, flawed test data hide lead contamination: Water systems muddy their results by testing homes least likely to have lead," *The News & Observer,* March 28, 2006; "NC Lead Poisoning: Pitt County issues advisory after lead discovered in children," *Associated Press*, May 3, 2005; "Tapping into Greenville's Lead and Water Issues," *The Experience*, Department of Environment and Natural Resources, North Carolina Division of Environmental Health, Vol. 1, July 2005.

[155] Subcommittee staff telephone interview with Dr. John Morrow, August 28, 2009.

[156] William O. Robertson, Medical Director, Washington Poison Center, Seattle, Opinion, Northwest Voices; "A sampling of readers' letters, faxes and e-mails," *The Seattle Times,* May 8, 2004, p. B7.

featured, and an inaccurate claim made that most of the people in the study reported drinking tap water – something the study never claimed.[157]

On May 21, 2004, Angela Logomasini, director of risk and environmental policy at the Competitive Enterprise Institute, told the House Government Reform Committee that lead in D.C.'s drinking water did not "warrant a panicked response" or the "frenzied reaction we've seen in D.C." The CDC's *MMWR* "study reinforces these findings," she wrote in her testimony. "It found that the elevated lead levels in D.C. water did not raise the level of lead in anyone's blood to a level of concern." She also drew the inaccurate conclusion that the CDC had found that every child with an elevated BLL lived in a home with peeling lead paint and/or lead-containing dust from renovations.[158]

On September 5, 2004, Dr. Dean Sienko, then the acting chief medical executive of the Michigan Department of Community Health and the Ingham County medical director, wrote an article in the *Lansing City Pulse* downplaying concerns about elevated WLLs in Lansing, Michigan. He cited the cross-sectional study in the *MMWR* article as a reason not to worry.[159]

Even Congress relied on the *MMWR* to evaluate the potential human health harm caused by the D.C. lead-in-water crisis. The Government Accountability Office (GAO), Congress's investigative arm, cited – without additional analysis – the conclusions of the two studies in its report on the District's attempt to reduce WLLs.[160]

EPA also relied upon the CDC's *MMWR* article. In July 2005, the agency posted a fact-sheet that summarized the findings. It referred to the cross-sectional study and said: "Residents with high lead levels in their tap water did not have elevated blood lead levels" and told readers that "blood lead levels in District residents have been decreasing steadily."[161]

In 2007, in an article in the Montreal paper *The Suburban,* Dr. Joe Schwarcz, the director of McGill University's Office for Science and Society, said: "I have scoured the literature for studies that link levels in the water with levels in the blood. The best studies I have come across which have surveyed really large numbers of homes was in Washington, D.C., where there is a huge problem with lead pipes in underprivileged areas. … [T]hey found that although the water

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[157] Sanjay Bhatt and Warren King, "Schools' lead danger disputed; Experts: water risk "extremely low" / Neurological problems unlikely to stem from exposure to drinking fountains," *The Seattle Times,* July 16, 2004, p. A1.

[158] Angela Logomasini, Director of Risk and Environmental Policy, Competitive Enterprise Institute, prepared testimony before House Government Reform Committee hearing titled: "Thirsty for Results: Lessons Learned from the District of Columbia's Lead Contamination Experience," May 21, 2004.

[159] Dr. Dean Sienko, Acting Chief Medical Executive of the Michigan Department of Community Health and the Ingham County Medical Director and Chief Medical Examiner, Editorial in the *Lansing City Pulse*, September 5, 2004 (the link to this article is no longer available), but the paper can be found here: http://www.lansingcitypulse.com/lansing.

[160] "District of Columbia's Drinking Water: Agencies Have Improved Coordination, but Key Challenges Remain in Protecting the Public from Elevated Lead Levels, Government Accountability Office (GAO), GAO-05-344, March 2005, available here: http://www.gao.gov/new.items/d05344.pdf.

[161] "Results of Blood Lead Level Testing of District of Columbia Residents," Environmental Protection Agency (EPA), July 2005, revised October 2006, available here: http://www.epa.gov/dclead/BloodLevelsFactSheet10_06_rev.pdf.

level was sometimes as high as 300 parts per billion, which is astounding, it didn't influence the blood levels."[162]

5. Efforts by CDC, DC and the Subcommittee to Identify Missing Blood Lead Level Data

Despite the insistence by Dr. Brown that complete data was not needed to understand what had been happening to D.C.'s children, CDC staff did attempt to obtain missing data for 2003. In March 2005 – a full year after the *MMWR* article was published – the CDC lead program tried to resolve the cause of the drop in 2003 blood lead test results. A chain of e-mails shows that Barry Brooks asked the D.C. CLPPP office to ask the laboratories to resubmit the 2003 BLL data. Brooks also told Subcommittee staff that he emphasized to District officials the importance of determining if there was missing data.[163] Despite this effort, according to Brooks, the re-submitted lab data regarding the number of children tested and the number with elevated blood lead levels did not change significantly from the "raw data" CDC used in the 2004 *MMWR* analysis.[164] Nothing the Subcommittee found during its investigation supports the view that the labs did not previously submit this information to the District. The problem appears to have been the incomplete recording of the results by the D.C. lead program staff.

This inability of the CDC to gather accurate data is difficult to understand because the CLPPP program had switched over to the LeadTrax system in April 2004, and had systematically entered all blood lead results from the labs into that system. Based on the material provided to the Subcommittee, it appears that thousands of the missing 2003 results should have been available to the CDC by March of 2005. Furthermore, the Subcommittee did its own collection of lab reports for 2002 and 2003 and had no trouble developing figures for those years that erased the "missing" 6,500 children.

LeadTrax

In April 2004, just after the *MMWR* was published, the District finally acquired the new LeadTrax database to track children screened for BLLs. Through the spring and summer of 2004, Offor worked closely with the manufacturer's technical support staff to acquire and upload the historical 2002/2003 BLL test data into the new system. In October 2004, the manufacturer ran an "historical analysis" of all existing BLL test data on the new LeadTrax software, although it apparently did not include all the results submitted by the labs. It did, however, point out reporting gaps in the D.C. blood lead test data, particularly for the 2003 period.

In a summary document, the manufacturer pointed out that data was "very likely missing" from the Children's National Medical Center from late 2003 into early 2004; data from the D.C. Public Health Laboratory was "very erratic over the same period," and all of it was "suspect"; there was an "aberration" in the data in early 2004; and that there was a "fairly

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[162] Joel Goldenberg, "No Worry on Water," *The Suburban*, March 14, 2007, available here: http://archive.thesuburban.com/content.jsp?sid=144004490012600201826492216 92&ctid=1000000&cnid=1010853

[163] Subcommittee staff interview of Barry Brooks, July 13, 2009.

[164] Subcommittee staff interview of Barry Brooks, July 13, 2009.

substantial drop-off in results from all labs combined for 2003." The major labs of LabCorp. and Quest, however, appears to have a "fairly consistent rate of reporting."[165]

By January 2005, as a result of switching from the poorly functioning STELLAR database to LeadTrax, D.C. had a new, more accurate set of blood lead level test numbers for 2002 and 2003. A January 2005 e-mail from an employee of the U.S. Department of Housing and Urban Development (HUD) to the CLPPP program manager included a table of elevated blood lead levels of D.C. children that had previously been provided by the D.C. Department of Health.[166]

The table, which appears to be sorted by the number of BLL tests conducted and not the specific number of children tested, shows that in 2003 D.C. conducted 22,138 blood lead tests and that at least 400 of those tests showed elevated blood lead levels.[167] The numbers reported to HUD from the D.C.'s lead program in 2005 show:

EBL data (in uniform table)

Year	# of Children Screened	# EBLs 10-14 ug/dL	# EBLs 15-19 ug/dL	Source of Data
2004	26,311			D.C. Department of Health
2003	22,138	244	156	D.C. Department of Health
2002	22,839	319	246	D.C. Department of Health
2001	22,218	378	104	D.C. Department of Health

Source: Subcommittee on Investigations and Oversight, based on D.C. Department of Health 2005 data.[168]

I&O Subcommittee Effort to Obtain Data

Initially, the Subcommittee was unable to get cooperation from the District in gathering up-to-date reports on 2002 and 2003 so staff initiated a survey of the labs. When Chairman Miller wrote to each of the seven laboratories providing BLL test data to the District and asked them to provide the number of children they reported to the D.C. CLPPP in 2002 and 2003 with BLLs above the action level of ≥10 μg/dL, the Subcommittee obtained drastically different numbers.

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[165] "Historical Analysis" of the DC blood lead reporting database, produced by Welligent LLC and run on the newly installed LeadTrax software, October 29, 2004.

[166] Tia Clark, Office of Healthy Homes and Lead Hazard Control, U.S. Department of Housing and Urban Development, e-mail to Christine Onwuche, the DC CLPPP program manager, Subject: "EBL table per our conversation," January 27, 2005. The accompanying chart was labeled: "EBL data (in uniform table)."

