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THE ENVIRONMENTAL PROTECTION AGENCY FISCAL YEAR 2008 RESEARCH AND DEVELOPMENT BUDGET PROPOSAL

HEARING

BEFORE THE

SUBCOMMITTEE ON ENERGY AND ENVIRONMENT

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

MARCH 14, 2007

Serial No. 110–11

Printed for the use of the Committee on Science and Technology

Available via the World Wide Web: http://www.science.house.gov

U.S. GOVERNMENT PRINTING OFFICE

33–802PS WASHINGTON : 2008

For sale by the Superintendent of Documents, U.S. Government Printing Office
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CONTENTS

March 14, 2007

	Page
Witness List	2
Hearing Charter	3

Opening Statements

Statement by Representative Nick Lampson, Chairman, Subcommittee on Energy and Environment, Committee on Science and Technology, U.S. House of Representatives	9
Written Statement	9
Statement by Representative Bob Inglis, Ranking Minority Member, Subcommittee on Energy and Environment, Committee on Science and Technology, U.S. House of Representatives	10
Prepared Statement by Representative Jerry F. Costello, Member, Subcommittee on Energy and Environment, Committee on Science and Technology, U.S. House of Representatives	10

Witnesses:

Dr. George M. Gray, Assistant Administrator for Research and Development, Environmental Protection Agency	
Oral Statement	11
Written Statement	13
Biography	16
Dr. M. Granger Morgan, Chair, Environmental Protection Agency Science Advisory Board	
Oral Statement	16
Written Statement	18
Biography	25
Dr. Jennifer Sass, Senior Scientist, Health and Environment Program, Natural Resource Defense Council	
Oral Statement	25
Written Statement	27
Biography	36
Dr. Bruce C. Coull, Carolina Distinguished Professor Emericut and Dean Emeritus, School of Environment, University of South Carolina; President, U.S. Council of Environmental Deans and Directors, National Council for Science and the Environment	
Oral Statement	36
Written Statement	39
Biography	51
Discussion	
The Superfund Innovative Technology Evaluation (SITE) Program	51
Laboratory Infrastructure	52
Employee Morale	67
Endocrine Disrupter Research	68
External and Internal Research	69
Data Sources and Concerns	70
Program Assessments	70
Integrated Risk Information Systems (IRIS)	73
Funding Reductions for Great Lakes Research	74
Nanotechnology Research	75

Page

Near Road Pollutants 78
EPA Budget Request 79

Appendix 1: Answers to Post-Hearing Questions

Dr. George M. Gray, Assistant Administrator for Research and Development, Environmental Protection Agency 82
Dr. M. Granger Morgan, Chair, Environmental Protection Agency Science Advisory Board 107
Dr. Jennifer Sass, Senior Scientist, Health and Environment Program, Natural Resource Defense Council 110

Appendix 2: Additional Material for the Record

Statement of the American Chemical Society 116

THE ENVIRONMENTAL PROTECTION AGENCY FISCAL YEAR 2008 RESEARCH AND DEVELOPMENT BUDGET PROPOSAL

WEDNESDAY, MARCH 14, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY AND ENVIRONMENT,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 2:00 p.m., in Room 2318 of the Rayburn House Office Building, Hon. Nick Lampson [Chairman of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

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Subcommittee on Energy and Environment

Hearing on

"The Environmental Protection Agency Fiscal Year 2008 Research and Development Budget Proposal"

2318 Rayburn House Office Building
Washington, D.C.

Wednesday, March 14, 2007
2:00 PM – 4:00 PM

WITNESS LIST

Dr. George Gray
Assistant Administrator for Research and Development,
Environmental Protection Agency

Dr. M. Granger Morgan
Chair,
Environmental Protection Agency Science Advisory Board

Dr. Jennifer Sass
Senior Scientist, Health and Environment Program,
Natural Resource Defense Council

Dr. Bruce C. Coull
Carolina Distinguished Professor Emeritus and Dean Emeritus,
School of Environment, University of South Carolina

HEARING CHARTER

SUBCOMMITTEE ON ENERGY AND ENVIRONMENT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

The Environmental Protection Agency Fiscal Year 2008 Research and Development Budget Proposal

WEDNESDAY, MARCH 14, 2007
2:00 P.M.—4:00 P.M.
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Purpose

On Wednesday, March 14, 2006 at 2:00 p.m. the House Committee on Science and Technology's Subcommittee on Energy and Environment will hold a hearing to examine the Environmental Protection Agency's (EPA) fiscal year 2008 (FY08) budget request for Science and Technology (S&T).

Witnesses

Dr. George Gray, Assistant Administrator for the Office of Research and Development and Science Advisor, U.S. Environmental Protection Agency.

Dr. M. Granger Morgan, Chair, EPA's Science Advisory Board (SAB); Lord Chair Professor in Engineering and Professor and Department Head, Department of Engineering and Public Policy, Carnegie Mellon University.

Dr. Jennifer Sass, Senior Scientist, Health and Environment, Natural Resources Defense Council.

Dr. Bruce Coull, Dean Emeritus, School of the Environment, University of South Carolina and the National Council for Science and the Environment.

Background

Overall FY 2008 for EPA

Environmental Protection Agency's (EPA) overall FY08 budget request is $7.2 billion, a reduction of 5.5 percent compared to the FY06 enacted level of funding for the Agency. EPA is one of two agencies that are cut in the President's FY08 request for federal spending.

The table below shows the eight primary accounts of the Agency's budget. The Environmental Program and Management (EPM) account funds the Agency's air, water, waste, toxics and pesticides programs. The Superfund account supports clean up of hazardous waste sites. The Superfund account also includes funds for Superfund enforcement, Science and Technology (S&T) to develop and test new methods for clean up and set clean-up standards, and funds for the Inspector General's office to address Superfund issues. The State and Tribal Assistance Grants (STAG) account provides grants to states and local communities to support water and sewage treatment infrastructure construction and improvements. The largest reduction is in the STAG account.

Figure 1: EPA FY 2008 Budget Request (Budget Authority in Millions of dollars)

EPA Account	FY 2006 Appropriation[1]	President's FY 08 Request	FY08 Request vs. FY06 Appropriation	% Change
Science & Technology[2]	**731**	**755 (690)[2]**	**+24 (-41)[2]**	**+3.3 % (-5.6)[2]**
Environmental Programs & Management[2]	2347	2298 (2363)[2]	-49 (+16)[2]	- 2.1% (+0.7 %)[2]
Inspector General	37	38	+ 1	+ 2.7 %
Buildings & Facilities	40	35	- 5	-12.5 %
Oil Spill Response	16	17	+ 1	+ 6.25 %
Program Funds	1199	1211	+	+ %
S & T	**30**	26	-	**- %**
Insp. General	13	7	- 6	-46%
Total SUPERFUND[3]	1242	1245	+ 3	+ 0.24 %
LUST	72	72	0	-
State & Tribal Asst. Grants	3214	2744	- 470	- 14.6%
Rescission	80	5	-	-
TOTAL EPA	**7,617 M**	**7,199 M**	**- 418 M**	**- 5.5 %**

[1] The total enacted appropriations for FY06 and the individual account lines include a 0.476 percent rescission and an additional 1 percent rescission. The $80 million rescission included in the Table reduced the funding to the Total shown.

[2] The values in the parentheses reflect the actual requested changes in program dollars. Funds to cover facilities infrastructure and operations for all Agency facilities prior to FY07 request were all included in the Environmental Programs and Management (EPM) account. Beginning with the FY07 request, the Administration's budget began to break out the funds requested for S&T facilities for infrastructure and operations from the EPM account and to include them in the S&T account. This had the effect of increasing the S&T account and lowering the EPM account by the amount needed to cover the costs of maintaining S&T facilities. The total for S&T shown in the Agency's budget request contains $65 million to cover the cost of S&T facilities. There is no impact on the total budget request for the Agency. (S&T-49 of the Congressional Justification)

FY 2008 Science & Technology Account

The presentation of the Administration's budget request in the Agency's Congressional Justification for S&T is $781 million. This includes the S&T account funding the Office of Research and Development (ORD) and S&T activities conducted by the program offices (e.g., Office of Air, Office of Water), $755 million, as well as funds requested for S&T activities associated with the Superfund program, $26 million. In the past, the Superfund S&T funds were drawn primarily from the Superfund trust that was funded by the dedicated Superfund tax. Since the expiration of the tax, this fund no longer exists and all funds must be appropriated from the general treasury.

Nearly $540 million (69 percent) of S&T funding is for EPA's Office of Research and Development (ORD), which is the primary research arm of the Agency. Typically, most of the remaining S&T funds go to the Office of Air and Radiation, and a smaller amount to the Office of Water and to the other program offices.

However, the S&T number presented in the FY08 request is not directly comparable to the FY06 enacted level of funding for S&T because it includes an accounting change the Administration initiated with the presentation of the FY07 budget request. The actual budget request for S&T programs is $690 million, a reduction of 5.6 percent below FY06 funding.

In the FY07 budget request, the Administration instituted an accounting change that transferred the cost of operations and maintenance of all S&T facilities from the Environmental Program and Management account to the S&T account. Prior to FY07, the funding for S&T facilities was included with all other facilities in the EPM account. When this transfer is accounted for, the actual FY08 S&T request is reduced by $65 million to $716 million, a $41 million reduction below FY06 enacted funding levels.

Office of Research and Development

ORD conducts and sponsors both fundamental research in environmental science and more targeted research that inform EPA's regulatory programs. For example, ORD develops the scientific risk information for the Agency's Integrated Risk Information System (IRIS), a database about human health effects from chemicals in the environment. This program is used by EPA, States, and other government agencies to determine hazardous waste site clean up levels, drinking water, and other health-based standards. In air quality, ORD develops the scientific underpinning for EPA's air quality standards in areas such as particulate matter and ozone. ORD also investigates emerging environmental questions such as the environmental implications and applications of nanotechnology.

To carry out these responsibilities, ORD conducts intramural research at EPA's laboratories, awards contracts, and supports fellowships and research at colleges and universities through the Science to Achieve Results (STAR) grant program. The table below provides the breakout of ORD funds among the various research programs at ORD.

Figure 2: EPA ORD Budget Changes
2006 Enacted versus Presidents FY 2008 Request (in millions)[1]

Program	FY 2006 Enacted	FY 2008 Request	Change in Millions	% Change
Air Toxics	$ 16.2	$ 0	- $ 16.2	- 100 %
NAAQS	$ 66.8	$ 0	- $ 66.8	- 100 %
Clean Air (shifting funds from Air Toxics and NAAQS with $1.9 M decrease)	$ 0.0	$ 81.1	+ $ 81.1	+ 100 %
Drinking Water	$ 45.2	$ 48.5	+ $ 3.3	+ 7 %
Water Quality	$ 51.3	$ 56.5	+ $ 5.2	+ 10 %
Land	$ 36.0	$ 32.4	- $ 3.6	- 10 %
SITE	$ 1.2	$ 0.0	- $ 1.2	- 100 %
Homeland Security	$ 31.7	$ 35.7	+ $ 4.0	+ 13 %
Human Health Risk Assessment	$ 39.4	$ 42.8	+ $ 3.4	+ 9 %
Computational Toxicology	$ 12.3	$ 15.1	+ $ 2.8	+ 23 %
Endocrine Disruptors	$ 10.5	$ 10.1	- $ 0.4	- 4 %
Global Change	$ 18.6	$ 16.9	- $ 1.7	- 9 %
Human Health and Ecosystems	$ 167.7	$ 145.0	- $ 22.7	- 14 %
Pesticides and Toxics	$ 30.4	$ 24.8	- $ 5.6	- 18 %
Fellowships	$ 11.7	$ 8.4	- $ 3.3	- 28 %
Environmental Technology Verification	$ 3.0	$ 0.0	- $ 3.0	- 100 %
Economic and Decision Sciences	$ 2.4	$ 0.0	- $ 2.4	- 100 %
Sustainability	$ 26.1	$ 22.5	- $ 3.6	- 14 %
Congressional Earmarks	$ 24.4	$ 0.0	- $ 24.4	- 100 %
Total	**$ 594.7 M**	**$ 539.8 M**	**- $ 55.1 M**	**- 9 %**

[1] Information for Figure 2 provided by EPA's Office of Research and Development briefing on March 1, 2007 to Subcommittee on Energy and Environment.

Budget Highlights

- If enacted, the FY08 request ($539.8 M) for ORD would be its lowest funding level since FY00 and $106.7 million less than its peak funding level of $646.5 million in FY04.
- The FY08 S&T request includes $10.2 million for research on the environmental implications of nanotechnology in the Human Health & Ecosystems program, a 91 percent increase over the FY06 enacted level.
- The FY07 S&T request includes $68.2 million for Ecosystem Research, $6 million (or eight percent) below the FY06 enacted level, and $28 million (26 percent) below the FY04 enacted level. Almost all of the FY07 reduction ($5 mil-

lion) would be taken from the Environmental Monitoring Assessment Program, (EMAP), which supports states' measurements of water quality conditions and ecosystem health.

- The FY08 budget proposes the elimination of the Superfund Innovative Technology Evaluation (SITE) Program ($1.2 million) and the elimination of funding for the Environmental Technology Verification (ETV) program ($3.0 million). Both programs support the development and testing of innovative environmental technologies for cleanup of hazardous substances. The SITE program was created in the Superfund statute.
- The FY08 President's Budget merges the Air Toxics and NAAQS programs into a Clean Air program which will focus on multi-pollutant sources and effects rather than sources and effects of individual pollutants.
- The FY08 budget reduces funding for the STAR grant program by nearly $10 million as compared to FY06 enacted funding to $61.9 million.

Key Issues

The overall spending by EPA's research programs has been declining for several years. The Administration argues that the Agency's research is adequately funded given overall constraints on the federal budget and that EPA S&T funds have been focused on emerging priorities, while programs that are not as pressing or effective have been scaled back. Critics of the budget, including EPA's Science Advisory Board, have argued that EPA's core research programs are being eroded in ways that will limit understanding of the environment and hamper the Agency's ability to formulate sound policies.

The information below describes programs that have received some of the most significant cuts or increases.

Land

The land research program is tasked with the objective of reducing potential risks to human health and the environment at contaminated waste sites by providing the science to accelerate clean-up decisions. Research activities focus on contaminated sediments, ground water contamination, site characterization, analytical methods, and site-specific technical support. The President's FY08 budget requests $32.4 million for the Office of Research and Development's land research program, a $3.6 million dollar decrease from FY06 enacted funding. This 10 percent reduction in funding could undermine future U.S. remediation efforts as the Agency will lack the necessary scientific research to cost-effectively clean contaminated waste sites.

Human Health

The human health research program leads the Agency's research efforts on cumulative risks to human beings. Research focuses on risk intervention and prevention strategies that aim to reduce human risk associated with exposures to single and multiple environmental stressors.