[167] Some children may have been tested multiple times so the number of children with elevated blood lead levels may have been lower. But the table also only includes elevated results from 10 ug/dL to 19 ug/dL. Presumably that random cut-off would have also excluded additional test data on children with EBLLs higher than 19 ug/dL.

[168] Tia Clark, Office of Healthy Homes and Lead Hazard Control, U.S. Department of Housing and Urban Development, e-mail to Christine Onwuche, the DC CLPPP program manager, Subject: "EBL table per our conversation," January 27, 2005. The accompanying chart was labeled: "EBL data (in uniform table)."

The labs' documentation of test results provided to the D.C. CLPPP showed that at least 949 D.C. children had BLLs ≥ 10 μg/dL in the critical years of 2002 and 2003, *three times* the 315 used in the 2004 *MMWR* article to tell the citizens of the District that excessive lead in water was not a serious public health issue. As discussed earlier, there was a tremendous backlog of data not entered into STELLAR in early 2004 when the initial set of raw data was submitted to CDC.

The elevated BLL test results that D.C. had in its LeadTrax system by January 2005 are generally in line with data provided to the Subcommittee by the commercial laboratories in 2009. But those are not the final numbers compiled by the D.C. CLPPP. Data for 2002 and 2003 currently available in LeadTrax show even larger discrepancies between the number of elevated BLL tests for the District's children and the number of elevated BLL tests still being reported by the CDC for those years. That data, detailed in the table below, shows that the number of children in D.C. that had elevated blood lead levels in 2002 and 2003 is actually ***three times*** higher than the CDC had used in the *MMWR* article.[169]

Number of D.C. Children Under Six Years Old
with Elevated Blood Lead Levels

YEAR	CDC	I&O Subcommittee
2002	122	457
2003	193	492
Total	**315**	**949**

Source: Subcommittee on Investigations and Oversight, based on data provided by seven laboratories which conducted BLL tests for the District of Columbia's CLPPP and data maintained on the CDC's Childhood Lead Poisoning Prevention Program web-page.[170]

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[169] The CDC's 2004 MMWR article used nearly 85,000 blood lead level "tests" to analyze historic lead levels in DC from 1998 to 2003. Separately, the CDC posts the number of individual "children," not tests, that public health surveillance shows have been identified with elevated blood lead levels annually. Those numbers show that 122 DC children had elevated blood lead levels in 2002 and 193 individual children had elevated blood lead levels in 2003. The blood "test" data results upon which those figures were based were used as the foundation for the historic blood lead level trend analysis in the 2004 MMWR article and were woefully incomplete.

[170] Cities and states that have cooperative agreements with the CDC and obtain CDC grant funds for their lead programs are required to provide CDC with their raw public health surveillance data regarding lead screening tests each year. Since 1992, the District of Columbia has received nearly $12 million in CDC lead grant funding. Once the CDC receives this raw surveillance data, which is supposed to include *all* blood lead tests performed that year, then CDC publishes a separate list based upon the number of children tested, not the number of tests conducted, on the CDC lead branch web-site. The incomplete raw surveillance data CDC received from DC regarding the city's 2003 blood lead tests in early 2004 were provided to the CDC for use in the March 2004 MMWR report. The numbers posted by CDC on its web-site in March 2005 regarding the number of individual children who had elevated blood lead tests in DC in 2003 was based on this incomplete and flawed data and remain there today, available here: www.cdc.gov/nceh/lead/data/State_Confirmed_byYear_1997_to_2006.xls.
The Subcommittee obtained summary data of the number of individual children five years old or younger who had elevated blood lead levels above the CDC "level of concern" of >10μg/dL [10 micrograms of lead per deciliter of blood] in 2002 and 2003 that were reported to the DC Department of Health. The Subcommittee wrote to all seven laboratories providing blood lead test data to DC back in 2002 and 2003, so that we could compare the data CDC

It is unclear why the CDC has not updated its database to remove its obviously incorrect data. It posts lead poisoning surveillance data from its 42 cooperating lead programs on its Web site, and its database manager is responsible for cleaning up the data by removing duplicate entries and making sure that the number of children tested is accurate. The final numbers are verified with the cooperating programs and posted. This process normally takes about six months. Even if the efforts in 2005 failed to get a clean LeadTrax report to the CDC, the subsequent complaints about data quality in the CDC database, and the availability of up-to-date reports from the D.C. government, should have induced the CDC to update those numbers.

The CDC also relies on the lead data it posts on its web site to evaluate CDC-funded lead programs to identify cities or states that have indications of elevated lead poisonings that might be caused by environmental factors. Local and state public health professionals and academics use the data to assess potential lead problems. "This is our basic data," acknowledges Barry Brooks. "When we judge programs, this is what we use."[171] The fact that the actual numbers of children in D.C. with elevated BLLs in 2002 and 2003 appears to have been ***three times*** higher than the number on the CDC Web site is significant. As Brooks admitted, "Elevated numbers drive everything."[172]

With the implementation of LeadTrax in 2004, the BLL test data subsequently reported to the CDC by the D.C. CLPPP was much more accurate, reliable and complete than data submitted under the old STELLAR system. What is much less clear is why CDC failed to understand either the cause or the significance of the 2003 "data gap" and acknowledge it in the *MMWR* article. And even when presented with more accurate data from the D.C. CLPPP and the Subcommittee, CDC has still refused to publicly state that the longitudinal study in *MMWR* report was fatally flawed and its conclusions are scientifically invalid.

2005: CDC Contractor Identifies Continuing Problem with D.C. CLPPP

Dr. Brown and Barry Brooks both expressed a belief that the "data gap" issues and the reported admission of "forgery" of quarterly reports were simply one-time, isolated instances that had no bearing on the integrity of the data CDC received from D.C., the conclusions of the *MMWR*, or their trust in the ability of the D.C. Childhood Lead Poisoning Prevention Program to effectively manage D.C.'s lead program.[173]

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posted on its website with the data the labs reported to DC. Under the CDC's lead grants to the District, copies of the raw public health surveillance data regarding blood lead tests provided to the DC government from these laboratories was supposed to be provided to the CDC.

[171] Subcommittee interview with Barry Brooks, Oct. 22, 2009.
[172] Subcommittee interview with Barry Brooks, July 13, 2009.
[173] The Subcommittee staff conducted a total of six interviews with Dr. Mary Jean Brown and Barry Brooks, three interviews with each of them. The first interview with Mr. Brooks via telephone was conducted on March 23, 2009 and the other two interviews were conducted in the Subcommittee offices in Washington, D.C. and occurred on July 13, 2009 and October 22, 2009. The first Subcommittee staff interview with Dr. Brown also occurred via telephone on March 19, 2009, followed by two interviews in Washington, D.C. on July 22, 2009 and October 22, 2009. Both Dr. Brown and Barry Brooks reiterated this position during each of these interviews.

In reality, even though the D.C. lead-in-water crisis had faded from national headlines soon after the *MMWR* article was published, the D.C. lead program continued to suffer from a host of unresolved problems. In October 2005, Dr. Brown's Lead Poisoning Prevention Branch at the CDC issued a sole source, non-competitive contract award to The National Center for Healthy Housing (NCHH) for "Building Capacity in Childhood Lead Poisoning Prevention Programs." The contract required NCHH to provide on-site technical assistance to the D.C. CLPPP office to help evaluate and revitalize the failing D.C. lead program.[174]

In September of 2007, NCHH completed an internal "Preliminary Work Plan" regarding a summary of their findings of the D.C. lead program. Barry Brooks, the CDC's project officer and health advisor in charge of the CDC lead grant to the District was one of the officials involved in the NCHH assessment. The review, which has never been publicly released, was damning.[175]

Among the report's findings:

- In many cases, children identified as having elevated BLLs in 2004 and 2005 never had risk assessments of their homes completed to identify the actual source of lead exposure. "There is a substantial backlog of EBL [elevated blood lead] cases for which risk assessments have never been performed," the report said, "or for which risk assessments were done too long ago to be valid now." In 2007, the assessment backlog was around 250 cases and growing.

- A review of 41 risk assessment reports found three cases had lead in the water above the EPA limit of 15 ppb with no other lead source identified. In about half of the 41 cases, drinking water had not even been tested for lead.

- There was a continuing mismatch between BLL data collected by the D.C. lead program and BLL test data reported by the CDC. The D.C. lead program "reports that in recent years 16,200 to 18,400 children in D.C. received blood lead tests per year, but CDC figures are substantially lower (12,300 to 14,500)." The report found that CDC reported only around 200 elevated BLL cases annually while D.C. reported 300 to 430 per year. The reason or reasons for this wide discrepancy, however, remained unclear.

A week after NCHH finished its "Preliminary Work Plan," Pierre Erville, the new chief of the District's Bureau of Environmental Hazards and Injury Prevention, wrote to Brooks. Erville, who now oversees the D.C. lead program, said he was writing to let Brooks know he was "concerned about what to me appears to be poor performance by our program," and that he was

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[174] "Building Capacity in Childhood Lead Poisoning Prevention Programs," Solicitation Notice, Oct. 27, 2005, available here: http://fedbizopps.info/archive/2005/10-October/29-Oct-2005/FBO-00922487.htm.

[175] "Preliminary Work Plan - Building Capacity in Childhood Lead Prevention Programs: Technical Assistance and Training to Support the Washington, DC Childhood Lead Poisoning Screening and Education Program's Case Management of Children with Elevated Blood Lead Levels," The National Center for Healthy Housing, September 20, 2007.

"dismayed" by the work of the CLPPP program manager. He assured Brooks that he planned to put "the District of Columbia on the right track to effectively prevent lead poisoning."[176]

Erville noted that he recently hired an epidemiologist for the lead program, that the various D.C. agencies working on lead issues were moving forward as a coordinated group, and that he had re-written the District's risk assessment protocols. "I plan to work closely with [the new epidemiologist] and to achieve long-needed data reliability and analysis," he wrote. "I am also working very closely with the IT folks to ensure Lead Trax is a smooth-functioning program component and putting pressure on supervisory staff to ensure case management follow-up work occurs consistently and in a timely manner," he emphasized.[177] Erville's frank assessment of the D.C. lead program's troubles came more than three years *after* the CDC published the *MMWR* article and the CDC lead program became keenly aware of these systemic problems.

6. Dr. Edwards' Investigation: The Missing Cross-Sectional Data

While the vast majority of those reading the *MMWR* article were reassured that District residents had suffered little, if any, harm from the elevated WLLs, a few were troubled by its conclusions. Dr. Marc Edwards, a civil engineering professor and water corrosion expert, who was named a MacArthur Fellow in 2007 with an accompanying $500,000 grant (often called a "genius grant")[178] to study drinking water safety issues, was more surprised by the findings than almost anyone else. Dr. Edwards, the Charles P. Lunsford Professor in the Civil and Environmental Engineering Department at Virginia Polytechnic Institute and State University, was investigating pinhole leaks in residential water lines in Washington, D.C. in the spring of 2003 when he discovered exorbitantly high levels of lead in the drinking water supply. He determined that chloramines, a chemical used as a disinfectant which had been added to the District's water supply in November 2000 by WASA, was causing lead to leach from household plumbing systems.[179] Edwards soon realized that traditional testing protocols were failing to identify the high lead levels in many homes with lead pipes. He also discovered that children in District homes with elevated water lead levels had elevated blood lead levels too.

Based on his research, Dr. Edwards believed that the *MMWR's* conclusions of no public harm contradicted the vast majority of published scientific findings regarding the effects of elevated WLLs on children's BLLs and their health. But after hearing it repeatedly cited by scientists and public health officials across the country and even internationally, Dr. Edwards sought to acquire the underlying data used for the *MMWR* article to do his own analysis.

In 2005, Dr. Edwards filed Freedom of Information Act (FOIA) requests with both the District of Columbia and the CDC for the raw data underlying the *MMWR* article.[180] He was

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[176] E-mail from Pierre Erville to Barry Brooks, entitled "DC grant reports," Sept. 27, 2007.
[177] *Ibid.*
[178] "MacArthur Fellows 2007: Marc Edwards," John D. and Catherine T. MacArthur Foundation, September 2007, available here: www.macfound.org/site/apps/nlnet/content2.aspx?c=lkLXJ8MQKrH&b=2913825&ct=4074601.
[179] Testimony of Marc Edwards, "Public Confidence Down the Drain: the Federal Role in Ensuring Safe Drinking Water in the District of Columbia," Committee on Government Reform, U.S. House of Representatives, March 5, 2004, accessed at http://www.dcwatch.com/wasa/040305h.htm
[180] For information on federal laws related to the Freedom of Information Act (FOIA) see U.S. Department of Justice's FOIA web-page, available here: http://www.justice.gov/oip/; For D.C. specific laws governing public

bounced between the D.C. Department of Health (D.C. DOH) and CDC and back again. "Trying to find the data was like a shell-game," Edwards said. "I went through about 1.5 years with DC DOH with hundreds of pages of FOIA letters, appeals, etc., before the mayors [sic] office ordered them to produce some of the data."[181]

Finally, at the end of May 2006, the District's general counsel ordered the D.C. DOH director to provide the data.[182] Dr. Edwards received a single Excel spread sheet that was apparently the only data that the Department had regarding the 300-ppb Cross-sectional study cited in the *MMWR* publication.[183]

As part of its investigation, the Subcommittee requested all available documents, including the raw data, survey questionnaires and related records, underlying the Cross-sectional study from the U.S. Department of Health and Human Services and its components, including the CDC, the Food and Drug Administration (FDA), and the PHS, and from the District of Columbia and its agencies[184] None of these agencies have provided the Subcommittee with any records directly related to the collection of the raw data for that study or its results.[185]

CDC, Dr. Cote and the other co-authors all told Subcommittee staff that they had no raw data or survey instruments used in the study. The *MMWR* editorial office also did not possess any of the raw data records. They only maintain "clearance sheets" for their articles for six months. But, Dr. Ward, the *MMWR* editor at the time the DC lead-in-water article was published, said: "I would expect the authors to maintain a copy of the data."[186]

In a letter from Chip Richardson, General Counsel to the Mayor of the District of the Columbia, responding to the Subcommittee on Investigations and Oversight Chairman Brad Miller's request for all records related to the cross sectional study, Mr. Richardson wrote that "No documents responsive to this request have been found."[187] When provided with a copy of the e-mail that the D.C. FOIA officer e-mailed to Dr. Edwards in 2006 which contained the Excel spreadsheet with the "raw data" purportedly used in the study, an official from D.C.'s

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access to District government records see: Council of the District of Columbia, Freedom of Information Act (FOIA) web-page, available here: http://www.dccouncil.washington.dc.us/foia

[181] E-mail from Dr. Marc Edward to Subcommittee on Investigations and Oversight staff, "Subject: Re: 300 ppb study," September 3, 2009.

[182] Leonard H. Becker, General Counsel, Government of the District of Columbia, letter to Dr. Gregg Pane, Director, District of Columbia Department of Health, "Re: Freedom of Information Act Appeal," May 31, 2006.

[183] E-mail from Tom Collier to Marc Edwards with Excel spreadsheet attached, May 31, 2006. In an earlier e-mail to Dr. Edwards, from Tom Collier on April 12, 2006, Collier had described the information as follows: "I will be mailing you spreadsheets showing blood level screening results for the period from February 3, 2004, to March 22, 2004, and February 3, 2004, to September 21, 2004, by first class mail tomorrow. *I will also be getting the raw data for the March, 2004, article and will be forwarding that to you tomorrow.* It should be in an electronic format. The other materials you have requested will be forthcoming, to the extent DOH has them (emphasis added)."

[184] Letter from Chairman Brad Miller, Investigations and Oversight Subcommittee, to Health and Human Services (HHS) Secretary Katherine Sebelius, Aug. 3, 2009; letter from Chairman Brad Miller to District of Columbia Mayor Adrian Fenty, Aug. 3 2009.

[185] Some records were received from CDC related to comments on the *MMWR* draft report.

[186] Subcommittee staff telephone interview with Dr. John Ward, former Editor of the MMWR Series and Director, Office of Scientific and Health Communications, Centers for Disease Control and Prevention, September 28, 2009.

[187] Letter from Chip Richardson, General Counsel to the Mayor of the District of the Columbia, to Brad Miller, Chairman, Subcommittee on Investigations and Oversight, September 3, 2009.

Office of Policy and Legislative Affairs, Executive Office of the Mayor responded that "there is no evidence that a document was attached to the e-mail you've referenced."[188]

Regardless of this incomprehensible explanation by the District government, it appears that the spreadsheet received by Dr. Edwards is both authentic and the only available record regarding the 300 ppb Cross-sectional study based on the correspondence between Tom Collier, the D.C. FOIA officer and Dr. Edwards in 2006.

Dr. Edwards' Analysis: Data in Spread Sheet Doesn't Match Cross-Sectional Study

The *MMWR*'s section on the "Cross-sectional study of Homes with >300 ppb Lead in Water" stated that the D.C. Public Health Laboratory had analyzed the BLL tests on 184 persons in 86 homes with WLLs at or above 300 ppb. In addition, the test results of 17 persons from 12 homes who had blood drawn and analyzed independently and then reported to the D.C. DOH were included for a total of 201 residents from 98 homes. Only 17 of these residents were children under six years of age. The *MMWR* says a total of 153 residents (76%) reported drinking tap water, but 52 households (53%) reported using a water filter on their taps.