In its budget analysis, EPA expresses the importance of funding critical research to address the health risks of susceptible sub-populations, including: children, adolescents, and the elderly. However, the President's FY08 Budget request for $56.8 million reflects a $4.7 million dollar decrease from the FY06 enacted funding. This seven percent cut in funding from $61.5 million stands at odds with the important mission of protecting human health, especially vulnerable populations. Furthermore, the overall budget request of Human Health and Ecosystem receives a $22.7 million decrease compared with FY06 enacted funding, a 14 percent cut.

Ecological Research

Within the Environmental Protection Agency, ecological research aims to assess ecosystem conditions and trends, diagnose impairments, forecast ecosystem vulnerability, and restore degraded ecosystems. The proposed FY08 budget request of $68.2 million represents an $18.1 million (31 percent) decrease from the FY06 enacted level and a $40 million (37 percent) reduction since FY04. The FY08 cut would be taken primarily in the Environmental Monitoring Assessment Program (EMAP), which supports data collection in the lower Mississippi River and Gulf of Mexico wetlands.

In the EPA budget analysis, the Agency describes the necessity of providing critical research on the restoration of large flood plain rivers and to improve scientific understanding of causal links between stressors and changes in ecosystem processes. However, the repeated cuts in funding for ecological research have drastically reduced the Agency's ability to monitor or protect our nation's ecosystems.

Pesticides and Toxics

The pesticide and toxics research program examines risks resulting from exposure to pesticides and toxic chemicals. This research supports the Agency's efforts to reduce current and future risk to the environment and humans by controlling the production and release of potentially hazardous chemicals. The President's FY08 Budget requests $24.8 million, which is a decrease of $5.6 million from the $30.4 million FY06 enacted funding level. This 18 percent reduction will negatively impact important research used to develop a screening process for potential neuro- and immunotoxicity of chemicals.

Fellowships

The Environmental Protection Agency created the Science to Achieve Results (STAR) grant program in 1995 and the program was funded at just over $100 million per year between the late 1990s and 2002. The program was recommended by an outside advisory panel convened in 1992 and reaffirmed in National Academy of Sciences reports in 2000 and 2003. These reports stated that EPA should increase its funding of students and research in academia to draw on a wider range of research. The bulk of STAR funds have been allocated to competitive research grants in targeted mission-critical areas, with a smaller portion reserved for graduate fellowships and for exploratory research on the next generation of environmental challenges.

The STAR program provides both research grants and graduate student fellowships. Since its peak funding level of just over $102 million in FY02, the grants program has declined every year. The FY08 budget proposes reducing the fellowships to a level of $8.4 million or $3.3 million (28 percent) below the FY06 enacted level of $11.7 million. STAR grants would be reduced to $61.9 million.

Technology Programs

The Superfund Act (Section 311) established the SITE program and directed EPA "to carry out a program of research, evaluation, testing, development and demonstration. . .of innovative treatment technologies." (Sec 311 (b)(1)). After significantly downsizing the program in FY06, EPA proposes eliminating it in FY07 and has again proposed its elimination in FY08. By all accounts, including EPA's own, the SITE program has conducted high-quality field demonstrations of remediation technologies, and there are many SITE evaluated technologies now on the market that have saved money and led to more effective remediation efforts.

The budget also proposes to eliminate the Environmental Technology Verification program. ETV was created in the mid-1990s to help technology developers verify the performance of their products in areas other than remediation technologies. It was developed using SITE as a model. The FY08 request would eliminate the remaining $3 million in funding that the Agency has used to partner with technology vendors to test the performance of their products.

Sustainability Research

EPA's Science and Technology for Sustainability program is designed to advance sustainability goals, specifically in the areas of air, ecosystems, energy, land, materials, and water. The Office of Research and Development's Sustainability Research program (formerly called the Pollution Prevention Research program) would receive a $3.6 million or 14 percent decrease in FY08 ($22.5 million) from the FY06 enacted level of $26.1 million.

Chairman LAMPSON. I am now happy to call this meeting to order. I wish everyone a good afternoon and welcome everyone here to today's Subcommittee hearing on the Environmental Protection Agency's fiscal year 2008 Science and Technology budget request.

Environmental issues present increasing challenges for our country. We all want a robust economy and access to products and services that sustain and improve our quality of life. We also want a clean, healthy environment. It is through our investments in research and development that we have been able to strike a balance between environmental protection and economic growth.

A clean, healthy environment is not a luxury. It is a necessity. For example, when water pollution problems result in beach closures or closure of fisheries, water pollution becomes a threat to public health and to the economic health of communities dependent upon recreation and fisheries.

Unfortunately, the Administration has failed for the 4th consecutive year to offer a budget that will enable us to achieve further successes in environmental protection. Four years ago the EPA's research budget sustained a five percent cut. In fiscal year 2006, it was reduced again by two percent, and this year's proposal further reduces that budget yet again.

Sustainability cannot be achieved by EPA in our society if the Agency cannot find a way to sustain the programs that support environmental protection in this country. EPA cannot advance environmental research with a retreating budget. Targets for cuts include programs studying children's health, endocrine disrupters, toxic waste cleanup, pesticides, ecosystem research, technology verification programs, and global climate change. Cuts to the STAR Grant and Fellowship Program not only reduces funding for research, it reduces essential funds for training the environmental scientists of the future.

The bottom line is this budget is inadequate to support the kind of research and development enterprise we need to find creative solutions to environmental problems.

I believe several of our witnesses today will be in agreement with me. First, I want to welcome our entire distinguished panel to this afternoon's hearing. I look forward to your testimony and to your recommendations for improving EPA's scientific enterprise.

And at this time I will recognize the distinguished Ranking Member, Mr. Inglis of South Carolina, for his opening statement.

[The prepared statement of Chairman Lampson follows:]

PREPARED STATEMENT OF CHAIRMAN NICK LAMPSON

Good Afternoon. I want to welcome everyone here to today's Subcommittee hearing on the Environmental Protection Agency's FY 2008 Science and Technology (S&T) budget request.

Environmental issues present increasing challenges for our country. We all want a robust economy and access to products and services that sustain and improve our quality of life. We also want a clean, healthy environment. It is through our investments in research and development that we have been able to strike a balance between environmental protection and economic growth.

A clean, healthy environment is not a luxury. It is a necessity. For example, when water pollution problems result in beach closures or closure of fisheries, water pollution becomes a threat to public health and to the economic health of communities dependent upon recreation and fisheries. Unfortunately, the Administration has failed for the fourth consecutive year to offer a budget that will enable us to achieve further successes in environmental protection.

Four years ago, the EPA's research budget sustained a five percent cut. In FY06, it was reduced again by two percent, and this year's proposal further reduces the budget yet again.

Sustainability cannot be achieved by EPA in our society if the Agency cannot find a way to sustain the programs that support environmental protection in this country. EPA cannot advance environmental research with a retreating budget. Targets for cuts include programs studying our children's health, endocrine disruptors, toxic waste cleanup, pesticides, ecosystem research, technology verification programs, and global climate change. Cuts to the STAR grant and fellowship program not only reduces funding for research, it reduces essential funds for training the environmental scientists of the future.

The bottom line is, this budget is inadequate to support the kind of research and development enterprise we need to find creative solutions to environmental problems. I believe several of our witnesses today will be in agreement with me.

I want to welcome our entire distinguished panel to this morning's hearing. I look forward to your testimony and to your recommendations for improving EPA's scientific enterprise.

Mr. INGLIS. Thank you, Mr. Chairman, and good afternoon. Thank you for holding this hearing about the President's fiscal year 2008 request for the Environmental Protection Agency's Science and Technology Account. Most of the budget requests before the Congress relate to the regulatory functions of the EPA, and of course, that is to be expected. The EPA also has within its request the Office of Science and Technology and the Office of Research and Development. Research from those offices is used to improve the regulatory framework of the EPA. I trust that the objective of that research is to use science to continually improve the regulatory framework.

As we discuss the proposed fiscal year budget request for EPA Science and Technology funding, I hope that the panel will help establish the priorities of the use of EPA's science resources. By investing in EPA scientific research and development today we can get better regulations for tomorrow.

I look forward to hearing from our witnesses today, and I am especially pleased to welcome Dr. Bruce Coull of the University of South Carolina here. So thank you, Mr. Chairman, for the hearing.

Chairman LAMPSON. You are welcome. Thank you, Mr. Inglis. And I ask unanimous consent that all additional opening statements submitted by Subcommittee Members be included in the record. Without objection, so ordered.

[The prepared statement of Mr. Costello follows:]

PREPARED STATEMENT OF REPRESENTATIVE JERRY F. COSTELLO

Good afternoon. I want to thank the witnesses for appearing before this subcommittee to examine the Environmental Protection Agency's (EPA) fiscal year 2008 (FY08) budget request for Science and Technology (S&T).

First, I am concerned about the Administration's FY08 budget proposal cuts to EPA programs because it represents the lowest funding request in this century. Consequently, this reduction will have a devastating impact on partnerships with academia and State and local governments to protect and safeguard human health and the environment, as well as curtailing on-going efforts to advance research in human health, ecosystems, the environment, and energy sustainability.

Further, I am concerned that the budget cuts to EPA's programs collection and data assessment programs will leave the Federal Government with inadequate information upon which to base policies and regulations. In particular, there are gaps in policy-relevant research needs that will not be filled by other agencies, industry, or academia. I am hopeful our subcommittee can work in a bipartisan fashion to ensure adequate funding is provided for the EPA to ensure its programs are not eroded in ways that could limit our understanding of the environment and hamper the Agency's ability to formulate sound policies.

Finally, I am opposed to the continuing trend within EPA of not providing full public access and proper oversight on the Agency's regulatory decision-making process. I believe the Science and Technology Committee must continue to monitor EPA's progress to ensure our nation's highest environmental research priorities are not undermined.

I welcome our panel of witnesses and look forward to their testimony.

Chairman LAMPSON. And it is my pleasure to introduce the excellent panel of witnesses that we have with us this afternoon. Dr. George Gray is the Assistant Administrator for the Office of Research and Development and Science Advisor with the U.S. Environmental Protection Agency. Dr. M. Granger Morgan is the Chair of EPA's Science Advisory Board. In addition, Dr. Morgan is a Lord Chaired Professor in Engineering and Department head with the Department of Engineering and Public Policy at Carnegie Mellon University. Dr. Jennifer Sass is a Senior Scientist with the Health and Environment Division of the Natural Resources Defense Council in DC.

And at this time I will recognize Representative Inglis for an introduction of Dr. Coull.

Mr. INGLIS. And we are particularly pleased, I mention, to welcome Dr. Bruce Coull, the Dean Emeritus of the University of South Carolina School of the Environment and a member of the National Council on Science and the Environment. We are particularly pleased to have you here today, sir.

Chairman LAMPSON. Thank you, Mr. Inglis, and welcome to all of you. You will each have five minutes for your spoken testimony. Your written testimony will be included in the record for the hearing. When all four of you have completed your testimony, we will begin with questions, and each Member will have five minutes to question the panel.

Dr. Gray, please begin.

STATEMENT OF DR. GEORGE M. GRAY, ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT, ENVIRONMENTAL PROTECTION AGENCY

Dr. GRAY. Thank you, Mr. Chairman, Members of the Committee. I am pleased to be here today to discuss the fiscal year 2008 budget request from the Environmental Protection Agency.

In keeping with the President's charge to EPA to accelerate the pace of environmental protection while maintaining our nation's economic competitiveness, the 2008, budget request includes $7.2 billion to support the work of EPA and our partners.

Included in that request is $754.5 million for science and technology. That request reflects the President's strong commitment to ensure that environmental regulations to protect human health and the environment are based on the best available science.

The request demonstrates the President's continued commitment to provide the resources needed to address our nation's highest environmental research priorities, enabling us to protect our environment while sustaining our environmental growth.

The request includes $539.8 million for the Office of Research and Development to continue the work of providing the sound science that informs the Agency's decision. Ninety-five percent of those resources are in the S&T budget.

We are always looking forward in ORD for ways to become more efficient and effective at both producing and assessing the best available scientific information to inform environmental decision-making, and that is reflected in our proposed budget. For example, in fiscal year 2008, at the advice of the Science Advisory Board, our Board of Scientific Counselors, the National Academy of Sciences and others, we are combining our $12.3 million Air Toxics Program with our $66.5 million National Ambient Air Quality Standards Research Program into an integrated Air Research Program. With increased resources and that reflects a shift to a more holistic view, more holistic approach of the science that poses, that addresses the challenges of air pollution.

We are also requesting increased funding for high priority work, including clean air, human health risk assessment, and research to study the fate, transport, and other issues that might be associated with nanomaterials.

Now, at EPA we are good stewards of our environment, but we are also good stewards of our nation's tax dollars. Importantly, this budget request will enable ORD to continue to fund critical research on the restoration of large flood plain rivers, develop decision support tools that enable managers to balance ecosystem requirements with human needs, and emphasize the development of methods to characterize the services that are provided by ecosystems.

The point is that this budget will enable ORD to continue to fund research and meet our critical performance commitments.

In addition to those areas of increased emphasis, I would like to highlight some work that EPA and ORD have done over the last year, contributions we have made and continue to make in the number of other key areas, including clean air, risk assessment, nanotechnology, homeland security, and global change.

The President's fiscal year 2008 budget includes a major commitment to strengthening the science that supports the Agency's efforts to ensure clean air for all Americans. The President is requesting $81.1 million for air quality research, which is a $3.4 million increase over the fiscal year 2007, request.

A major focus of this increase will be improving our understanding of air pollution near roads. This is an area of special concern for children especially because of the location of many schools and playgrounds for example. Using both ORD's in-house expertise and the unique capabilities of America's universities and research institutions, we plan to improve measurement and characterization of emissions near roads, study the extent of human exposure and health effects from these emissions, and examine the effectiveness of potential controls such as barriers or changes in building or roadway design.

Our fiscal year 2008 request also includes $42.8 million for human health risk assessment, an increase of $4.5 million over the 2007 request. This increase will primarily support two areas; an enhanced process for science reviews to support National Ambient Air Quality Standards, and enhanced characterization of risk in our IRIS system and other risk assessments.

Nanotechnology is another important area. It has the potential to improve the environment through direct applications to detect

and remove pollutants, to reduce pollution from manufacturing processes and products, or to serve as sensors of pollution in the land, air, or water. However, some of the novel beneficial properties, such as greater reactivity that make nanomaterials especially useful, also raise questions about potential risks of nanomaterials for both humans and the environment.

This year ORD began an in-house research program focusing on the human health and environmental implications of engineered nanomaterials to complement our existing Extramural Grants Program. In fiscal year 2008, we plan a modest expansion of our efforts by $1.6 million to study the fate and transport of engineered nanomaterials in the environment.