But the numbers in the Excel spreadsheet provided to Dr. Edwards are dramatically inconsistent with the numbers referred to in the *MMWR*. For instance, the Excel spreadsheet lists only 194 residents, not 201. It also shows only 136 residents drank tap water, while the *MMWR* claims 153 residents drank tap water. In addition, the raw data reports that 131 of the 194 residents in the spreadsheet say they drank bottled water. Bottled water is not even mentioned in the *MMWR*, despite suggestions by three co-authors and collaborators that bottled water consumption by those surveyed may confound the results. According to the spreadsheet provided to Dr. Edwards, only 13 individuals in 11 homes did not drink bottled water or use a water filter. In other words, only 13 of the 194 residents in the spreadsheet drank unfiltered tap water, with its highly elevated lead levels, exclusively.

The spreadsheet raised other serious questions about the scientific integrity of the *MMWR* publication. Ninety five people, or nearly half of the 194 participants, have no blood "draw date" listed. This date is important because lead in the bloodstream has a half-life of around 30 days. If survey participants stopped drinking tap water after the D.C. lead-in-water crisis first came to the public's attention at the end of January 2004, there could be a significant difference between those that had their blood drawn in February and those that had their blood drawn in March. From a public health perspective, this is something that the *MMWR* should have addressed. Despite assurances by Dr. Cote that those entering data on the Cross-sectional study used a "double entry" method to help ensure data integrity, the missing "draw dates" and other issues raise troubling questions about the overall quality and integrity of the study's data.

Dr. Regina Tan, a co-author of the *MMWR* article and a PHS officer who volunteered to assist in the D.C. lead-in-water crisis, told the Subcommittee staff that there were significant software and IT-related issues that impacted the entry of the survey data used in the Cross-sectional study. She was deployed for six days from March 15 - 20, 2004, and was in charge of

[188] E-mail response to Subcommittee from Jamal H. Anderson, federal affairs advisor, Office of Policy and Legislative Affairs, Executive Office of the Mayor, District of Columbia, Sept. 11, 2009.

overseeing the PHS data entry team. Dr. Tan, who has since left the U.S. Public Health Service, said: "There was a lot of frustration beyond normal data entry, because the system kept crashing and we had to keep re-entering the data. We had to go back to the original data and manually re-enter the data," Tan said. "I recall being frustrated because there wasn't a fix. … We just started again every time the system crashed and hoped we got to the end before it crashed again. We would just enter and enter and enter until it got done." Dr.Tan said that Dr. Cote was well aware of these issues.[189]

Once a blood sample is obtained, it normally takes several days for the laboratory to analyze the results in order to determine an individual's blood lead level. According to Subcommittee staff interviews with officials from the D.C. Public Health Laboratory, which analyzed and processed the blood lead samples for the Cross-sectional study, the timeline for those samples was similar. Yet, the raw data spreadsheet provided to Dr. Edwards lists two individuals as having their blood drawn on March 30, 2004, the same day the *MMWR Dispatch* was published. Another individual is listed as having blood drawn on September 30, 1952, *almost 52 years prior to* the publication of the *MMWR*, and one person is listed as having blood drawn on December 3, 2004, *nine months after* the *MMWR* was published.

When asked about these anomalies in the spreadsheet, Dr. Cote, the PHS official who was the lead author on the cross-sectional study, said the data contained in the spreadsheet must have been corrupted "after the fact." It is true that the Subcommittee cannot verify that the table provided Dr. Edwards is accurate or the final basis for the work done in the *MMWR*. However, since the study lead (Dr. Cote) did not retain records, the lead authors (Dr. Stokes and Dr. Brown) did not retain records and neither the District nor the agencies involved retained records, it is hard to give merit to simple assurances that the data was of high quality and the analysis robust.

Despite the data integrity issues raised in the Edwards data file and by the unacknowledged presence of confounding variables that coauthors were aware of at the time of the *MMWR*, Dr. Cote said he believed the data behind the *MMWR* study is still scientifically sound.[190]

Besides the exclusion from the *MMWR* study of the one child who had an elevated blood lead level of 14 ug/dL and lived in a home with more than 300 ppb of lead in the water, there were other significant omissions. On March 25, 2004, Dr. Cote sent an e-mail to Dr. Brown and Dr. Lucey. Dr. Cote said he had taken "a hard look at how BLLs varied by responses to the questionare [sic] on drinking water exposures (among houses with >300ppb lead measured)." Dr. Cote found that those who drank tap water had a 1 microgram per deciliter higher blood lead level than those who said they did not drink tap water at all. "This is exciting and interesting and we'd better be sure about it before we let it out," Dr. Cote wrote.[191] But in the end, this "exciting and interesting" finding was not included.

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[189] Subcommittee staff interview with Dr. Regina L. Tan, November 5, 2009.
[190] Subcommittee staff interview with Dr. Cote, September 8, 2009.
[191] E-mail from Dr. Tim Cote to Mary Jean Brown and Dr. Daniel Lucey entitled "Relationship between drinking tapwater and BLLs," March 25, 2004.

One week after this e-mail was sent, however, and the day after the *MMWR* article was released, Dr. Brown was quoted in a story in *The Washington Post* saying: "There is no safe level of lead. Even a small contribution, especially in small children, is not something that we want to happen. . . . We don't want to increase the blood lead levels of those individuals by even 1 microgram if it can be prevented," Dr. Brown said.[192] Yet, a 1 microgram increase in BLLs due to drinking D.C. tap water apparently was not important enough to warrant a mention in the *MMWR* article.

In the end, Dr. Edwards believed the problems in the spreadsheet's data for the cross-sectional study were so egregious, and the resistance from CDC and D.C. DOH to his request for the actual raw data so strong, that he began to believe that it may actually have been fabricated. He also questioned the data used in the *MMWR*'s longitudinal study because of the dramatic and unexplained drop of more than 6,500 in the number of children that were tested in 2003 compared to previous years.[193]

In January of 2007, Dr. Edwards sent a formal complaint to the CDC alleging "possible fabrication and falsification" of the data used in the CDC's March 2004 *MMWR* article. CDC responded that his allegations were directed at District, not CDC, employees.[194] Dr. Edwards then sent a second, more detailed letter to CDC in September 2007 with specific allegations of possible scientific misconduct by CDC scientists.

Dr. James Stephens, CDC's acting associate director for science, was tasked with looking into Dr. Edwards' allegations. But Dr. Stephens never fully investigated Dr. Edwards' allegations because he determined the allegations did not merit an investigation as they did not meet the threshold definition of research misconduct specified in federal regulations. Therefore, an investigation was not required.[195] To qualify as "research misconduct" under the federal

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[192] Avram Goldstein, "Water Treatment Affected Levels In Some Children, Study in D.C. Says," *The Washington Post*, March 31, 2004, p. B1.

[193] "Number of Children Tested and Confirmed EBLLs by State, Year, and BLL Group, Children < 72 Months Old," Childhood Lead Poisoning Data, Statistics, and Surveillance, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), available here: http://www.cdc.gov/nceh/lead/data/State_Confirmed_byYear_1997_to_2006.xls

[194] Letter from Dr. James W. Stephens, Associate Director for Science, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) to Dr. Marc Edwards, Virginia Polytechnic Institute and State University, Blacksburg, Virginia, September 18, 2007. See also: E-mail from James Stephens to Marc Edwards, "Subject: RE: Outcome of the assessment," October 10, 2007, in which Dr. Stephens wrote: "Per my letter, I would advise raising your concerns with the DC Office of the Inspector General." Some CDC officials did not see how any of the allegations applied to CDC officials because the data that Edwards questioned on both the longitudinal study and the cross-sectional study came from the District government and the U.S. Public Health Service, not the CDC. But others found this a weak position. "We do have some accountability since the data was published in the MMWR and MJB [Mary Jean Brown] is the 1st author," wrote Dr. Tom Sinks, deputy director of NCEH/ATSDR. E-mail from Dr. Tom Sinks to Dr. Brown, Dr. Howard Frumkin, cc'd to Dr. James Stephens, entitled "RE: Allegations of possible scientific misconduct," Jan. 18, 2007.

[195] Subcommittee staff interview of Dr. James Stephens, June 30, 2009. During this interview Dr. Stephens acknowledged: "I did not say I did an investigation because that is not what I did." He did not investigate Dr. Edwards' allegations because it did not reach the definition of federal "research misconduct," he said, which can be found here: "Public Health Service Policies on Research Misconduct; Final Rule, 42 CFR Parts 50 and 93," Department of Health and Human Services, printed in the Federal Register, Vol. 70, No. 94, Tuesday, May 17, 2005, available here: http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf. Other CDC staff apparently

definition, intentional deception must be alleged. Dr. Edwards' allegations may not have been sufficient to charge intentional deception.

But other CDC officials, while agreeing that Dr. Edwards' complaint did not allege research misconduct, thought the issues he raised were troubling and warranted some sort of investigation. "[T]he questioned data were not acquired as a research activity but as surveillance data," wrote Dr. John Dahlberg, director of CDC's Investigative Oversight Division, Office of Research Integrity. As a result, "the research misconduct policy . . . does not apply to the concerns that have been raised." Still, wrote Dahlberg, "The apparent absence of much of the lead data is also troubling. Given the importance of this issue, and the apparently real concerns raised, it would appear that some sort of review should be undertaken. Possibly this could be done by either the DC Inspector General and/or by the HHS IG office."[196] The CDC never informed the D.C. OIG about these allegations. Instead, they suggested to Dr. Edwards that if he had concerns with the data used in the *MMWR* that he should raise those concerns with the D.C. OIG.

7. CDC Response to Critics and New Unpublished Analysis

CDC's Notice of Misinterpretation: Resistance and Eventual Publication

One positive result of Dr. Edwards' complaint, however, was that it alerted CDC officials to the fact that the March 30, 2004 *MMWR* was being relied upon by state and local officials to make public health decisions regarding elevated levels of lead in drinking water. Some CDC officials believed that it was being "misinterpreted" to conclude that elevated WLLs were safe.

The result was a decision by CDC in March 2007 to issue a "notice" on the MMWR Web site to address the "misinterpretations." The notice was intended to reiterate what the CDC now claimed were the main conclusions in the 2004 article – that there are no safe levels of lead exposure, and that the *MMWR* never implied that D.C.'s elevated WLLs were safe. But Dr. Brown resisted issuing any sort of "alert" or "notice" for months. In August 2007, she wrote: "Tom Sinks and I had a conversation regarding the misinterpretation of the results published in the MMWR article on lead in water in D.C. We agree that the article is clear that CDC DOES NOT conclude that 300 ppb of lead in water is 'safe.' We also agreed that authors are not responsible for possible misinterpretations of their studies." (emphasis added)[197]

Dr. Brown said she did not want to set an "unwanted precedent" by publishing an alert. "I know CDC data is misunderstood and used inappropriately all of the time," she told Subcommittee staff, "but I did not believe this was a good precedent to set." Brown also said she did not believe the issues raised by Dr. Edwards were "related to science," but rather, there were "people pushing this." She implied that local D.C. activists were somehow behind the allegations

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believed Dr. Stephens had done a full investigation and exonerated the agency and its officials. See, *e.g.*, Subcommittee staff interview of Dr. Mark Bashor, Associate Director for Science, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR), Centers for Disease Control and Prevention (CDC), Sept. 2, 2009.

[196] E-mail from Dr. John Dahlberg to Dr. James Stephens, entitled "RE: Allegation of misconduct," Feb. 2, 2007.

[197] E-mail from Mary Jean Brown to Jim Rabb and Andrew Dannenberg, cc'd to Sharunda Buchanan, Aug. 3, 2007.

by Dr. Edwards and she suggested that Marc Edwards did not understand the limitations of the *MMWR* or public health surveillance data in general since he was an "engineering professor" and not a public health official.[198]

Dr. Mark Bashor, the associate director for science at NCEH/ATSDR, pushed repeatedly to issue a "notice" or "alert" in the spring and summer of 2007 but faced Dr. Brown's resistance. On August 10, 2007, Dr. Bashor, tried to put an end to the continuing delays in posting the "notice:"

> To bring closure to the issue that I thought we had closed on earlier (March 26th), I met with Dr. Sinks yesterday.
>
> Our decision is that the program should draft a notice to be posted on the web, explaining how the 2004 MMWR article is being misinterpreted/misused, providing appropriate additional information and clarification, and reiterating our position on Pb [lead] in drinking water.[199]

Dr. Bashor's e-mail, however, was not sufficient. On August 14, 2007, Dr. Frumkin, NCEH/ATSDR's director, ordered Dr. Brown to write the notice they had discussed.

> This will confirm our phone call today in which I directed you to write the short clarifying text on the correct interpretation of our DC water lead data, which has been questioned, for posting on the web site. Please provide it to Mark Bashor by the end of this week. Thank you.[200]

Finally, after a five-month delay, the notice was posted on the CDC web-site.[201] The notice was to be the extent of CDC's response to Dr. Edwards' allegations. On September 18, 2007, Dr. Stephens wrote to Dr. Edwards and said he had found no evidence of misconduct by CDC, and that the questions he raised "pertained to data collected by others outside of CDC." Dr. Stephens recommended that Dr. Edwards contact the D.C. Office of Inspector General with his allegations.[202]

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[198] Subcommittee staff interview of Dr. Mary Jean Brown, July 22, 2009.

[199] E-mail from Mark M. Bashor to Sharunda D. Buchanan, cc'd to Tom Sinks, James Stephens and Jana Telfer, entitled "Notice re: 2004 MMWR Pb in D.C. Water paper," Aug. 10, 2007 1:02 pm.

[200] E-mail from Howard Frumkin to Mary Jean Brown, cc'd to Sharunda Buchanan, Mark Bashor and Tom Sinks, entitled "102 paragraphs on correct interpretation of lead data," Aug. 14, 2007, 11:52 a.m.

[201] "Addendum: Following the release of the MMWR, "Blood Lead Levels in Residents of Homes with Elevated Lead in Tap Water -- District of Columbia, 2004", some reports have suggested erroneously that the Centers for Disease Control and Prevention has determined that lead in residential tap water at concentrations as high as 300 parts per billion is 'safe'. CDC would like to reiterate the key message from the 2004 article that because no threshold for adverse health effects in young children has been demonstrated (no safe blood level has been identified), all sources of lead exposure for children should be controlled or eliminated. Lead concentrations in drinking water should be below the U. S. Environmental Protection Agency's action level of 15 parts per billion." The note clarifying the CDC's position on their MMWR article was posted to the CDC web-site on August 17, 2007, available here: http://www.cdc.gov/nceh/lead/tips/water.htm.

[202] Letter from Dr. James W. Stephens to Dr. Marc Edwards, Sept. 18, 2007.

CDC's Inadequate Review of Dr. Edwards' Allegations

As stated earlier, Dr. Stephens did not conduct a full investigation of the facts underlying Dr. Edwards' allegations. When he wrote his September 2007 letter to Dr. Edwards, Dr. Stephens had not even spoken to Dr. Brown, the primary author of the *MMWR* article. He did not do so until October 2007. During that meeting, Dr. Brown apparently mentioned the "challenges" of relying on public health surveillance data because of missing or incomplete data and the overall problems in obtaining all BLL test data from commercial laboratories in a timely manner. She reiterated the unsubstantiated claim that the Quest lab was to blame for the drop in BLL screening data from 2002 to 2003, and that she was convinced that the CDC was not missing any "elevated" BLL test results. This explanation appeared to have appeased any concerns Dr. Stephens may have had about the integrity of the data underlying the *MMWR*.[203]

Dr. Edwards was not satisfied and sent a follow-up e-mail to Dr. Stephens asking for clarification and then sent a second more detailed letter alleging "Possible Scientific Misconduct by CDC Scientists and Officials."[204] "In this letter," wrote Dr. Edwards, "I allege scientific misconduct by CDC employees, which is something you claim necessary before your office will consider an investigation into this matter."[205]

On October 10, 2007, Dr. Stephens responded in an e-mail: "I was not able to identify any evidence of falsification, fabrication, or plagiarism related to CDC's involvement in the MMWR Dispatch either from the materials you provided or from any internal information," and made it clear that CDC did not believe this issue warranted any further efforts on its part. Once again, he advised Dr. Edwards to go to the District's Office of Inspector General if he still had concerns about the data in the *MMWR*.[206]

CDC's New Study on the Impact of Elevated WLLs in D.C.

Dr. Edwards' skepticism about the conclusions of the *MMWR* also encouraged him to look at the risk assessments that the health department had done of the homes with elevated WLLs and children with elevated BLLs. He found that CDC's and the District's statement that lead paint was the only source of those elevated BLLs was not true. In, 2006, Dr. Edwards told the local public radio station that some of the city's assessments pointed to water as the key source of lead in the home. "The message sent – that very high levels of lead in water did not cause any measurable public harm – is a false message and it has to be retracted," Edwards said. The radio station reviewed department records and confirmed his statement.[207] Four days after that report, CDC announced that it would conduct a new study to determine whether its original finding was correct. Dr. Brown, the primary author of the original study, said she had not known about the home assessments done by the D.C. DOH. "We think everything's safe," she said, but

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[203] Subcommittee staff interview of Dr. James Stephens, June 30, 2009.
[204] E-mail from Marc Edwards to James Stephens, entitled "Please clarify the meaning of the September 18th letter," Sept. 22, 2007. See also, letter from Marc Edwards to James Stephens, Sept. 18, 2007.
[205] Dr. Marc Edwards sent his second letter regarding potential CDC scientific misconduct to Dr. James Stephens on September 18, 2007, with the heading: "Re: Possible Scientific Misconduct by CDC Scientists and Officials."
[206] E-mail from James Stephens to Marc Edwards, entitled "RE: Outcome of the assessment," Oct. 10, 2007.
[207] WAMU 88.5FM, Transcript of "Questions over Harm Caused by Lead in the Water," Sept. 21, 2006, accessed at http://wamu.org/news/06/09/lead_questions.php