The Office of Research and Development also has responsibilities in the area of homeland security. Our Homeland Security Research Program continues to develop, enhance, and disseminate information on the decontamination of buildings, the protection of water systems, and rapid risk assessment. For example, this past year ORD revised its Standard Analytical Methods Manual that helps ensure consistency in sample analysis during emergencies.

Finally, with global change, I am sure many of you closely watched the release from the Intergovernmental Panel on Climate Change, their fourth assessment for policy-makers. Global change is an issue that EPA is very active in, and the President's fiscal year 2008 budget includes $16.9 million for global change research in ORD. EPA is a member of the U.S. Climate Change Science Program, and ORD's highest priorities for fiscal year 2008, will be working with our partners to support completion of the two CCSP assessments for which EPA is responsible; a preliminary review of adaptation options for climate-sensitive ecosystems and resources, and an analysis of the effects of global change on human health, welfare, and human systems.

So by uniquely combining human health and ecological research in one federal agency, employing world-class scientists, ORD continues to develop a better understanding of environmental risks to both human health and ecosystems. The results of this research consistently and effectively inform EPA's environment decision-making, as well as that of others, leading to environmental policies that are based on sound science at the federal, State, tribal, and local levels.

Well, thanks for the opportunity to tell you about some of the exciting work that we conduct in ORD, and I would be happy to answer any questions that you have.

[The prepared statement of Dr. Gray follows:]

PREPARED STATEMENT OF GEORGE M. GRAY

Mr. Chairman and Members of the Committee, I am pleased to be here today to discuss the Fiscal Year (FY) 2008 budget request for the Environmental Protection Agency (EPA). In keeping with the President's charge to EPA to accelerate the pace of environmental protection while maintaining our nation's economic competitiveness, the 2008 budget request includes $7.2 billion to support the work of EPA and our partners.

Included in this request is $754.5 million for science and technology (S&T), a significant increase over the 2007 Enacted. The request reflects the President's strong commitment to ensure that environmental regulations to protect human health and the natural environment are based on the best science available. The request demonstrates the President's continued commitment to provide the resources needed to

address our nation's highest environmental research priorities, enabling us to protect our environment while sustaining our economic growth.

This request includes $539.8 million for the Office of Research and Development (ORD) to continue the work of providing the sound science that informs the Agency's decisions. Ninety-five percent of these resources are requested in the S&T account.

We are always looking for ways to become more efficient and effective at both producing and assessing the best available science to inform environmental decision-making and this is reflected in our proposed budget. For example, in FY 2008 we are combining our $12.3 million Air Toxics and $65.5 million NAAQS research into an integrated air research program, with increased resources, that reflects a shift to a more holistic approach for addressing the science challenges air pollution poses. We are requesting increased funding for high priority work including clean air, human health risk assessment and research to study fate, transport and other issues associated with nanomaterials.

At EPA, we are good stewards of our environment AND good stewards of our nation's tax dollars. Importantly, the budget request will enable ORD to continue to fund critical research on the restoration of large flood plain rivers, develop decision-support tools that enable managers to balance ecosystem requirements with human needs, and emphasize the development of methods to optimize the services provided by ecosystems. The budget will also enable ORD to continue to fund research and meet our critical performance commitments. The human health research funding will allow us to conduct research regarding the health risks of susceptible populations. Additionally, the President's budget request will provide funding for two additional Children's Environmental Health Centers, increasing the number from seven to nine.

In addition to these areas of increased emphasis, I would now like to highlight progress ORD has made, and continues to make, in a number of other key areas, including homeland security, global change, and computational toxicology.

FY 2008 President's Budget
Integrating and Enhancing Air Research

The President's FY 2008 budget includes a major commitment to strengthening the science that supports the Agency's efforts to ensure clean air for all Americans. The President is requesting $81.1 million for air quality research, which is a $3.4 million increase over the FY 2007 request. A major focus of this increase will be improving our understanding of air pollution near roads. This is an area of special concern for children, due to the location of many schools and playgrounds. Using both ORD's in-house expertise and the unique capabilities of America's universities and research institutions, we plan to improve measurement and characterization of emissions near roads, study the extent of human exposure to and health effects from these emissions, and examine the effectiveness of potential controls such as barriers or changes in building and roadway design.

This "source-to-health-outcome" approach—from vehicle emissions in the near-road micro-environment, to health effects, and ultimately to control strategies—is emblematic of a larger shift in ORD's air quality research. In FY 2008, in response to recommendations from external scientific reviews, the President's request reflects an integration of the National Ambient Air Quality Standards (NAAQS) and air toxics research programs into a single "one atmosphere" research program. This integration will facilitate a multi-pollutant approach that better tracks emissions from sources to outcomes.

Enhancing Health Risk Assessments

Our FY 2008 request also includes $42.8 million for human health risk assessment, an increase of $4.5 million over the FY 2007 request. This increase will primarily support two areas: an enhanced process for science reviews to support National Ambient Air Quality Standards, and enhanced characterization of risk in our IRIS system and other risk assessments.

As part of the new NAAQS process developed by the Agency, we are committed to meeting the Clean Air Act mandate that EPA assess the science of six "criteria" air pollutants every five years (we have never met this goal) and this funding increase will help us develop the Scientific Assessments (formerly known as Criteria Documents) to support this process.

One of my goals is to both to enhance the transparency of EPA's process for developing health values for the Integrated Risk Information System (IRIS) chemical profiles and the scientific characterization they contain. IRIS is a database containing information on human health effects that may result from exposure to various chemicals in the environment. It has grown into a premier national and international source for chemical hazard and effects. These increased resources will

make IRIS stronger through an enhanced development process and by supporting the development of quantitative risk assessment methods to allow improved analysis and characterization of uncertainty.

Expanding Nanotechnology Research

Nanotechnology has the potential to improve the environment through direct applications to detect and remove pollutants, to reduce pollution from manufacturing processes and products or to serve as sensors of pollution in land, water or air. However, the novel beneficial properties, such as greater reactivity, also raise questions about the potential risks of nanomaterials for both humans and the environment. EPA, under its various authorizing statutes, has a responsibility to ensure that any potential environmental risks are adequately understood and managed.

This year ORD began an in-house research program focusing on the human health and environmental implications of engineered nanomaterials to complement our existing extramural grants program. In FY 2008, we plan a modest expansion of our effort by $1.6 million to study the fate and transport of engineered nanomaterials in soils and aquatic ecosystems.

Homeland Security

ORD's homeland security research program continues to develop, enhance and disseminate information on the decontamination of buildings, the protection of water systems, and rapid risk assessment. For example, this past year ORD revised its Standard Analytical Methods Manual (SAM) that helps ensure consistency in sample analysis during emergencies. The SAM was used recently during a water security threat in Blackstone, Massachusetts, and has since been incorporated into the emergency response plans for each of the 10 EPA regions. We also developed more than 80 oral and inhalation draft Provisionary Advisory Levels for different levels of exposure to agents of potential homeland security concern. To aid responders in detection and sampling, ORD, in conjunction with the Department of Defense, built a prototype of a portable, real-time anthrax and ricin detector, which is currently undergoing testing and modification for ruggedness.

Global Change

I am sure many of you closely watched the release from the Intergovernmental Panel on Climate Change's fourth assessment. Global change is an issue that EPA is very active in, and the President's FY 2008 budget includes $16.9 million for global change research in ORD. We are focusing our efforts on assessing how climate change will affect air and water quality, human health, and the condition of ecosystems and on providing natural resource managers with the information needed to respond effectively to climate change. For example, climate change and variability are expected to produce more frequent and more intense rainstorms in certain areas, and the results of our research are providing local officials with the information they need to make informed decisions on water infrastructure investments.

EPA is a member of the U.S. Climate Change Science Program (CCSP), and ORD's highest priority in FY 2008 will be working with our partners to support completion of the two CCSP assessments for which EPA is responsible—"Preliminary review of adaptation options for climate-sensitive ecosystems and resources" and "Analyses of the effects of global change on human health and welfare and human systems." [1]

Computational Toxicology

ORD will continue its important work in computational toxicology, applying molecular biology, information management and mathematical and computer models to assess the risks chemicals may pose to human health and the environment. The resulting tools could build upon and replace traditional ways to screen and test chemicals, increasing the efficiency and effectiveness of risk assessment processes while reducing the use of animals. In FY 2008, ORD's computational toxicology research program will focus on information-mining technology, chemical prioritization and categorization tools, systems biology models, and cumulative risk assessment.

Water Infrastructure

Our nation's extensive water infrastructure has the capacity to treat, store, and transport trillions of gallons of water and waste water per day through millions of miles of pipelines. However, as our infrastructure deteriorates, there are increasing concerns about the ability of this infrastructure to keep up with our future needs.

[1] OAR is leading the CCSP assessment titled "Coastal elevation and sensitivity to sea level rise."

As part of our effort to address these concerns, in FY 2007 ORD initiated a new water infrastructure research program. This program will generate the science and engineering needed to evaluate promising, innovative technologies to repair existing and provide new water infrastructure that improve effectiveness at reduced cost.

Conclusion

By uniquely combining human health and ecological research in one federal agency employing world-class research scientists, ORD continues to develop a better understanding of environmental risks to both human health and ecosystems. The results of this research consistently and effectively inform EPA's environmental decision-making, as well as that of others, leading to environmental policies based on sound science at the federal, State, tribal and local levels.

As our nation shifts to a green culture, Americans are realizing that environmental responsibility is everyone's responsibility. Today, EPA has 300 million citizen-partners. President Bush's budget request will fund EPA's role as our country enters this next phase of environmental progress.

Thank you for this opportunity to tell you about the exciting work we conduct in ORD. I would be happy to answer any questions you have.

BIOGRAPHY FOR GEORGE M. GRAY

On November 1, 2005, Dr. Gray was sworn in to serve as the Assistant Administrator for the Office of Research and Development, which is the 1,900-person, $600 million science and technology arm of the Environmental Protection Agency. Dr. Gray was appointed to this position by President George W. Bush and confirmed by unanimous consent by the U.S. Senate.

Prior to joining EPA, George was Executive Director of the Harvard Center for Risk Analysis and a Lecturer in Risk Analysis at the Harvard School of Public Health. In 16 years at HSPH, his researched focused on scientific bases of human health risk assessment and its application to risk policy with a focus on risk/risk tradeoffs in risk management. George taught toxicology and risk assessment to both graduate students and participants in the School's Continuing Professional Education program.

George holds a B.S. degree in biology from the University of Michigan, and M.S. and Ph.D. degrees in toxicology from the University of Rochester. He and his wife, Ann, and their two children make their home in McLean, Virginia.

Chairman LAMPSON. Thank you, Dr. Gray, and Dr. Morgan, please proceed.

STATEMENT OF DR. M. GRANGER MORGAN, CHAIR, ENVIRONMENTAL PROTECTION AGENCY SCIENCE ADVISORY BOARD

Dr. MORGAN. Thanks very much. I appreciate the opportunity to appear here this afternoon.

The mission of EPA is to protect human health and the environment. While the challenge and the complexity of environmental problems continues to grow, between 2004 and the proposed 2008 budget, support for R&D at EPA has declined by 25 percent in inflation-adjusted terms. This year the Science Advisory Board adopted a strategic approach in its annual budget review. They asked EPA to give us a cross-cutting look at all the research they are doing to better address four big environmental challenges: climate change; sensitive human and ecological populations; environmental and ecological consequences of urban sprawl, and natural and terrorist-caused environmental disasters. Our written testimony details some of the specifics of what we learned, from which we drew the following, more general insights.

Because the EPA's research programs have long been overstretched, the planning process in many programs has fallen into a reactive mode, too often playing catch-up. Too many R&D funding decisions are incremental rather than strategic.

On the positive side the introduction of a new system of national program directors holds the promise to improve strategic design and balance within existing program areas. However, the Agency urgently needs to develop a higher-level research planning effort that: considers and adjusts the balance and focus among major program areas; breaking down the stovepipes within which they operate; better coordinates with the research programs of other federal agencies; benchmarks the quality and content of programs; and restores our National leadership in environmental science and engineering so as to assure that our international competitiveness is sustained and provide the knowledge and technology that Americans will need for a clean and healthy environment in the 21st century.

I turn now to a few comments on the proposed 2008 budget. The decline in funding for ecosystem research has continued, down roughly 40 percent in inflation-adjusted terms between 2004, and the proposed 2008 budget. The agency is abandoning past efforts to monitor key ecosystems. For example, terminating a long-term program to track the impacts and benefits of reduced acid rain.

The agency has expressed a commitment to estimate the economic value of ecosystem services. However, the proposed budget eliminates many of the financial and human resources needed to do that. Economics and decision science resources at the Agency have always been small. The proposed budget will reduce them by more than half, and an associated reorganization will essentially eliminate behavioral social science disciplines that are key to effective risk management and risk communication.

An equally-disturbing trend is the continuing decline in support for extramural research through the STAR Program, down 32 percent in inflation-adjusted terms between 2004 and the proposed 2008 budget.

There are a few bright spots. These include growth in support for the program in nanotechnology and the small new effort in sustainability research and the remarkable continued effort by staff to make the best of an ever-worsening financial environment. But that said, we are deeply concerned about staff morale as budgets shrink. There is also a growing risk that as ORD struggles to maintain staff size, an ever-higher proportion of funds will have to go to salaries with less to cover all the other costs of doing research.

As you on the House Committee on Science and Technology confer with your colleagues on the Appropriations Committee, we particularly urge four actions. One, reverse the downward trend in support for ecosystem research so that that program can continue its essential monitoring of the health of vital ecosystems, develop and implement new measures of the value of environmental services, and create the basic understanding that will be needed to respond to the challenges of climate and new technology, such as biomass fuel and nanotechnology.

Two, reverse the downward trend in support for the STAR extramural and Fellowship Programs so that the Agency can continue to benefit from fresh ideas from the outside and continue a robust program of educating the next generation of environmental scientists and engineers.

Three, reinstate the program in economics and decision sciences within ORD and add support for sustainability increase or for substantially increasing its capabilities in behavioral social science. Even the best science and engineering is useless if it is not combined with a sufficient understanding of human risk perception and behavior.

And finally, four, provide a significant increase in support for the programs in sustainability and global change, because these topics are both inherently important, and they provide effective vehicles for moving the Agency in the direction of the innovative, cross-cutting research needed to address the critical environmental problems of the 21st century.

Thanks very much.

[The prepared statement of Dr. Morgan follows:]

PREPARED STATEMENT OF M. GRANGER MORGAN

Good morning, Mr. Chairman and Members of the Subcommittee on Energy and Environment. My name is Granger Morgan. I chair EPA's Science Advisory Board (SAB or Board). I am a faculty member at Carnegie Mellon University where I am a University Professor, hold the Lord Chaired Professorship in Engineering, and am Head of the Department of Engineering and Public Policy, a department in the Engineering College.

Thank you for this opportunity to present the SAB's views about the Agency's 2008 Research and Development budget request.