CDC would re-analyze the data and would look at the assessments. That study was supposed to be completed in "several months."[208]

Although when CDC published the *MMWR* in 2004, officials stated that it was a "preliminary investigation", and that it was still "ongoing,"[209] there was no follow up until Dr. Edwards' radio appearance. Since 2007, Dr. Brown and CDC colleagues had been working on a revised D.C. lead-in-water study based, at least partly, on the same incomplete data used in the March 2004 *MMWR* article. But when the conclusions were released at an American Public Health Association conference in November of 2007 they shattered the finding of the 2004 *MMWR* that the elevated WLLs had no impact on public health. Even when controlling for all the "confounders," such as the age of the housing unit, researcher Jaime Raymond found that "Children who were tested and BLLs ≥5 µg/dL or ≥10 µg/dL were significantly more likely to have lived in a HU [Housing Unit] with a LSL [Lead Service Line] compared to children with lower BLLs." In addition, when chloramine was added to the water system as a disinfectant, the CDC found, it may have caused lead service lines to leach lead into the water, contributing to the rise of BLLs in young children. "When chloramine was eliminated as the drinking water disinfectant," Raymond noted, "we saw a dramatic reduction in BLLs in children < 6 years old in Washington DC."[210]

Another key finding of the new study was that the risk of elevated BLLs for children in homes with partial lead line replacements was four times higher than in homes without lead service lines.[211] Despite the significance of these findings both in health and financial terms to the nation's children and the water systems that initially saw partial line replacement as a solution to lead leaching into drinking water, the study has never been published.

In 2004, even before the publication of the *MMWR* article, water experts, including Dr. Marc Edwards, had warned that "partial" lead line replacements would actually increase the water lead levels at least in the short run increasing the potential human health dangers of D.C.'s residents.[212] But in the wake of the D.C. lead-in-water crisis, WASA spent over $100 million to replace publicly owned lead pipes throughout the city before deciding the program was a waste

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[208] WAMU 88.5FM, Transcript of "CDC Lead Study," Sept. 25, 2006, accessed at http://wamu.org/news/06/09/lead_questions.php

[209] *MMWR Dispatch, supra,* p. 1.

[210] "Association between lead poisoning among children less than six years old and lead service pipes in Washington DC," Abstract #166176, 135th American Public Health Association (APHA) Annual Meeting, Jaime Raymond, MPH, Chinaro Kennedy, DrPH, MPH, and Mary Jean Brown, ScD, RN, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), Wednesday, November 07, 2007, available here: http://apha.confex.com/apha/135am/techprogram/paper_166176.htm.

[211] *Ibid.*

[212] Based on his research in 2003, the resulting increase in WLLs caused by chloramines and partial line replacement was identified by Dr. Edwards even before the CDC completed its March 30, 2004 MMWR article. In a Feb. 19, 2004, letter to an expert panel at WASA, Dr. Edwards wrote: "[N]ot does chloramine worsen galvanic corrosion between brass/copper or lead/copper, but it also increases the amount of lead leached to the water when the metals are coupled. . . . replacing a half a lead service with copper is going to dramatically worsen the galvanic corrosion . . . Such partial replacements should be stopped immediately." Dr. Edwards repeated his warning at a Congressional hearing. Testimony of Marc Edwards, "Public Confidence Down the Drain: The Federal Role in Ensuring Safe Drinking Water in the District of Columbia, U.S. House of Representatives, Committee on Government Reform, March 5, 2004.

of money and actually caused a temporary increase in WLLs.[213] Many states, including Michigan, Rhode Island, Wisconsin, New York and Washington have also invested hundreds of millions of dollars in replacing lead service lines.[214] In most cases, however, homeowners responsible for replacing the portion of lead pipe from the street to their home declined to spend the several thousand dollars to do so. By mid-February 2004, for instance, of 526 D.C. residents who had the WASA-owned service lines on their street replaced, only *one* resident chose to pay for the replacement of the line to his home.[215]

In December 2008, the new draft CDC study, co-authored by Raymond, Dr. Brown and other CDC officials was finally submitted for "clearance" at CDC. But the allegations concerning the credibility of the underlying data were raised and have never been resolved. On January 25, 2009 – two days before Dr. Edwards came out with a peer-reviewed article that concluded that very young children in the District were more than four times as likely to have BLLs ≥10 µg/dL – Dr. Bashor weighed in with his comments. Among his many concerns:

> Regarding some big-picture comments based on my reading (NOT clearance review) to date:
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> (a) At the center of this paper is the blood lead data from 1998-2006, "…derived from the Washington D.C. Childhood Lead Poisoning Prevention Program…." The strength or weakness of the present draft relies on the accuracy, completeness, and comparability of the blood lead data for each year and across years. The only descriptions I could find regarding the analytical methods and QA/QC methods was a single sentence: "Blood lead tests were analyzed at various laboratories across the United States and were reported as whole numbers to the DC CLPPP." The fact that multiple laboratories over multiple years contribute to the database argues for a more detailed discussion of analytical methods, QA/QC, and implications for the ability to compare with confidence the results from multiple labs across multiple years. The NCEH/DLS could assist in developing this discussion.
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> (b) As just noted, the integrity of the blood lead level database is a centerpiece of the entire paper. It appears to be public knowledge (at least reporters' knowledge) that allegations have been made challenging the

[213] Michael Ruane, "WASA Backs off Lead Pipe Program," *Washington Post,* Sept. 5, 2008.

[214] See: Christian Czerwinski, "Lead line replacement ahead of schedule," Lansing State Journal, May 31, 2006; "Kinetico offers solutions to high lead levels in Ontario water," Canada NewsWire, June 15, 2007; Dean Mosiman, "Mayor: Spend More on Water; Cieslewicz Will Propose a Spending Increase of More Than 50 Percent for Madison Water Utility Infrastructure," The Capital Times & Wisconsin State Journal, August 31, 2006; "Neighbors Syracuse: City to Begin Lead Pipe Replacement in Spring, The Post Standard/Herald-Journal, August 19, 2004; "WASA prioritizing lead line replacement plan," Associated Press, April 15, 2004; "Rhode Island Daybook: Lead Pipe Protest," Associated Press, April 12, 2010; Sanjay Bhatt, "Options presented to clean up water; Estimates vary | Seattle Schools study 3 options to reduce lead," Seattle Times, October 20, 2004.

[215] E-mail from EPA lead expert Michael Schock to EPA colleague Ronnie Levin and cc'd to nearly three dozen other colleagues including the CDC's Dr. Henry Falk, Subject: "FW: WP 2/11: WASA Avoided Replacing Lead Service Lines," February 18, 2004 7:54 am.

> integrity of this database due to the (alleged?) loss of thousands of data points in a critical year (2003) of this study. … I am very concerned that we are treating this data as if it were entirely accurate and complete, without having seen anything regarding the District's finding(s) regarding public allegations. Has CDC/NCEH/EEHS/LPPB received assurance(s) regarding the accuracy and completeness of the database? I am especially concerned that we have clarity on this matter, since CDC is using the data, and further, CDC could be perceived as having some responsibility if we fund this data collection program through a Cooperative Agreement (substantial Federal Involvement, by definition).
>
> (c) Given the enormous amount of time that has been consumed addressing controversy regarding the 2004 MMWR paper on this situation, I am surprised that the present draft manuscript—while it cites the subject MMWR—does not include any comparative discussion regarding the findings of that publication, and the present draft manuscript. Is there a reason for this? If not, I think the findings of both should be discussed.[216]

Dr. Bashor returned the paper for revisions. He rejected it a second time on February 27, 2009. But somehow, after the second rejection, the paper went to Dr. Peter Briss, the science officer in the CDC's Coordinating Center for Environmental Health and Injury Prevention (CCEHIP), where Dr. Henry Falk was the director. That was an unusual event. "They had gone over my head and up the chain," said Dr. Bashor in an interview. Asked if that had ever happened before, Bashor said: "I don't think that's *ever* happened, except in this case."[217]

Dr. Tom Sinks, NCEH/ATSDR's deputy director, then spent months revising the paper, and Dr. Briss approved it in CK-May 2009-CK. In fact, because of his substantial involvement in revising the study, Dr. Sinks became a co-author of the new report. But, despite Dr. Bashor's clearly expressed concerns about the use of seriously flawed data in an article to be submitted for peer review, neither Dr. Brown, Dr. Sinks nor any of the other co-authors ever sought to address those criticisms or to obtain the missing blood lead level test data.

The manuscript was sent to the journal *Environmental Health Perspectives* (EHP) last summer which rejected it. It was then submitted to the journal *Environmental Research*, where it underwent peer review. Once again, the issue of the integrity of the underlying data was raised. One reviewer pointed out that the 2003 missing blood lead level data "raises a lot of questions."