The mission of the Environmental Protection Agency is to protect human health and the environment. To do that in an effective and efficient way requires a deep understanding of environmental science and technology. However, between 2004 and the proposed 2008 budget, the overall support for Research and Development at EPA has declined by 25 percent in inflation adjusted terms.[1]

For many years the EPA Science Advisory Board (SAB) has performed detailed reviews of the Agency's Research and Development (R&D) budget. However, we have seen little noticeable effect from our annual plea to redress what we have seen as the continuing erosion of the ability to grow the knowledge base at EPA. This year, therefore, the SAB decided to take a different approach. I have submitted our final report from this review to this subcommittee for today's hearing record.

While we again offer some commentary about some specifics of the Agency's research budget, we have focused much of our attention on a longer-term more strategic look, attempting to assess how well the EPA's current research program is likely to prepare the Agency to address four key environmental challenges over the coming decades.

While the Agency will face many challenges, the four we chose to focus on, and asked EPA to address, are:

a) *Climate change,* including both impacts (for example on: natural ecosystems; water, coastal regions through sea level rise; air quality) as well as key issues such as terrestrial and deep geological sequestration that may arise as a result of future efforts in abatement.

b) *Sensitive populations,* both human and ecological.

c) *Urban sprawl* and the associated consequences for land use, stresses on ecosystems, stresses on sensitive populations, water contamination, air quality, loss of open space, and related issues.

d) *Environmental disasters,* both those that may arise as a result of natural causes (such as hurricanes, ice storms, drought, earthquakes and volcanism) as well as terrorist induced events.

The full text of our request to Dr. George Gray, Assistant Administrator for Research and Development, is attached.

Agency staff made a serious attempt to respond to this request, revealing a mixed picture. While the Agency can identify a variety of lines of research relevant to each problem, it is very clear that there has been far too little cross-EPA or interagency research planning on these topics. Specifically:

[1] As reported by the AAAS R&D Budget and Policy Program at *http://www.aaas.org/spp/rd/cht9508b.pdf.*

a) Research related to climate change was identified to us as the most coherently planned. While there is clear coherence within the domains of climate change impacts on air and water, there are large and important issues not being addressed. For example, while the Department of Energy is performing research on deep geological sequestration of CO_2, the EPA is not looking carefully at whether this research will provide the necessary basis for future science-based regulation. Similarly, land use, soil and water issues that may arise in connection with biomass energy production are not being seriously studied, nor, to our knowledge, are these and several similar issues being addressed elsewhere across the federal system.

b) The Agency has ongoing, though shrinking, programs to study certain human populations that are sensitive to some important environmental stressors. However, studies of sensitive ecosystems are very limited, as are studies of human populations which are dependent upon those ecosystems.

c) While there is considerable research directed at cleaning up legacy problems in land contamination (some of which remain very important), there is not yet a coherent program to systematically understand and redress the environmental problems arising from such land-use issues as shifting population distributions, urban sprawl, and development pressures on already vulnerable low-lying coastal areas which will become even more stressed in the future as a result of sea level rise and other impacts of climate change.

d) While there is limited work drawing lessons from Hurricane Katrina, we found no systematic research program to anticipate and mitigate possible future environmental disasters. Indeed the proposed budget would totally eliminate Central Basin (Mississippi-Missouri River) monitoring, and cut EPA's already under-funded wetlands program. While the EPA has only partial regulatory and management responsibility for dealing with natural or terrorist-induced environmental disasters, this is no justification for devoting so little attention to this critical topic.

From this look at a sample of four important environmental problems, we draw the following general conclusions:

- The Agency's research programs have long faced greater demands than they have had money, time, or attention to address; the planning process has fallen into a reactive mode that is too often playing catch up.
- With a few important exceptions, the Agency's funding decisions in R&D appear to be incremental rather than strategic, leaving allocations within and across major program areas rather stable. In many cases there is an overemphasis on yesterday's problems and insufficient attention to new and emerging problems.
- On the positive side, the introduction of a new system of National Program Directors, with wide-ranging responsibility to set priorities within specific program areas (such as air, water, or human health), and across Centers and Laboratories, holds the promise of improved balance and a more strategic design of research plans within existing program areas.
- The Agency urgently needs to develop a higher level research planning effort that can:
    - consider and adjust the balance and focus among major program areas and increase coordination and collaborations across program areas (i.e., begin to break down the "stovepipes" within which many of these program have been operating);
    - be better coordinated with, and build upon, the research programs of other federal agencies;
    - benchmark EPA's research with other cutting edge programs in environmental research around the world; and
    - restore our national leadership in environmental science and engineering so as to assure our international competitiveness and provide the knowledge and technology that Americans will needs in the 21st Century.

However, effective high level research planning is unlikely to occur in the face of a continually eroding research budget, when so much attention must be directed at simply holding things together.

In addition to this general assessment, the SAB also reviewed the Agency's existing program structure, in each case asking:

1. Is the balance within the program appropriate? Are the most critical scientific questions receiving a high priority? Have adequate financial resources been allocated to address them? Are there important questions that have been left out?
2. Is the Agency, and particularly the Office of Research and Development (ORD), being sufficiently proactive in designing research programs that will adequately meet the Agency's likely future needs?

The Agency scientific and technical staff and managers are doing a remarkable job of sustaining high quality research in the face of a continuing erosion of financial support. However, in our examination of existing research program areas, we found three developments to be especially troubling.

The decline in funding for ecosystem research has continued (see Figure 1). One consequence of these cuts is that the Agency is largely abandoning past efforts to monitor the status of key ecosystems (e.g., terminating a long-term program tracking the impacts and benefits of reduced acid deposition on streams and lakes in the mid-Atlantic and North East). The Agency has expressed a commitment to estimate the economic value of "ecosystem services." However, as explained below, many of the financial and human resources needed to do this well, have been eliminated.

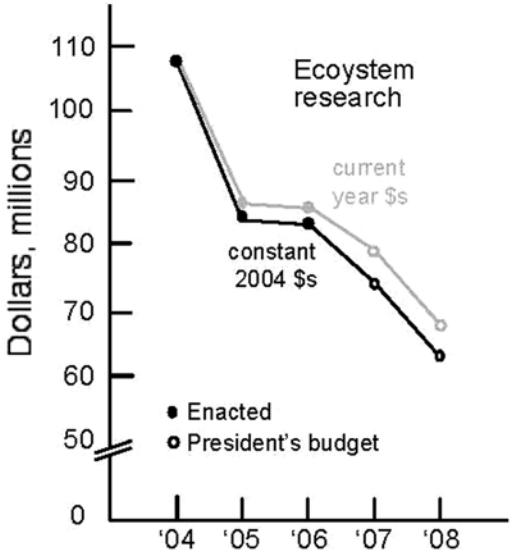

Figure 1: Recent history of EPA ecosystem research funding. Adjustment to constant dollars done with the NASA Gross Domestic Product Deflator/Inflation Calculator available at http://cost.jsc.nasa.gov/inflateGDP.html

In order to assess ecosystem services it is essential to collect the data needed to assess the health of ecosystems over time and to develop a basic scientific understanding of the complex interactions within ecosystems. For example, as climate changes, not all species will be able to respond in the same way so entire coherent ecosystems will not be able to gradually move north (or up mountains). Instead, separate species will, or will not, be able to move, new pests will emerge, etc. The current EPA ecosystem research program will not provide the science needed to understand, predict, and plan for these changes, their consequences or how they might be mitigated. As a result, EPA will fail the country in this vital mission.

One argument that has been used to justify the ongoing cuts in support for ecosystem research has been that this program has not been able to quantify the bene-

fits that it is producing. At the same time there is a proposal to eliminate the ORD program in Economics and Decision Sciences Research. It appears seriously misguided to raise the bar for comprehensive cost-effective or benefit-cost justification for environmental science research, while simultaneously shrinking the resources devoted to the types of research needed to assess the net social benefits of the outcomes of environmental science research.

Economics and Decision Science resources at the Agency were small to start with (about $2.5 million). This budget has been reduced to about $1 million as staff from the program in ORD are relocated to the National Center for Environmental Economics (NCEE) within the Office of Policy, Economics and Innovation (OPEI). In jeopardy are the already very limited resources for extramural research. Also threatened will be Agency's tradition of partnering with other institutions to co-sponsor (at roughly $10–20,000 each) its series of recurring research workshops and conferences. These events have long been a key forum in which to identify and explore the frontiers of environmental economics research. The transition to the NCEE also appears to almost completely eliminate other social sciences disciplines, so that the representation of essential human behavior disciplines (such as psychology, sociology, and anthropology) is decreased to near zero.

An equally disturbing trend is the continuing decline in financial support for extramural research through the STAR program. Figure 2 shows this trend. A number of EPA research programs that could greatly benefit from contributions from extramural research conducted through the STAR program, are not participating.

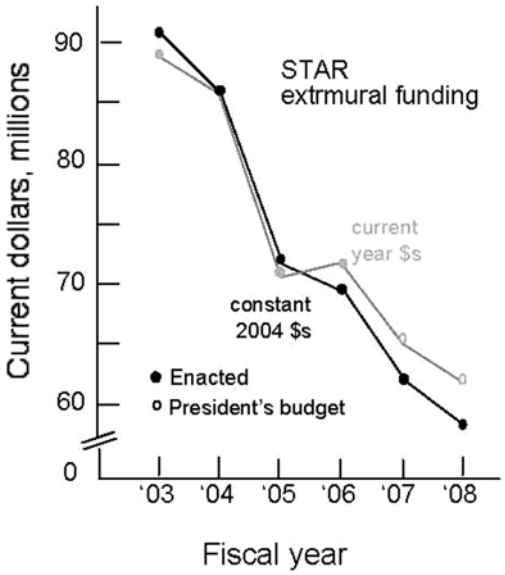

Figure 2: Recent funding history of the EPA STAR extramural program. Adjustment to constant dollars done with the NASA Gross Domestic Product Deflator/Inflation Calculator available at http://cost.jsc.nasa.gov/inflateGDP.html

An especially troubling part of this downward trend is the erosion of the STAR Graduate Fellowship program, down from $9.7 million in FY 2003 to a proposed $5.9 million in 2008. This program has been critically important in educating the next generation of environmental scientists and engineers who will be needed by EPA, the States and the private sector. It has played a vital role in supporting interdisciplinary study of environmental problems. There are several changes that we found to be very positive. The current focus and modest growth in support for the program in nanotechnology are both good developments, because understanding the fate and transport of nanomaterials is likely to be increasingly important to the

Agency in the future. It is also time to begin a modest program of research to identify possible strategies for regulation, because the classic "toxicological testing" approach is unlikely to be viable if it is applied unchanged to nanotechnology evaluations.

Although very small, the new Sustainability Research Strategy and associated Multi-year Plan could provide a valuable integrating framework for EPA core and problem-driven research. These efforts support the transition from the traditional single media approach of environmental protection to a more systems-based and fully integrative process based on life cycle principles. ORD's sustainability research program should be developed in a way that enables the Agency to address the most challenging and multi-faceted environmental issues, such as urban sprawl, climate change, the environmental consequences of biofuels production, and ecosystem degradation in interdisciplinary ways that can provide cost-effective options for reducing a range of environmental impacts. In addition to the modest progress in nanotechnology and sustainability, there are other fine research programs and activities within ORD.

The SAB is concerned that, as the overall level of financial support for research in the Agency continues to decline, despite the growing number of difficult and complex environmental challenges, two dynamics will further erode the EPA's research capabilities:

- Staff morale will suffer, resulting in an accelerated loss of outstanding people, and it will be increasingly difficult to recruit new young scientists and engineers, who will see options for more rewarding careers elsewhere.
- As budgets shrink, and the Agency struggles to keep staffing size reasonably stable, a higher proportion of funds will go to salaries, and less to the other costs of research (laboratories, field studies, computers, research travel for collaboration and discussion of findings at professional conferences, etc.).

Agency staff are doing an outstanding job of nurturing and sustaining a high quality program of research in the face of very serious constraints. They must be provided far better budgetary support if they are to lead and catalyze our efforts to develop the knowledge and approaches necessary to protect the Nation's human health and the environment in the face of hazards that increasingly exhibit integrated characteristics resulting from man-made behavior and natural processes.

As the House Committee on Science and Technology confers on these matters with its colleagues on the Appropriations Committee, we urge particular attention to the following needs to:

- Reverse the downward trend in support for ecosystem research so that this research program can continue its essential monitoring of the health of vital ecosystems, develop and implement new measures of the value of environmental services, and create the basic understanding that will be needed to respond to the challenges facing our ecosystems from climate change and from the "externalities" of new technologies such as biomass fuel and nanotechnology.
- Reverse the downward trend in support for the STAR extramural and Fellowship programs so that the Agency can continue to benefit from fresh ideas and flexibility provided by institutions from outside EPA and continue a robust program of educating the next generation of environmental scientists and engineers.
- Reinstate the program in economics and decision sciences within ORD and add support to substantially increase its capabilities in behavioral social science. Even the best science and engineering results are useless if they are not combined with a sufficient understanding of human risk perception and behavior.
- Provide a significant increase in support for the programs in sustainability and global change, because these topics are both inherently important and provide effective vehicles for moving the Agency in the direction of the innovative, cross-cutting research needed to address the critical environmental problems of the 21st century.

Thank you again for the opportunity to testify about EPA's research and development strategy and budget request for 2008. I would be pleased to answer your questions.

Attachment

January 22, 2007

MEMORANDUM

FROM: Dr. M. Granger Morgan /S/
Chair
US EPA Science Advisory Board

TO: Dr. George M. Gray
Assistant Administrator for
Research and Development
US Environmental Protection Agency

As we have in past years, the meeting of the EPA Science Advisory Board on February 22-23, 2007 will be devoted to a review of the Agency's research budget – not just the budget of ORD but of all research across the Agency. However, in contrast to years past, this year we do not want to do a detailed program-by-program review. Rather we want to try to take a somewhat longer term strategic perspective. In that regard we ask that you and your colleagues do two things that are more focused on the long term:

1. Briefly identify 3-5 issues which the agency believes will represent key environmental challenges over the coming decade or longer and explain how, whether, and to what extent, the R&D budget is designed to place the agency in a position to meet these challenges.