> First, since the labs are identified did you consider obtaining the unreported data and adding them to the analysis? That would seem

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[216] E-mail from Dr. Mark Bashor, Associate Director for Science, NCEH/ATSDR, Centers for Disease Control and Prevention (CDC), to Howard Frumkin, Tom Sinks, James Stephens, Peter Briss, Sharunda Buchanan, Andrew Dannenberg and Mary Jean Brown, "Subject: INITIAL COMMENTS ON BROWN'S DRAFT MS: ASSOICATION BETWEEN CHILDREN'S BLOOD LEAD LEVELS…IN WASHINGTON DC…" Sunday, January 25, 2009, 4:18 pm.

[217] Subcommittee interview with Dr. Mark Bashor, Sept. 2, 2009.

> to be the most straightforward way to address the situation. Second, if that is not possible for some reason, it would be preferable for you to provide a quantitative analysis of how the unreported data compare with the results that are reported. Your statement that they were "more likely" to be <10 leaves a lot to be imagined."[218]

A second reviewer identified other problems as well.

> There are some biases that are inherent in the analysis, but not identified. For instance, the targeting of children for screening in CLPPPs assumes a principal exposure of dust/paint/soil. The highest risk for elevated exposures due to drinking water is in formula-fed infants. No data for this population were obtained in this study. As such, this analysis likely underestimates the full impact of the elevated lead levels in DC's drinking water. Also, using age of housing to control for lead paint, reduces the significance of the water.[219]

The article has not yet been published.

8. Dr. Edwards' Peer-Reviewed Research: Elevated Water Lead Levels Endangered District's Children

At the same time Dr. Bashor was questioning Dr. Brown's reliance on faulty data, Dr. Edwards published a peer-reviewed study in the January 2009 issue of *Environmental Science & Technology* journal that found that in Washington, D.C., the youngest children aged15 months or less were four times more likely to have an elevated BLL from 2001-to-2003 when water lead levels were at their highest compared to 2000 before water lead levels had increased.[220] Along with co-authors Simoni Triantafyllidou and Dr. Dana Best, an epidemiologist and pediatrician at Children's National Medical Center (CNMC) in Washington, D.C., Dr. Edwards had examined 28,000 BLL test results submitted to the D.C. Childhood Lead Poisoning Prevention Program from CNMC between 1997 and 2007. The data showed that hundreds of the youngest D.C. children were exposed to damaging levels of lead in their blood while the District's drinking water supply had high levels of lead – a markedly different conclusion than that of the CDC's 2004 *MMWR* article.

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[218] Letter from Ellen Kovner Silbergeld, PhD, Editor-in-Chief, *Environmental Research* to Mary Jean Brown, "Subject: ER-09-0331: Interim Decision," re: Title: Association between Children's Blood Lead Levels, Lead Service Lines, and Chloramines for Water Disinfection, Washington, D.C., 1998-2006, Corresponding Author, Dr. Mary Jean Brown, Authors: Jaime Raymond, MPH; David Homa, PhD, MPH; Chinaro Kennedy, DrPH, MPH; Thomas Sinks, PhD, Aug. 13, 2009.

[219] *Ibid.*

[220] Marc Edwards, Simoni Triantafyllidou, and Dana Best, "Elevated Blood Lead in Young Children Due to Lead-Contaminated Drinking Water: Washington, DC, 2001-2004," *Environmental Science & Technology,* published by the American Chemical Society, March 1 2009, pp. 1618-1623; published on-line on January 27, 2009, available here: http://pubs.acs.org/doi/abs/10.1021/es802789w.

Dr. Edwards had obtained a copy, via a FOIA request, of the nearly 85,000 blood lead test results reported to the D.C. lead program from 1998 to 2003 from all laboratories, including CNMC, that were used in the 2004 *MMWR* article's analysis of historical blood lead tests in Washington, D.C. But when the authors of the Edwards paper tried to compare the CDC records to the CNMC records they found an error rate of more than 50 percent, in five separate domains, including sample data, blood lead level and subject's age. "Because repeated attempts to resolve this and other discrepancies in the CDC data were not successful," the authors wrote, "only the CNMC data were used for analyses and conclusions in this work."[221]

In addition, according to the records in the CNMC database, Children's National Medical Center reported 80 elevated blood lead level test results to D.C. in the second half of 2003. However, when Edwards compared this data to the database of BLL tests that CDC used in the *MMWR* study it showed that the database had only 23 elevated BLL test results from D.C. for that same period [CK]. In 2003, CNMC was one of seven labs reporting BLL tests to the D.C. Department of Health. So, the information D.C. reported to CDC should have been a compilation of all of the BLL tests reported to D.C. from all of these labs. Yet, the CDC database contained fewer tests than the CNMC alone.[222] [CK]

The Edwards article sparked widespread media coverage and a hearing by the Council of the District of Columbia.[223] The CDC's response to Dr. Edwards' award-winning research, however, was to downplay the significance of any findings that could be seen as contradicting the basic conclusions from the 2004 *MMWR* article that no one had suffered undue harm from the D.C. lead-in-water crisis. In a follow-up article in *The Washington Post*, Dr. Frumkin – contrary to other lead experts – even implied that the reduction in the IQ of children exposed to elevated water lead levels in D.C. was not a cause for concern. "At these levels, the effects are subtle," said Frumkin. "They are detectable in population studies but generally not in individual

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[221] Edwards, Triantafyllidou and Best, *supra,* p. 1620. The CDC also provided the Subcommittee with a copy of the underlying raw data of those 85,000 blood lead tests. As Dr. Edwards pointed out, the data includes 9,766 blood test results for 2003, but the vast majority contained no indication of the age of those being tested. Of the 9,766 test results, 8,939 listed the age as zero months. This is indicative of other problems in the underlying data from the DC lead program and CDC.

[222] In an interview with Subcommittee staff in September 2009, Pierre Erville, Associate Director for Lead and Healthy Housing in the DC Department of the Environment which now overseas the District's lead program, said that after the Edwards article came out in January 2009 the District went back to Children's National Medical Center and obtained a copy of the data they used for the Edwards study. Erville admitted that the data contained records that were not available in the District's own blood lead database, but should have been. Eight months after the Edwards paper was published, Erville said DC was still analyzing the CNMC data to see how many records may be missing from the District's blood lead database.[222]

[223] See, *e.g.,* Carol Leonnig, "High Lead Levels Found in D.C. Kids," *Washington Post,* A1; "Lead Probe Sought in D.C.," *Washington Post,* B1. Dr. Edwards' work was subsequently cited as the best paper of 2009 in the science category by the journal, and he was given the Praxis award for professional ethics by Villanova University in April of 2010 "because of his exemplary dedication to the ethical ideals of his profession as an engineer," said Mark Doorley, director of Villanova's Ethics Program. "Out of a concern for the public welfare, a central value of the engineering profession, Professor Edwards pursued what he thought was a highly dangerous claim about lead in the water of Washington, D.C." Villanova press release, "Dr. Marc Edwards will receive Villanova's 2010 Praxis Award in Professional Ethics," Sept. 28, 2009, accessed at: http://www.villanova.edu/artsci/ethics/praxisaward/release.htm

children," he said.[224] Once again, the message from the CDC was that there was no reason for D.C. parents to worry. . The message was repeated – once again – by WASA officials. In a D.C. Council meeting, WASA General Manager Jerry Johnson said he would allow a child to drink the water, stating that he relied on CDC for information that residents' health had not been harmed. "I'm not a physician; I'm not an epidemiologist. We had to rely on outside services," he said.[225]

Internally the CDC spent significant time and energy strategizing about how to respond to the Edwards paper. Dr. Frumkin proposed a letter to the *The Washington Post*. His draft letter mentioned the new study on the D.C. lead-in-water crisis that Dr. Brown had been working on since 2007. But Glen Nowak, CDC's director of media relations, sent an e-mail to several CDC officials, questioning how CDC could claim to promise the study would provide "critical information the city can use to help vulnerable children," but not release it until later in the year.[226]

Those were reasonable questions that never received clear answers. In the end, officials at the Department of Health and Human Services Department officials (HHS) killed Dr. Frumkin's proposed letter about the new study. The CDC had informed EPA officials about the preliminary conclusions in 2007.[227] But the citizens of the District – those that would benefit most from the CDC's new findings – have never been told of the results of this study. There was no new *MMWR Dispatch* to inform public health officials worldwide that, even when adjusted for the age of the housing unit, children whose water came from lead service lines had a significantly more likely to have an elevated BLL. There was no new *MMWR Dispatch* warning cities that partial lead line replacements or the addition of chloramine would cause a spike in children's BLLs.