2. The SAB would especially like to learn about how the Agency's research plans will allow EPA to address four key problems that we believe will be of continued and growing importance over the coming decades. These are:

    a) Climate change, including both impacts (for example on: natural ecosystems; water, coastal regions through sea level rise; air quality) as well as key issues such as terrestrial and deep geological sequestration that may arise as a result of future efforts in abatement. While we realize that the agency has a modest research program that is labeled as climate change, we would actually like to hear a more cross-cutting view. That is, how have concerns about the potential impacts of climate change, and possible abatement activities, influenced a range of research plans both within ORD and elsewhere across the agency?

b) Sensitive populations, both human and ecological. We realize that ORD has specific research programs targeted at specific human populations such as children. While we'd like to hear briefly about those we'd also like a cross cutting view of how research plans will address other issues such as the immune suppressed, those with asthma, as well as a variety of other conditions. We are equally interested in learning how research across the Agency is being shaped to identify and address specific ecosystems that are at high risk and certain populations that are particularly sensitive and vulnerable to current or likely environmental stress and change.

c) Urban sprawl and the associated consequences for land use, stresses on ecosystems, stresses on sensitive populations, water contamination, air quality, loss of open space, and related issues.

d) Environmental disasters, both those that may arise as a result of natural causes (such as hurricanes, ice storms, drought, earthquakes and volcanism) as well as terrorist induced events. In the case of the latter we would be particularly interested in learning how research across the Agency is helping to prepare EPA for the possible need to clean up after widespread contamination resulting from chemical, biological or radiological attack, contamination that may result from attacks on facilities such as chemical plants and transportation systems, and contamination that may result from the interruption of key infrastructure services such as electric power (e.g. many sewer systems can not operate without electric pumps).

If some of the topics addressed in 1 above are the same as those we have identified in item 2 that would be fine with us.

3. In addition, we have two shorter term requests for information.

   a. Please identify any research program for which the proposed FY 2008 budget level will substantially differ from the budget that was proposed for FY 2007 (for example, 20% or more would be a substantial increase or decrease). We understand that in fact the Agency is running under a continuing resolution and so will use the proposed FY 2007 budget only as a benchmark. Please provide us with a brief explanation of the proposed decrease or increase.

   b. As always, the SAB must be prepared to comment to the U.S. Congress on the actual budget submission for FY 2008. Thus, we also need information on the full research program at the

level of Program Projects that are a part of the EPA research effort. We received an informative set of background descriptions last year for the FY 2007 budget review and an update of this set would be helpful as the SAB considers commenting on the 2008 research budget. However, an alternative would be to provide information on Program Projects as envisioned in the ORD December 14, 2006 discussion with the SAB on this topic. In this discussion, ORD representatives noted that it could provide background information based on NPD Key Recommendations from the ORD December and January strategic discussions on program change 2008-2012.

If in the course of addressing any of the topics listed above, you and/or your colleagues can point to any examples of ways in which the past R&D budget reviews by the SAB have influenced or shaped subsequent Agency budgetary plans, either in the short or long run, we would be most grateful if you would list them for us. To be frank, a number of members of the SAB are beginning to think that the annual budget review has little or no effect on Agency plans and they question why members should spend so much time on an annual review if in fact that impression is correct. Anything that you or your colleagues can present that would enlighten members on this point would be much appreciated.

Thanks very much to you and your staff for your assistance in these matters. We look forward to meeting with you and other agency staff on February 22-23.

BIOGRAPHY FOR M. GRANGER MORGAN

U.S. EPA Science Advisory Board

Dr. M. Granger Morgan is University Professor and Head of the Department of Engineering and Public Policy at Carnegie Mellon University where he is also Lord Chair Professor in Engineering, and is a professor in the Department of Electrical and Computer Engineering and in the H. John Heinz III School of Public Policy and Management. He holds a B.A. from Harvard College (1963) where he concentrated in physics, an M.S. in astronomy and space science from Cornell (1965), and a Ph.D. from the department of applied physics and information sciences at the University of California at San Diego (1969).

Dr. Morgan's research addresses problems in science, technology, and public policy. Much of it has involved the development and demonstration of methods to characterize and treat uncertainty in quantitative policy analysis. He works on risk analysis, management and communication; on problems in the integrated assessment of global change; on energy systems, focused particularly on electric power; on problems in technology and domestic security; on improving health, safety, and environmental regulation; and on several other topics in technology and public policy.

Chairman LAMPSON. Thank you very much. And now Dr. Sass.

STATEMENT OF DR. JENNIFER SASS, SENIOR SCIENTIST, HEALTH AND ENVIRONMENT PROGRAM, NATURAL RESOURCE DEFENSE COUNCIL

Dr. SASS. Thank you. My name is Jennifer Sass. I am a senior scientist with the Natural Resources Defense Council, which is an environmental advocacy group, and I am based here in DC. I am

a toxicologist and developmental neurobiologist by training, and I will be focusing primarily on health impacts of this budget.

EPA is finding itself spiraling into an increasingly weaker scientific state. It is faced with the impossible task of balancing a decreasing budget with an increasing need for robust data in order to design and inform human health and environmental regulations that are protective. To deal with this, the Agency often turns to the regulated industries or paid contractors who often have clients or members from the regulated industries to supply it with data, data that is often suspect and selectively biased. The lack of resources in staff within EPA leaves it unable to provide adequate oversight of these data or the scientific products, which are often shielded from public scrutiny by confidential business information claims. The result is that EPA is increasingly under pressure to make regulatory and policy decisions with inadequate data or sometimes even no data at all.

We strongly recommend that EPA reverse its trend of reducing its own in-house scientific and technical experts. These civil servants represent the Nation's brain trust. Lacking these experts, EPA decisions, relying on confidential data, lack transparency, oversight, and clear lines of accountability. For example, the Agency's relationship with the International Life Sciences Institute, ILSI, demonstrates how scientific quality may be compromised when transparency and oversight are lacking. ILSI represents several hundred corporations, including DuPont, and reportedly received at least $2.1 million in EPA grants in 2005, the last date for which I can get publicly-available information. In 2003, EPA paid an ILSI subgroup to draft an EPA policy document assessing a large class of toxic chemicals that included some of the Teflon chemicals manufactured by DuPont, one of ISLI's members. The ILSI draft was rejected by an expert review panel, but it did recommend that those chemicals should be deemed safe. Two years later, more recently, DuPont was fined by EPA, the largest fine in EPA's history, for withholding data on the hazards of these chemicals while releasing them as waste products into the surrounding water. Just today a local newspaper reported on a Government study that showed elevated cancer rates in the people that live around the DuPont Manufacturing Plant that makes these chemicals.

The fiscal year 2008 budget cuts funding to core priorities such as susceptible populations, ecological research, and human health diminish EPA's ability to make informed and effective regulatory decisions and to allocate its resources wisely and to evaluate the efficacy of its programs. These cuts impair the ability of regional and state regulators to assess real world problems as well. For example, the budget reduces funding for the National Children's Study, a landmark study that would enhance global understanding of childhood afflictions such as obesity, autism, early onset diabetes, learning disorders, and asthma and could potentially lead to healthcare savings of between 3.3 and $5.5 billion annually.

These kinds of budget reductions or cuts to these programs are also being seen in the area of publicly available information, such as the Integrated Risk Information System, the IRIS database, and also EPA libraries. The IRIS database contains publicly-available EPA scientific consensus positions on potential human health ef-

fects from environmental contaminants. State and federal and even international regulators routinely rely on this information to support an array of critical environmental health measures such as setting clean-up standards at waste sites. The IRIS database is likely to slow its pace because the fiscal year 2008 budget diverts resources to redundant layers of review by the Office of Management and Budget and others that serve no purpose other than to delay final action because of additional review time. For decades EPA's network of scientific libraries has served as a goldmine of resources for EPA and the public, but over the past months EPA has closed five of these libraries and reduced access to four others, despite EPA's own cost benefit analysis showing that the libraries actually save approximately $7.5 million annually in staff time and cost only $2.5 million to operate.

Finally, the fiscal year 2008 budget increases funding to support research in new technology areas such as nanotechnologies but fails to develop a clear research agenda that is actually strategically designed to support policy and regulatory needs. We know that EPA has already reviewed 15 of these new nano-scale chemicals, but because of confidential business information protection claims, we can't learn the names of these chemicals, their uses, or even their manufacturers. EPA is considering a voluntary pilot program now where industry could submit data on nanomaterials to fill the regulatory breach, but EPA still appears unwilling to commit to comprehensive, enforceable regulations.

Congress should direct the Agency to allocate adequate resources to examine toxicity and to develop a robust regulatory framework to insure that nanomaterials in the marketplace are safe and that unsafe materials are appropriately managed from cradle to grave. We recommend that Congress increase the research budget for EPA, specifically favoring programs that provide publicly available, policy-relevant data for priority issues such as children's health, environmental justice, and susceptible populations. And Congress should insure that EPA's funds are used in a manner that preserves scientific integrity, insures adequate transparency, and encourages public accountability. And most importantly, EPA must expand and support its technical in-house experts, its most valuable asset.

Thank you.

[The prepared statement of Dr. Sass follows:]

PREPARED STATEMENT OF JENNIFER SASS

SUMMARY

EPA is finding itself spiraling into an increasingly weaker scientific state. It has been dealt a decreasing budget for providing scientific infrastructure and resources, despite an increasing need for robust data to support human health and environmental protective policies and regulations. Unable to provide for all the data needs of the Agency, it is increasingly reliant on data supplied by the very industries that it regulates and by paid contractors who often have clients or members from the regulated industries. In all cases, the data are suspect, and in some cases, the data are selectively biased. To make matters worse, EPA is increasingly unable to provide adequate oversight of industry data submissions or contractor-generated scientific products due to lack of staff and resources. Moreover, industry data are often shielded from public scrutiny by claims of confidential business protections on matters that would have to be more transparent if the work was done by civil servants. The result is that EPA is increasingly under pressure to make regulatory and policy decisions with no data, inadequate data, or poor-quality data. These increasing sci-

entific uncertainties leave EPA programs vulnerable to a poor grade by the Office of Management and Budget.

The Administration's fiscal year (FY) 2008 budget proposal cuts programs in the Environmental Protection Agency by $400 million from the Continuing Resolution for FY 2007 to $7.2 billion. This proposal represents the lowest funding request in this century in real dollars, FY 2004 being the high at $8.4 billion. In fact, this request cuts almost $2.5 billion from the Agency high when accounting for inflation. The FY08 EPA funding dedicated to Research and Development (R&D) would be cut by 3.5 percent from the FY07 level, to $547 million.

Many of the cuts to EPA scientific research will not be compensated by related research spending in other agencies. Although overall federal investment in R&D would increase by 1.4 percent (to $143 billion) from FY07, an analysis by the American Association for the Advancement of Science indicates that the increase is all in development rather than research, and that generally, this budget, like last year's, increases spending for weapons, defense, and homeland security, while decreasing health, environment, and discretionary spending across the federal agencies.[1]

The mission of EPA is to protect and safeguard human health and environment; yet, this budget continues down the path of deep cuts and out-sourcing in the face of overwhelming evidence of need.

We recommend that Congress increase the research budget for EPA specifically favoring programs that provide publicly available policy-relevant data for priority issues such as children's health, environmental justice, and susceptible populations.

QUESTION ONE: Is the overall level of Science and Technology (S&T) funding in the FY 2008 budget request for EPA appropriate and does the budget request allocate funds in a way to best achieve the Agency's mission?

EPA's Office of Research and Development has identified the following high priority research goals in its FY08 multi-year plan, with a total level of appropriations of $539.8M:

- Goal 1 ($81.1M): Clean Air (Toxics; Particulates)
- Goal 2 ($105M): Clean Water (Drinking Water; Water Quality)
- Goal 3 ($32.4M): Land Preservation and Restoration (Contaminated Sites; Hazardous Waste)
- Goal 4 ($298.9M): Healthy Communities and Ecosystems (Ecological Research; Human Health; Human Health Risk Assessment; Global Change; Mercury; Endocrine Disruptors; Safe Pesticides/Safe Products)
- Goal 5 ($22.4M): Compliance and Environmental Stewardship (Economics and Decision Science; Science and Technology for Sustainability)

While these are laudable goals, sadly, the budget cuts to critical data collection and data assessment programs that support these priorities will leave the Federal Government with inadequate information upon which to base policies and regulations. In particular, there are gaps in policy-relevant research needs that will not be filled by other agencies, industry, or academia. Bluntly put, no, this budget allocation will *not* achieve the Agency's mission. Moreover, decreasing data and the consequent increasing scientific uncertainties leave EPA programs at a disadvantage during review by the Office of Management and Budget (OMB) Program Assessment Rating Tool (PART), which favors measurable program impacts and demonstrable efficiency and efficacy.[2]

My detailed response follows.

I. The FY08 budget cuts funding to programs that gather reliable real-world data that would reduce scientific uncertainty, often leaving EPA increasingly reliant on either no data or data provided by the regulated industries.

EPA recognizes the need to reduce uncertainty in the science that supports risk assessment, risk management, and regulatory decisions in all of its programs. Sadly, budget cuts to key monitoring and data collection programs will result in less data, and therefore greater scientific uncertainty. In many cases, "free" or "cheap" data are volunteered by the regulated industries. The increased reliance on data from the regulated industries calls into question the quality and credibility of the

[1] American Association for the Advancement of Science. AAAS Analysts See Mixed Prospects for Federal R&D Investment in 2007 and 2008. Edward W. Lempinen. February 12, 2007. *www.aaas.org/news/releases/2007/0212budget.shtml*

[2] *http://www.whitehouse.gov/omb/part/*

data. This problem is exacerbated by the decreasing ability of EPA to provide adequate oversight due to budget cuts for staffing, resulting in reduced technical expertise within EPA, and by frequent Confidential Business Information (CBI) protections that prevent public scrutiny to the data.

For example, the Clean Air Mercury Rule (CAMR, May, 2005) requires EPA to reduce and permanently cap mercury emissions from coal-fired power plants. Coal-fired power plants are the largest source of human-derived mercury emissions in the U.S., with much of it ending up in fish that people eat.[3] Although implementing this rule requires data to evaluate the effectiveness of reduction and control measures (S&T–8), EPA abandoned its promise to fund a mercury hot-spot monitoring study focused on mercury power plant emissions. The Scientific Advisory Board (SAB) noted that "the support for research on global sources, transport, and fates" of mercury is "seriously deficient," and that the 2007 budget levels "cannot even begin to address the issue."[4] The reality of these budget slashes has left EPA reliant on the regulated industry to provide monitoring capacity (S&T–8), calling into question the ability of EPA to deliver credible, reliable data to inform and implement the CAMR adequately.

The Air Toxics Program presents another example of the impact of these budget cuts on acquiring reliable scientific data. The program identified the need to, "reduce uncertainty in both national- and community-scale assessments as well as residual risk" (S&T–65). It also noted that OMB rated its program more favorably when improvements were made to "reducing uncertainty in the science that supports standard-setting and air quality management decisions" (S&T–68). The budget report notes that the Air Toxics Program is reviewing other federal research programs with the goal of measuring progress "toward reduction in scientific uncertainty" (S&T–68). In fact, the FY08 budget provides additional funding to develop "quantitative risk assessment methods to allow improved analysis and characterization of uncertainty in human health risk assessment."[5] Despite the expressed need to reduce scientific uncertainty, air monitoring activities that would have provided EPA with real-world data to reduce uncertainty are significantly reduced. Although the SAB praised the Air Toxics Program for its efforts to evaluate the current air monitoring systems, SAB was highly critical of EPA's failure to support air monitoring resources overall, noting that this "diminishes the ability of EPA to make informed decisions on the effective and efficient management of air quality."[6] A robust, reliable empirical database is essential for reliable human health risk assessment.