In September 2009, after WASA had halted its partial lead line replacement program, Dr. Brown finally informed WASA that CDC's study indicated "that the risk of elevated blood lead levels $\geq$ 10 ug/dL in homes with partial replacements of lead service lines is about 4 times that of the risk for blood lead elevations in homes without lead service lines. We also noted an increase in risk for elevated blood lead levels when homes with partial replacement were compared to homes with full replacement of lead service lines."[228]

In January 2010, a full year after the CDC's Nowak questioned the rationale for sitting on presumably critically important public health information, Dr. Frumkin finally posted a two-paragraph update for lead program managers on the CDC web-site regarding some of the results

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[224] David Brown, "Study Can't Pinpoint Extent of Lead Exposure," *The Washington Post,* January 31, 2009, B1, available here: http://www.washingtonpost.com/wp-dyn/content/article/2009/01/30/AR2009013003666.html.

[225] Nikita Stewart, "Water Assessment is Murky; Comments at Hearing Fail to Ease Concern about Lead," *Washington Post,* Feb. 11, 2009, B4.

[226] E-mail from Glen Nowak (CDC/OD/OEC) to Dr. Mary Jean Brown, Dr. Howard Frumkin, Dr. Tom Sinks, and others on January 28, 2009 12:14 pm.

[227] See: E-mail from Edward V. Ohanian, Ph.D., Director, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, Environmental Protection Agency to Mary Jean Brown, "Subject: Re: CDC Draft Letter to WASA," August 17, 2009. In the e-mail Ohanian wrote: "Mary Jean: We appreciate the CDC's urgency in providing information to local officials regarding the findings of the draft study currently undergoing peer review. … We first discussed this study with you in a meeting on December 14, 2007, and our health scientists reviewed a draft of this report in February, 2009."

[228] Letter from Mary Jean Brown to Avis Russell, Interim General Manager, DC WASA, cc'd to District Department of Environment and Environmental Protection Agency's Office of Water, Sept. 4, 2009.

of Dr. Brown's new paper. "I wanted to bring the preliminary results [of this study] to your attention as they underscore the need to provide health education materials to families that include advice for lead safe water practices following plumbing work in housing with lead water lines or lead solder."[229]

Meanwhile, District of Columbia officials were again quick to rely on the misleading statements made by senior CDC officials about the potential human health dangers of lead in drinking water. On February 10, 2009, in the wake of the release of Dr. Edwards' paper, George Hawkins, then the District Department of Environment director, told a D.C. City Council public hearing on water quality issues that his office was aware of the Edwards' study and had asked CDC to analyze it for them. In the meantime, Hawkins said, he had relied on the "initial analysis" from "experts such as Dr. Howard Frumkin" and quoted Frumkin's remarks to *The Washington Post* that the effects of lead exposure to children was "subtle" and not detectable "in individual children."[230] The take home message nearly five years after the CDC's publication of the *MMWR* was still the same. The lead-in-water crisis in D.C. did not result in any measurable public harm to the Capitol's children.

In April 2009, Rebecca Renner published a story about the CDC's *MMWR* article and the flawed data they relied upon for that study in an article on Salon.com, based partly on her interview with Dr. Frumkin the previous summer. The article focused on the thousands of "missing" blood lead level test results for D.C. children not reported to CDC in 2003. It raised questions regarding why the CDC's 2004 *MMWR* drew such a different conclusion about the public health impact of elevated lead levels in water in D.C. than Marc Edwards' January 2009 paper or the 2007 presentation by the CDC's own Jaime Raymond at the American Public Health Association. "This is a disaster of accountability from the CDC's point of view," John Rosen, a pediatrician and national expert on lead poisoning at Montefiore Medical Center in New York City told Renner. "This raises troubling questions about CDC's complicity in passing on dubious data," Rosen said.[231]

Rather than spending their time, effort and energy trying to finally investigate the cause of the 2003 blood lead level "data gap," the CDC issued a lengthy media statement responding to the Salon.com article defending the scientific merits of the *MMWR* article. "Now, as in 2004, CDC continues to stand by its *MMWR* statement, that, "Because no threshold for adverse health effects in young children has been documented, public health interventions should focus on eliminating all lead exposures in children," the CDC said. Regarding the "missing data," the CDC stuck to the same factually inaccurate claim they had been espousing for half-a-decade regarding the 2003 gap

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[229] "Important update: lead-based water lines," Howard Frumkin, M.D., Dr.P.H., Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, posted on-line January 2010, available here: http://www.cdc.gov/nceh/lead/waterlines.htm.

[230] Statement by George S. Hawkins, Esq., Director, District Department of Environment, Washington, D.C, Joint Public Hearing on Water Quality in the District of Columbia, Committee on Government Operations and the Environment and Committee on Public Works and Transportation, February 10, 2009, available here: http://www.ddoe.dc.gov/ddoe/cwp/view,a,1209,q,499285.asp

[231] Rebecca Renner, "Health agency covered up lead harm: The Centers for Disease Control and Prevention withheld evidence that contaminated tap water caused lead poisoning in kids," Salon.com, April 10, 2009, available here: http://www.salon.com/env/feature/2009/04/10/cdc_lead_report/

in blood lead level reporting data from the District's Childhood Lead Poisoning Prevention Program.

> In 2004, a participating commercial laboratory stopped reporting test results that fell below the CDC level of concern of 10 ug/dL. CDC believes this failure of reporting accounts for the missing data because the laboratory continued to report BLLs greater than 10 ug/dL. To the extent "missing" data would have affected overall results, it would have exaggerated the apparent problem, not masked it.[232]

The CDC statement also misconstrued its own "investigation" into Dr. Edwards' scientific misconduct complaint and said the CDC "thoroughly investigated this complaint and found no evidence of scientific misconduct." In fact, CDC had never actually "investigated" Dr. Edwards' allegations. Instead they decided the allegations were not aimed at CDC officials and pointed Dr. Edwards towards the D.C. government.

9. Conclusion

The leaders of CDC's lead program never questioned their fundamental assumptions about the D.C. lead-in-water issue. Rather than attempting to unearth the root scientific explanations for the surprising findings of the 2004 *MMWR* article, or conceding that they may have overlooked, underemphasized or dismissed critical problems in the D.C. lead program their agency continued to fund, the CDC simply refused to acknowledge anything in either the D.C. lead program or their own analysis of the D.C. lead-in-water crisis could potentially be amiss.

The flawed foundation upon which the CDC's *MMWR* article has stood for more than six years has undermined public health efforts to fully and completely investigate lead-in-water issues as a potential public health hazard around the nation. The leadership of CDC's Childhood Lead Poisoning Prevention Program made scientifically unsound assumptions about the data they were analyzing, ignored critically important issues and simply discounted others.

None of the long standing and substantial problems in the D.C. lead program should exonerate the CDC or CDC officials involved in the publication of the *MMWR* lead-in-water article. In fact, given the extent of the problems in the D.C. lead program it is simply astounding that these issues did not receive adequate attention from CDC lead program officials who had been providing the D.C. CLPPP office with millions of dollars in lead grants. The CDC appears to have been blinded to the problems that were brewing in the D.C. lead program. They also failed to take adequate action to either investigate or rectify any of the problems they did become aware of in the D.C. CLPPP. Their lack of action and dismissal of known problems dramatically undercut the scientific integrity of the *MMWR* article on potential human health effects of lead-in-water in Washington, D.C.

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[232] "CDC Responds to Salon.com Article," Media Statement, Office of Enterprise Communication, Centers for Disease Control and Prevention, April 10, 2009, available here: http://www.cdc.gov/media/pressrel/2009/s090410.htm.

The Subcommittee's investigation into the D.C. lead-in-water issues makes it clear that both the 300 ppb cross sectional study and the D.C. lead program's 2002-2003 blood lead test data provided to CDC and used as a foundation for the *MMWR* article were incomplete and untrustworthy. As a result, the full extent and impact this public health crisis had on the city's residents has remained unclear. What is clear is that the public health information the CDC provided in the *MMWR* article, while reassuring, was based upon fundamentally flawed and incomplete data. Rather than immediately and aggressively attempting to address the known questions surrounding the 2003 blood lead level "data gap" and the allegations of forgery, CDC officials cloaked the *MMWR*'s fundamental data integrity failings and the obvious management short-comings in the D.C. Childhood Lead Poisoning Prevention Program from a rigorous, immediate and comprehensive examination.

The nation and the world have relied upon the Centers for Disease Control and Prevention to provide unvarnished scientific facts and forthright analysis regarding critical public health related issues for decades. The imprimatur of the CDC on the *MMWR*'s D.C. lead-in-water article had an impact on local and state public health officials who were investigating lead-in-water health issues of their own. They viewed it as scientifically sound and the public health conclusions it offered as being reliable and responsible. But the main public health messages conveyed to the public in the *MMWR* article resulted in underestimating the potential public health dangers of lead exposures in drinking water. The faulty assumptions and flawed data used in that article have had a long-lasting and wide-spread impact on objectively, thoroughly and properly confronting the lead-in-water issue in D.C. and in other cities around the country.

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