II. FY08 budget continues the trend of reducing funding for agency growth of scientific expertise, despite spending significant funds to out-source these tasks.

One of the most significant changes at EPA in recent years has been the degree to which the Agency has out-sourced responsibility for some of its important functions in a manner that undermines scientific credibility and public accountability.

EPA is accountable to the people of the United States, the Congress, and the Executive Branch to fulfill its mission in a manner that meets both the letter and intent of the law and that appropriately identifies protecting human health and the environment as the primary objective of the Agency's activities. Both public trust and EPA's ability to meet its obligations to the public are seriously undermined when the Agency farms out critical task without any transparency, oversight or accountability, in many cases to the very industries that it is charged with regulating.

In fact, EPA is spending millions of dollars to fund entities that are specifically beholden to the industries that EPA regulates. Moreover, in many cases, this funding is directed toward activities that are central to the Agency's regulatory decision-making process. EPA does this without ensuring transparency, without adequate oversight, and without demanding public accountability. In particular, these ar-

[3] Once in the human body, mercury acts as a neurotoxin, interfering with the brain and nervous system. Exposure to mercury is particularly hazardous for developing fetuses and small children. More than 13 million lake-acres and 750 thousand river-miles in the United States are subject to fish consumption advisories due to mercury contamination. In addition to mercury, coal plants also emit soot and soot-forming pollutants, which can cause attacks, heart disease and other health problems, shortening the lives of nearly 24,000 Americans each year. Children and the elderly are especially vulnerable.

[4] Report of the U.S. EPA Scientific Advisory Board (SAB), 2007 Budget Review, March 2–3, 2006.

[5] Teichman, K. Acting Deputy Assistant Administrator for Science, ORD. Power Point presentation to the EPA Science Advisory Board Executive Committee, February 22, 2007.

[6] Report of the U.S. EPA Scientific Advisory Board (SAB), 2007 Budget Review, March 2–3, 2006.

rangements are not subject to important "sunshine" laws intended to provide the public with access to the regulatory process and to prevent undue industry influence over Agency decisions. These laws, including the *Federal Advisory Committee Act* and the *Freedom of Information Act,* play a critical role in ensuring government accountability.

Originally the practice of encouraging these cooperative partnerships was intended to bring all stakeholders together for constructive dialogue regarding regulatory policy; however, in recent years it has transformed into something quite different, and many stakeholders (such as NRDC and other environmental and public health groups) have been shut out of the process. In many cases these partnerships have developed into little more than opportunities for the regulated industry to take over direct responsibility for key activities that provide the foundation for EPA's regulatory functions—in particular scientific analysis and risk assessment. This trend has had significant implications for the quality of the science upon which EPA relies for its regulatory activities.[7]

One example of a relationship that has demonstrably compromised the quality of EPA's scientific inquiry is the Agency's relationship with the International Life Sciences Institute (ILSI). ILSI represents several hundred corporations in the chemical, processed food, agro-chemical and pharmaceutical industries and received at least $2.1 million in EPA grants in 2005.[8] Members of ILSI include companies such as DuPont, 3M, Syngenta, Eli Lilly, ExxonMobil Biomedical Sciences, and Dow Chemical.[9] ILSI routinely hosts workshops (often co-funded by EPA) where industry specialists, academics and agency officials come together to discuss science and policy. There often is little or no effort made to inform the public or the public interest community about these meetings, and as a result the public health and environmental voice is frequently entirely absent, marginalized, or ignored when final decisions are made. As a result, EPA policy decisions that emerge from this kind of process are flawed, and those decisions are being overturned.

For example, in 2003, EPA issued a proposed a guidance (based on a proposed policy that was drafted by a sub-group of ILSI) on how to assess a class of chemicals that includes perfluorochemicals used by DuPont to make Teflon. The ILSI–EPA proposed policy claimed that while these chemicals caused cancer in laboratory animals, they were not carcinogenic to humans. An independent scientific panel rejected the ILSI–EPA draft policy because it was not supported by data.[10] In fact, laboratory studies reported that these chemicals are associated with liver and testicular cancer, developmental impairment, and immune system suppression. Later, in December of 2005, DuPont paid more than $16 million to settle charges that it hid information for more than two decades showing that its Teflon chemicals are a significant threat to human health.[11]

In response to a request under FOIA, we have received a list of projects that EPA has undertaken with ILSI. Below we list selected current and recent-past projects between EPA and ILSI:[12]

- The Office of Pesticides (OPP) reports that they have numerous ILSI agreements that incurred the following costs: $58,000 in FY06, $60,500 in FY05, $245,000 in FY04, $150,000 in FY03, and $287,500 in FY02, for a cost to the program over five years of $801,000.
- Project title: cross-study analyses of children's biomonitoring cohort studies. Description: ILSI Health and Environmental Sciences Institute (ILSI–

[7] A very similar issue was recently raised with regard to the National Institute of Health (NIH). In January of this year, Members of Congress, 44 prominent physicians, and 16 health organizations agreed that, in order to preserve scientific integrity, when appointing committees for drafting guidelines the NIH "must strive to ensure that all members are free from conflicts of interest." This letter was prompted in part by specific concerns regarding the fact that many recent committees have been dominated by Members with conflicts of interest. These same problems exist, perhaps to an even greater degree, at EPA.

[8] The ILSI IRS Form 990 for 2005 lists $2.5 million in government contributions. The EPA Grants Awards Database reports over $2 million in awards to the ILSI Risk Science Institute. In a January, 2007 response to a FOIA request from NRDC, the EPA provided a list of the ILSI projects that EPA participates in. FOIA Request HQ–RIN–0029–07 to Jennifer Sass, NRDC.

[9] See the ILSI website for a full list of its membership: *http://www.ilsi.org/AboutILSI/*.

[10] See EPA Advisors Split Over Use of Animal Studies In Human Risk Reviews, Inside EPA (Dec. 10, 2003).

[11] See DuPont fined more than $10M over Teflon, Randall Chase, Associated Press (December 14th, 2005); Consent Agreement, December 14, 2005. (available at: *www.epa.gov/compliance/resources/cases/civil/tsca/eabmemodupontpfoasettlement121405.pdf*).

[12] Freedom of Information Request HQ–RIN–0606–07 to Jennifer Sass, NRDC.

HESI)[13] will identify relevant cohorts and data sets, recruit participation from researchers, work with researchers to develop a data analysis and quality assurance plan, compile the data, coordinate the cross-study analyses, and compile results for reporting to EPA. Timeline: EPA received a proposal from ILSI–HESI in December, 2006. Funding: Anticipated level of funding is $100,000 from EPA ORD under Goal 4 (Healthy Communities and Ecosystems).

- Project title: International biomonitoring workshop. Description: EPA co-sponsored a workshop on September, 2004 with ILSI–HESI and the American Chemistry Council, a trade organization for the chemical industry. Key questions relate to the use of biomonitoring data for environmental public health protection. Funding: $50,000 from EPA ORD under Goal 4 (Healthy Communities and Ecosystems).
- Project title: Cooperative agreement for working groups, workshops, and other events on topics in risk assessment. Time: 1999–2002. Funding: $333,330 over several years from ORD.
- Project title: Mode of action in assessing human relevance of animal tumors. Description: A systematic evaluation of comparability, or lack of comparability, between the postulated animal mode of toxicity and related information from human data sources. Time: 2000–2003. Funding: amount not disclosed. Cooperative agreement with the EPA Office of Pollution Prevention and Toxics (OPPTS) and Office of Pesticide Programs (OPP). Additional support was provided by Health Canada. *http://rsi.ilsi.org/Projects/Human_Relevance.htm*
- Project title: Using mode of action (MOA) and life stage information to evaluate the human relevance of animal toxicity data. Description: The purpose of this project was to draw on the ILSI-Risk Sciences Institute (ILSI–RSI) project for MOA analysis of animal tumors and to expand this into a harmonize framework for all endpoints including reproductive, neurological and developmental effects. Time: 2004–2005. Funding: amount not disclosed. ILSI–RSI project was funded by EPA's Office of Pollution Prevention and Toxics (OPPT) via their cooperative agreement and Health Canada. *http://rsi.ilsi.org/Projects/Human_Relevance.htm*
- Project title: Training course on use of mode of action in assessing human relevance. Description: The purpose of this project is to train the scientific community on how to conduct mode of action analyses for evaluating the human relevance of animal responses. Participants consisted of experts from various government agencies, including the EPA and Health Canada. Time: 2006, ongoing. Funding: amount not disclosed. *http://rsi.ilsi.org/HumanRelevance.htm*
- Project title: ILSI Risk Science Institute Developmental Neurotoxicity (DNT) Project. Description: The goal of this project was to assess the lessons learned from the implementation of standardized tests for developmental neurotoxicity in experimental animals, such as the U.S. EPA OPPTS Health Effects Test Guideline 870.6300 (Developmental Neurotoxicity Study) and similar protocols, and the subsequent application of test results to human health risk assessment. Time: 2004–2007. Funding: OPP funded this ILSI–RSI project via a Cooperative Agreement.

EPA's continued use of agency funds to support closed-door, industry-driven science that feeds directly or indirectly into the regulatory process raises tremendous concerns from a public health and sound science perspective.

III. FY08 budget is cutting funding to core priorities such as susceptible populations, ecological research, and human health.

Research on human health and ecosystems has seen a steadily declining budget over the last three years, from $242.9M (2006), to $228.2M (2007), to $217.5M (2008) (S&T–3). However, from the FY08 budget it is impossible to identify exactly what programs will be impacted, because the document fails to clearly link funding

[13] The ILSI Health and Environmental Sciences Institute (HESI) reports to the ILSI Assembly of Members. Although HESI is structured and claims to operate as a "public, non-profit scientific foundation" (*www.hesiglobal.org/AboutUs/*), they state in their recent job advertisement for an Executive Director of ILSI–HESI that this person should "ensure that the scientific issues important to [ILSI] member companies are raised and appropriately addressed by the organization." (E-mail to: *hesi@hesiglobal.org.* Subject: Executive Director of HESI Job Description. Tuesday, 10 Oct. 2006).

amounts with projects, and fails to clearly identify projects that will be reduced or eliminated. A short list of specific programs that are slated to be reduced or eliminated was identified in a Power Point presentation by ORD Acting Deputy Assistant Administrator for Science.[14] This list included:

- The loss of data collection in the lower Mississippi River and Gulf of Mexico wetlands, despite the increased awareness that these precious areas are critical to mitigating severe flooding in the Katrina and Rita hurricane hit areas.
- The loss of funding for ECOTOX, a critical searchable, publicly-available web-based database of ecological effects of toxic chemicals.
- Reduce assistance to states for development of their watershed management plans and establishment of Total Maximum Daily Load values, which are the maximum allowable level of a pollutant that a waterbody can receive without exceeding water quality standards. These standards are set to protect the drinking water supply, swimming areas, and aquatic life.
- Reduced efforts to collect data on the exposure and effects of toxic chemicals in children, adolescents, older adults, and other identifiable susceptible populations.
- Reduce support for the National Children's Study.

These cuts will eliminate significant research and public access to important data. They will also diminish the ability of EPA to make informed and effective regulatory decisions, to allocate its resources wisely, and to evaluate the efficacy of its programs. In particular, much of the results of the ecological research identified above is particularly valuable to regional, state, and local communities and regulators who are tasked with assessing real-world problems in regional ecological systems such as watersheds. The SAB identified that the need for these data are of great importance to EPA, and that the data are not likely to be supplied by other sources such as industry and academia.[15]

The reduced support for the National Children's Study highlights the extent to which vulnerable sub-populations will suffer under the proposed budget. As noted in a 2006 letter from pediatricians, public health specialists, and patient advocacy groups to the Senate Committee on Appropriations, the National Children's Study would provide substantial information for regulators to allocate resources directed towards improvements in the health of children and adults.[16] The research results of this important study are estimated to provide potential health care savings in the range of $3.3–$5.5 billion annually based on an economic analysis by the National Institute of Child Health and Human Development (NICHHD). Information from the National Children's Study will enhance global understanding of childhood afflictions such as obesity, autism, early-onset diabetes, developmental delay, mental illness, learning disorders, lead poisoning, asthma, auto-immune disease, and chemical intolerance/sensitivity. The data from these and similar initiatives will be of particular help to economically-disadvantaged communities whose members often must play, work, and learn in polluted outdoor and indoor environments. Compared with adults, prenatal and later periods of development are uniquely vulnerable to many pollutants in both the outdoor and indoor environments, due in part to rapid growth and development, behaviors and activities, eating patterns, and physiology. Understanding and reducing the severity and/or incidence of diseases and disabilities will require sustained public investment in research on childhood exposures to environmental toxicants.

IV. FY08 budget eliminates or diminishes support for publicly available information on toxics: the IRIS chemical evaluation program, EPA libraries.

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[14] Teichman, K. Acting Deputy Assistant Administrator for Science, ORD. Power Point presentation to the EPA Science Advisory Board Executive Committee, February 22, 2007.

[15] Report of the U.S. EPA Scientific Advisory Board (SAB), 2007 Budget Review, March 2–3, 2006.

[16] Letter to Honorable Thad Cochran, Chairman, and Honorable Robert C. Byrd, Ranking Member. Senate Committee on Appropriations. From E. Miller, R. Zdenek, D. Croser, J. Greenwood, C. Gavigan, F. Perera, P. Shah, J. Balbus, P.J. Wood, N. Gendel, C. Barnett, D. Wallinga, S. Gilbert, T. Hill, K. Lawson, J. Behm, H. Loukmas, L. Redwood, T. Schettler, V. Garry. February 14, 2006.

Inadequate resources and OMB interference have prevented EPA from keeping the IRIS chemical database as up-to-date as would be expected for a source of information so important to U.S. policy decisions.

Many of the EPA assessments of regulated chemicals are publicly available on its database, the Integrated Risk Information System (IRIS), which contains EPA scientific consensus positions on potential human health effects from environmental contaminants. While not a legal regulatory standard *per se,* such information is used by regulators at the State and federal level and by the international community in combination with exposure data to set cleanup standards and various exposure standards for air, water, soil, and food. The database receives over a half-million visits monthly, from over fifty countries, underscoring its widespread use. At this time, there are over 540 chemicals listed on IRIS. While a substantial number of these chemicals are economically significant (i.e., they are produced or imported at a rate greater than 10,000 pounds per site annually), these chemicals make up a small percentage of the over 8,000 economically significant chemicals found in the U.S. and 15,000 chemicals in commerce altogether.[17] Even when compared to a smaller subset of chemicals that should have assessments available, IRIS is obviously insufficient. For instance, the EPA is responsible for regulating the emissions of 188 hazardous air pollutants (HAPs) under the *Clean Air Act.* Of these 188 HAPs, only 129 do appear in the IRIS database—meaning that in almost 20 years since IRIS, the EPA has been unable to complete assessments of the toxicity and carcinogenicity of nearly one-third of these dangerous pollutants. Even when important chemicals are on the IRIS database, the risk assessments available for these chemicals are often quite old. The average assessment on IRIS is over 13 years old.

According to its website on "what's new" *(www.epa.gov/iris/whatsnewarch.htm),* in addition to performing a literature screen and confirming about a dozen existing IRIS assessments annually, EPA finalized the following number of new chemical assessments:

- In 2006, IRIS finalized two new assessments.
- In 2005, IRIS finalized five new assessments (n-hexane, toluene, zinc and compounds, barium and compounds, perchlorate and perchlorate salts).
- In 2004, IRIS finalized three new assessments (boron and compounds, dibromomethane, lead and inorganic compounds).

With so few assessments finalized each year, it is evident that EPA needs more resources, both money and personnel, to develop robust timely IRIS assessments. The FY08 budget promises that IRIS will complete 16 health hazard assessments of high priority chemicals and post eight finalized assessments on the Internet (S&T–89). Its hard to see how IRIS is going to finalize eight assessments, given its recent trend of finalizing two to five each year. In fact, the IRIS program should be finalizing as many as 16 assessments each year. Unfortunately, the reality is that IRIS is likely to slow its pace further because of FY08 initiatives to "expand opportunities for interagency review and public comment" and expand "consulting with the National Academies of Sciences" on risk assessment methods and approaches (S&T–89), as required by the OMB PART review (S&T–90). These costly and time-consuming delays will significantly slow an already delayed process. Moreover, OMB interference has also weakened the utility of IRIS assessments:

- OMB has blocked IRIS from posting acute (less than 24 hrs.) risk values.[18] Acute risk values are relevant to communities that are exposed by burst releases of toxics (smokestacks, etc.) that may not exceed short-term (days-weeks) or long-term (months-years) regulatory standards, but may still pose a hazard to acutely exposed individuals.
- OMB is blocking IRIS from posting summaries of its assessments, arguing that the summaries give a naïve public and regulators inaccurate impressions, contribute to misunderstandings, and are misused. EP staff should be able to post summaries of IRIS data on chemicals to the public.

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[17] American Chemistry Council: Federal Regulations That Help Ensure Chemical Safety, available at *http://www.accnewsmedia.com/docs/1200/1156.pdf* (last updated April 1, 2003).

[18] *EPA Eyes Expanded Risk Database Used In Toxic Regulation, Cleanups.* The managers of an EPA chemical risk database are considering adding short-term and acute exposure categories on several chemicals to gauge the resources needed to add the broader risk data to the system. January 27, 2003. Inside Washington Publishers.

- OMB has blocked the implementation of the supplemental cancer guidelines on children's exposure.[19] Ethylene oxide is the first example where IRIS staff recommended applying a 10-fold safety factor to site-specific assessments where children may be exposed. OMB blocked this. The next relevant chemical for this process will be acrylamide, for which children's exposures are high.

IRIS has come under intense scrutiny from OMB and the regulated industries, and that the EPA goal of producing robust scientific assessments of toxic chemicals in a timely manner is *not* shared by OMB.

Closing EPA Libraries limits public access to information.

For decades, EPA's network of 26 scientific libraries has served as a gold mine of resources for scientists, community members, and EPA's own staff. Expert librarians made themselves available to locate information, and the library collections themselves contained unique materials, not available elsewhere. Over the past four months EPA has closed five libraries and reduced access at four others, including my local EPA library.[20]

According to press reports, the EPA libraries fielded about 134,000 information requests in fiscal year 2005.[21] Of these, the now-closed EPA regional libraries in Chicago, Kansas City, and Dallas handled more than 32,000 requests for information.[22] Representatives of 10,000 EPA scientists, engineers, environmental protection specialists and support staff protested the closure of the technical libraries in a letter to the Chair and Ranking Member of the Senate Appropriations Committee, Interior and Related Agencies Subcommittee in June of 2006.[23] This letter noted that EPA's own cost-benefit analysis[24] estimated that the library networks saved Agency staff time, resulting in annual cost savings of approximately $7.5 million, far more than the library budget of $2.5 million. Thus, the Public Employees for Environmental Responsibility suggest that, "while cloaked as a budgetary measure, the actual motives appear to be rooted more in controlling access by both EPA staff and the public to information."[25]

Linda Travers, acting Assistant Administrator for the EPA Office of Environmental Information said in December 2006 that "all EPA-generated documents from the closed libraries would be online by January and the rest of the Agency's 51,000 reports would be digitized within two years."[26] Not surprisingly, this has not been done. Digitizing between 50,000 and 80,000 reports is a monumental task and there does not appear to be any budget for carrying this out. Rather than saving the Agency money, these closures will cost the Agency in staff productivity, and in money and time for digitization. The cost to local communities is hard to calculate, since information—when you really need it—is priceless.

IV. The FY08 budget increased funding to support research on new technology areas such as nanotechnologies, but has failed to develop a clear research agenda that would support policy and regulatory needs.

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[19] *OMB Opposes First-Time Child Cancer Factor Use In EPA Risk Assessment.* The White House Office of Management & Budget (OMB) is reportedly objecting to EPA's first-time use of a new children's cancer guideline in a draft risk assessment for ethylene oxide (EO) that seeks to significantly strengthen the safe exposure level, according to EPA sources. . .. The draft risk assessment, released Sept. 22 of last year by the Agency's National Center for Environmental Assessment, proposes tightening the Agency's 1985 bench point of 3.6 parts per billion to 0.06 parts per trillion—a significant change that could have a host of ramifications for industry. . .. Ethylene oxide is a common chemical that is widely manufactured, and is used as a medical sterilant as well as to make anti-freeze, detergents and polyester. January 26, 2007. Inside Washington Publishers.

[20] Congressional Research Service. Restructuring EPA's Libraries: Background and Issues for Congress. RS22533. January 3, 2007.

[21] Joal A. Mintz and Rebecca Bratspies. Closing Agency Libraries Deals Serious Blow. *South Florida Sun-Sentinel.* December 11, 2006.

[22] Robert McClure. EPA gets an earful on library closures. *Seattle Post-Intelligencer.* January 22, 2007.

[23] Letter from Dwight A. Welch et al. Presidents of 16 Local Unions to Conrad Burns and Byron Dorgan, United States Senate. June 29, 2006. *www.peer.org/docs/epa/06_29_6_union_library_ltr.pdf*

[24] EPA Office of Environmental Information. Business Case for Information Services: EPA's Regional Libraries and Centers. EPA 260–R–04–001. January 2004.

[25] *http://www.peer.org/campaigns/publichealth/epa_library/index.php*

[26] Tim Reiterman. Closure of six federal libraries angers scientists: Cost-cutting moves at the EPA and elsewhere deny researchers and the public access to vital data, critics say. *Los Angeles Times,* December 8, 2006.

Nanotechnology (the convergence of biology, chemistry, and engineering at the nanoscale) has emerged as one of the most rapidly developing, dynamic, and exciting fields of scientific research and commercial development. Nanoscale materials approximately 100 nanometers (nm) or less in any dimension offer potentially tremendous advances in fields ranging from medical technologies to power generation and storage to environmental remediation strategies. However, the rapid emergence of new nanomaterials and their increasing use in products and processes raises serious concerns regarding the potential for adverse impacts on human health and the environment. Already, EPA has reviewed 15 new chemical uses that were small enough to be considered nanoscale; all are protected by Confidential Business Information (CBI) provisions under the Toxic Substances Control Act; the public is unable to learn the names of these chemicals, their uses, or even their manufacturers.

Current EPA research activities include assessing potential ecological and human health exposures and effects from nanomaterials likely to be released into the environment (S&T–108, –109). However, this research is poorly coordinated, inadequately funded, and poorly tailored to EPA's authority to regulate nanomaterials.[27] In fact, in September, 2006, the House Science Committee Chairman Sherwood Boehlert (R–NY), Ranking Minority Member Bart Gordon (D–TN) and non-government witnesses identified the need for EPA to develop a better-funded research strategy to address health and environmental risks, noting that the current research agenda lacked coordination.[28]

A voluntary pilot program now under consideration by the EPA will request that industry participants submit data on material characterization, toxicity, exposure potential, and risk management practices. While this program may act as a stopgap to fill the regulatory breech, it would only involve those companies that volunteer to participate and would gather data regarding only those products that participating companies choose to disclose. Companies with the riskiest products, as well as those with poor business ethics—that is, those most likely to need government oversight—are least likely to participate. A coalition of more than 20 public interest groups including NRDC, Friends of the Earth, Greenpeace, and Sierra Club insist that a voluntary program without a mandatory regulatory component will not be able to address potential risks. The reliance on voluntary stewardship initiatives has left a regulatory void that could harm both human health and the economic stability of the nanotechnology industry. Nonetheless, the EPA appears unwilling to commit to comprehensive, enforceable regulations.

Congress should specifically direct EPA to allocate adequate resources not only to examine nanomaterial toxicity (an absolutely essential first step), but also simultaneously and aggressively develop a robust regulatory framework that will adequately ensure that nanomaterials in the marketplace are safe, and that unsafe materials are appropriately managed from cradle to grave. Any such framework should be based on a precautionary approach to managing toxic chemicals and should:

- **Prohibit the untested or unsafe use of nanomaterials.** Because preliminary data demonstrates the potential for toxicity, unsafe or untested nanomaterials should not be used in a manner that may result in human exposures or environmental releases over the life cycle of the material.
- **Conduct full life cycle environment, health, and safety impact assessments as a prerequisite to commercialization.** Robust testing is urgently needed to identify potential risks early in development, across the life cycle of the material. The results of testing should made available to the public.
- **Facilitate full and meaningful participation by the public and workers in nanotechnologies development and control; consider the social and ethical impacts of nanotechnologies.** The potential of nanotechnologies to transform the global social, economic, and political landscape means we must move the decision-making out of corporate boardrooms and into the public realm.
- **Implement precautionary regulatory requirements for nanomaterials.** We urgently need regulations to ensure that risks are adequately addressed and that communities and workers are protected.

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[27] Summary Report of the Peer Review Workshop on the Nanotechnology White Paper: External Review Draft. Washington, DC, April 19–20, 2006. Prepared by the US EPA Office of the Science Advisor, by Versar, Inc. *www.epa.gov/OSA/pdfs/nanotech/nanotechnology-peer-review-workshop-summary-report-final-070706.pdf*

[28] U.S. House of Representatives *(www.house.gov/science)* Science Committee. Boehlert calls for better coordination and greater funding to understand nanotechnology risks: Administration Releases Report on "Research Needs." September 21, 2006.

Nanomaterials represent a large, but not a new, challenge for the regulatory agencies. The need to regulate a commercial material about which little is known of its safety is reminiscent of our introduction of asbestos into global markets. By the 1930s, asbestos was being linked to deaths; as of 2004, the cumulative financial liabilities from the substance were projected at more than $200 billion. In the U.S., we still have more than one death per hour—approximately 10,000 per year—as a legacy from past and continuing exposure to asbestos; the global death rate is estimated at 10 times higher. Insurer Lloyds of London and Swiss Re have already noted that asbestos serves as a warning to the nanotech industry. To use another analogy, with nanotechnologies we are right now at the point of deciding whether to put lead into gasoline.

QUESTION TWO: What roles should research partnerships, extramural grants, contracts, and in-house research play in helping the Agency to obtain the scientific information needed to serve their mission of environmental and public health protection?

Congress adopted strong sunshine laws in part to prevent clandestine manipulation of the regulatory process, and that objective is in serious jeopardy if EPA is permitted to out-source critical responsibilities. Congress should ensure that the money going to EPA is used in a manner that preserves the scientific integrity of the regulatory process and that any important science activities funded by EPA are conducted with adequate transparency and direct lines of public accountability. In particular, EPA should not be funding or relying on regulated industries or their representatives to develop EPA guidance or policy documents, or to develop scientific assessments of their own chemicals for EPA. Rather, industry-funded or industry-supported assessments and recommendations should be submitted to EPA as a public comment, publicly available, and subjected to the same consideration and review as all public comments.

EPA should support and expand its use of in-house scientific and technical experts. These people represent the Nation's brain-trust, and their work products should be publicly available. The Agency's own technical experts have to be enabled to investigate and disclose what dangers we truly face from environmental pollutants, despite myriad influences of business interests. Grievous and irreversible damage is being done to this Agency's capacity to protect human health and the environment.

BIOGRAPHY FOR JENNIFER SASS

Jennifer Sass is a Senior Scientist at the Natural Resources Defense Council (NRDC) based in Washington, DC. She works in the Health and Environment Program, which reviews the federal regulation of industrial chemicals and pesticides. Over her five-plus years with NRDC, Dr. Sass has published over two dozen articles in scientific journals, provided written and oral testimony to the Environmental Protection Agency and National Academies of Science, as well as served on federal scientific and stakeholder committees. Dr. Sass completed postdoctoral studies at the University of Maryland in toxicology, doctoral studies at the University of Saskatchewan in developmental biology, and a Master's thesis in neurobiology.

Jennifer also directs NRDC's work on nanotechnologies, and has served on several U.S. federal scientific and stakeholder committees related to nanotechnology, including the National Toxicology Program Nanotechnology Working Group, NIEHS. Jennifer has published articles on the risks of nanotechnologies, and need for regulations, including: Nanotechnologies: The promise and the perils. *Sustainable Development Law & Policy* journal (Spring, 2006).

Chairman LAMPSON. Thank you, Dr. Sass. Please now proceed, Dr. Coull.

STATEMENT OF DR. BRUCE C. COULL, CAROLINA DISTINGUISHED PROFESSOR EMERITUS AND DEAN EMERITUS, SCHOOL OF ENVIRONMENT, UNIVERSITY OF SOUTH CAROLINA; PRESIDENT, U.S. COUNCIL OF ENVIRONMENTAL DEANS AND DIRECTORS, NATIONAL COUNCIL FOR SCIENCE AND THE ENVIRONMENT

Dr. COULL. I am here actually, well, I am from the University of South Carolina. I am proud to be a South Carolinian, Bob, okay.

I am actually here representing the National Council of Environmental Deans and Directors of the United States, of which there are 134 colleges and universities who are members of the Dean's Council.

The Dean's Council is part of that National Council for Science and Environment, whose mantra is we need good science to make informed decisions. And the tenet of our major discussion today is that we don't think that EPA has had the resources to generate the science that is needed for good decisions across the board in various aspects of the environment.

As you have heard from Dr. Sass and Dr. Morgan, the EPA research budget has been declining over the last several years, and my written testimony and their work lays out the details for you. The EPA budget has essentially been flat for a quarter of a century, which the environmental challenges have become much more complex, and there are needs for new approaches. We didn't know 25 years ago about endocrine disrupters. We didn't know 25 years ago about nanoparticles. We didn't know about a lot of things then. It is time to ratchet up the EPA research budget for these new modern looks at the environment, and the tables in the handout give you the details of the declines that we have seen, and you have seen the data from the others.

It is almost across the board that we look at this. One of the things that I think we need to consider is what don't we know that we should have known, and I want to specifically give you an example from South Carolina. I have colleagues at the university, at Clemson University, and I do talk to people at Clemson, and at the National Ocean Science Laboratory in Charleston, who have been funded by EPA through the STAR Program to look at endocrine disrupters in coastal ecosystems. This is particularly relevant to your statement, Mr. Lampson, about economic health of communities dependent upon recreational and fisheries. This work was done primarily in the Hilton Head region, very close to your birthplace, Congressman, and the results are that crustaceans, which are an important part of the industry in South Carolina, shrimp, particularly, and crabs, are inhibited in their reproduction by several of the endocrine disrupters sprayed on golf courses at Hilton Head.

Two kinds. One, a particular pesticide called Fipronil, which the EPA has indeed identified as a potential endocrine disrupter, which is sprayed on golf courses so we can keep the bugs down, and we don't have too many bugs on your green while you are trying to punt, excuse me, trying to putt. All right. And secondly, it may be trying to punt, and secondly, the town of Hilton Head actually used sewage effluent from the city to spray on the golf courses. This is all within regulation. Bacteria are killed, the water is clean per se, but it hasn't cleaned the water of those birth control products that are still in the water, Viagra has been measured in the water. I guess that is to keep the shrimp going. I don't know. And various antibiotics in the particular system. My colleagues at the three institutions had been funded significantly by the EPA STAR Program. They are now receiving 25 percent of the funding. They do not know, they cannot tell us now how this, these endocrine disrupters are passed up food chains. Am I eating endocrine

messed up shrimp? That doesn't do anything to me. I am well past the reproductive age. Okay. But it may for others in the environment.

Secondly, we also have a problem with mercury, and that budget has been zeroed out in the proposed budget. The endocrine disrupter budget has been zeroed out in the proposed budget. Mercury is a goal of EPA's from last year, and the goal is to find out where it is and how it affects the population. There is no way that the Agency, either through its labs or through its extramural programs, can attempt to look at those things. Promising approaches mentioned by Dr. Morgan in sustainability, socio-economic aspects, and ecosystems are also being greatly reduced across, and we can't go into the details of all of those.

It is nice to see the influence and the money coming in to the Nano Program. Nanoparticles are an important part of our life. They are going to either be the PCBs of the next generation, or they are going to be the world savers, or they are going to be something in-between.

Our point is you cannot make science-based decisions without the science. The role of extramural research, academic research, which is, as a former administrator, and I must tell you that one of the best names to have in a university setting attached to your name is emeritus. That means you are retired, and you don't have to deal with lots of other things. All right. But our schools, our 134 said schools, all right, are producing 40 to 50 percent of the students, the grants, and the publications of all ORD research. So the said schools represent a good portion of the extramural research going on in the United States through the Office of Research and Development. We bring the expertise of the entire scientific community to bearing problems. We provide the training for the next generation. We are the people who do that. Of the STAR Fellows Program 88 of our 134 institutions have educations STAR Fellows, that is the fellows that are declining so rapidly as we saw in Dr. Morgan's presentation.

And the thing that is so interesting here is that extramural research, both grants and fellowships, can be ramped up very quickly with additional funding. We don't need new infrastructure. We have it. We don't need new people to run this personnel. This is out there, and there are very hungry, bright, young faculty, not emeritus ones, but bright, young ones out there who are very capable at all institutions ready to do these kinds of things.

Just knowing that this is not within your purview, I also want to reiterate the statement of Dr. Sass on environmental libraries, and I also want to reiterate the statement we have heard before related to environmental education. We in universities, of course, are educators primarily, and the Environmental Education Program and the Library Programs have been significantly cut from the general EPA budget. And we would hope that your Committee could work with the Education Committee to try to make that something we need. Environmental education now as our Earth becomes more and more under siege is critical if we don't educate the public and our students how they are doing.

It is time for the Science Committee to provide leadership, send a strong message to the appropriators and other authorizing com-

mittees, as well as the Agency itself. We need a strong investment in environmental research, education, and information. EPA needs to be the Agency that takes the lead in this and needs to be consistent with the rederick about science-based decision-making.

[The prepared statement of Dr. Coull follows:]

PREPARED STATEMENT OF BRUCE C. COULL

Summary

The U.S. Environmental Protection Agency research budget situation is chronically bad and getting worse. In order to fulfill its mission, EPA needs increased investments in both its intramural and extramural science programs as well as associated services such as environmental education and libraries. The proposed cuts in research areas are devastating exactly the areas EPA ought to be investing in socioeconomic, sustainability, ecological, and exploratory research as well as partnerships with academia and State and local government. These areas are essential to move environmental protection from a command-and-control regulatory system to a more rational, compliance-based approach.

The National Council for Science and the Environment (NCSE) urges Congress to appropriate a minimum of $700 million for EPA's Office of Research and Development (bringing it back to FY 2004 levels), including at least $150 million for EPA's Science to Achieve Results (STAR) research grants program and $20 million for EPA's STAR graduate fellowship program. We recommend a total of $900 million for EPA's Science and Technology account. NCSE also urges Congress to restore full funding for the Office of Environmental Education at a level of at least $10 million. Finally, we urge Congress to stop the ill-conceived and poorly-executed closure of EPA's libraries.

The National Council for Science and the Environment is dedicated to *improving the scientific basis for environmental decision-making*. We are supported by over 500 organizations, including universities, scientific societies, government associations, businesses and chambers of commerce, and environmental and other civic organizations. NCSE promotes science and its essential role in decision-making but does not take positions on environmental issues themselves.

NCSE's Council of Environmental Deans and Directors (CEDD) includes the leaders of environment programs at more than 130 colleges and universities in the U.S. These institutions produce the bulk of the Nation's environmental scientists and environmental professional workforce. CEDD meets the critical national needs to ensure continued excellence in academic environmental programs and to provide a high quality environmental workforce and an informed public.

Introduction

Mr. Chairman, thank you for the opportunity to testify at this important hearing on science and technology at the Environmental Protection Agency (EPA). My name is Bruce Coull. I am testifying in my capacity as 2006–2008 President of the U.S. Council of Environmental Deans and Directors (CEDD) a program of the National Council for Science and the Environment (NCSE). I am also Carolina Distinguished Professor Emeritus and Dean Emeritus, School of the Environment, University of South Carolina in Columbia, South Carolina.

Previously, as Dean of the School of the Environment, I led the University of South Carolina (USC) to approach environmental issues through multi-disciplinary research, education and community outreach. I headed the South Carolina Sustainable Universities Initiative (*http://www.sc.edu/sustainableu*), a multi-university project educating about frugal use of Earth's resources and was the architect of the greening of the University of South Carolina. I also led USC's environmental efforts in the Ukraine related to the Chernobyl nuclear accident of 1986. Currently, I direct the South Carolina Lowcountry Initiative of the Chicago and New York-based Center for Humans and Nature (*http://www.humansandnature.org*). This initiative aims to assist local decision-makers in making sensible use of resources in the South Carolina coastal region.

I am a marine biologist by training. I am here today to discuss the importance of greater investments in environmental research, education, and information and the consequences of chronic under-investment on environmental decision-making.

Environmental Science and Decision-making

The call for decisions, environmental and otherwise, to be made on the basis of science is almost a mantra used across the political spectrum. Yet, behind the rhet-

oric, a simple truth remains. Without investment in science and in scientists, there can be no science-based decision-making.

Despite this statement of the obvious, many federal departments and agencies and those in Congress who fund them try to get environmental decision-making on the cheap. This has been the case with the Environmental Protection Agency for a very long time and the proposed budget only worsens this sorry situation. The EPA R&D portfolio of $540 million in the FY 2008 budget request would be a 3.3 percent cut from the likely 2007 funding level with increases for homeland security-related research somewhat masking cuts to most research areas. This would leave EPA's Office of Research and Development with its lowest budget since 2000 in nominal dollars and its lowest budget in constant dollars since at least 1990 (AAAS data).

In real dollar terms, **EPA's funding of science is nearly unchanged since at least 1990, and has been steadily declining since FY 2004** (Figure 1). In fact, the flat budget extends back at least as far back as the early 1980s. During these decades, the magnitude and complexity of our nation's environmental challenges has increased many-fold. Science, including that conducted by EPA, has helped us to make great advances with the local issues of point-source pollution. But the problems faced by EPA, our nation and our planet today encompass local, regional, national and even global scales. They will not be addressed by science-funding as usual. As then-Chairman Representative Vernon Ehlers said last year, "just as we can't afford to spend too much, we can't afford to spend too little."

A research budget of less than $600 million for an agency dealing with these challenges is simply unacceptable. In contrast, the National Institutes of Health (NIH) has an R&D budget of over $28 billion (50 times more than EPA research). NASA's budget of $12 billion is almost 20 times larger than EPA's research budget.

In order to focus on the highest priority issues and provide coordination for achieving its research goals, EPA's Office of Research and Development has produced multi-year plans (*http://www.epa.gov:80/osp/myp.htm*) for the following high priority research areas that are linked to EPA's five major strategic goals:

Goal 1: Air

- Air Toxics
  Particulate Matter

Goal 2: Water

- Drinking Water
  Water Quality

Goal 3: Land

- Contaminated Sites
  Hazardous Waste

Goal 4: Communities & Ecosystems

- Ecological Research
  Human Health
  Human Health Risk Assessment
  Global Change
  Mercury
  Endocrine Disruptors
  Safe Pesticides/Safe Products

Goal 5: Compliance and Environmental Stewardship

- Economics and Decision Science
  Science and Technology for Sustainability

Nearly half of these issues were largely unknown 25 years ago, yet the amount of available funding is actually less. In fact, even the meager amount of money for most of these issues continues to decline.

We increasingly understand the connection between environmental quality and human health. Last month, "Integrating Environment and Human Health" was the theme of NCSE's 7th National Conference on Science, Policy and the Environment, which involved more than 800 scientists and decision-makers. Numerous examples were presented to demonstrate the dependence of human health on the quality of the environment, including emerging diseases such as avian influenza, episodic diseases such as cholera, toxicants such as arsenic and mercury, and illnesses that result from our lifestyle such as the relationship between suburban sprawl, urban

blight, other aspects of the built environment and a host of health problems including cardiovascular diseases and obesity.

Additionally, climate change is already having impacts on health, including more than 30,000 Europeans who died in the heat wave of the summer of 2003, Arctic peoples who are unable to continue subsistence hunting due to the rapidly melting polar ice caps, and the residents of the Gulf Coast and Atlantic coast killed, sickened or made homeless by intensified hurricanes such as Katrina. Scientists and professionals are once again realizing that we can't have healthy people in unhealthy environments. EPA, with its mission to protect human health and the environment is the ideal place for integrated research to happen and be funded, but funding levels are not sufficient to be effective. An editorial from this week's issue of *Science* magazine, by Richard Jackson, former Director of the CDC National Center for Environment and Health, who was one of the speakers at our recent conference, that shows the tight connection between environment and health is attached to this testimony.

EPA's strategic plan calls for science-based decision-making, but it's not possible to achieve this goal if the Agency's capacity to conduct science is continually reduced. EPA's strategic plan for 2003–2008 says, "EPA has identified reliance on sound science and credible data among the guiding principles we will follow to fulfill our mission to protect human health and the environment." EPA needs to reverse the decline in its capacity to conduct science in order to fulfill its mission.

EPA's proposed science budget

Compared to FY 2006, EPA's overall budget would fall $400 million or 5.5 percent to $7.2 billion under the President's FY 2008 budget, after a similar cut in 2006. EPA's shrinking R&D portfolio would decline to $540 million in FY 2008, after declining to $595 million in FY 2006 from $621 million in FY 2005 and a high water mark of $647 in FY 2004. Funding for most EPA research areas would decline. **EPA's R&D funding would fall to its lowest level in almost two decades in real terms** (Figure 1). If EPA's FY 2008 budget proposal is enacted, the Agency's Science and Technology (S&T) funding would decline by $71 million or 12 percent since FY 2004 and the Office of Research and Development budget would decline by $107 million or 16.5 percent during the same period.

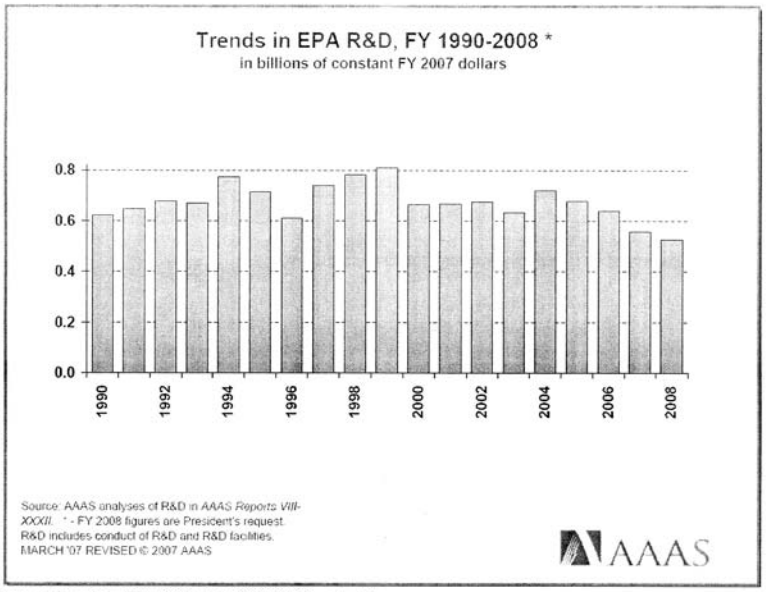


Figure 1. Trends in EPA R&D, FY 1990-2008 in real dollars.

A healthy research program depends on having sufficient resources to:

a. keep up with and use the newest scientific methods,
b. provide the most up-to-date scientific information for the Agency's regulatory decisions and core research programs, and
c. build and maintain strong ties with the external research community and foster graduate student work in the environmental sciences.

Unfortunately EPA's research program is in a chronically unhealthy state. Despite major successful reforms (including a new extramural research and fellowship program) in response to criticisms leveled in the 1980s and early 1990s, EPA's ability to garner the best science for its decision-making has been constrained severely by a lack of resources. This is particularly vexing given the desire of many policymakers to move away from a "command and control model" to a more rational market-based approach to environmental performance. A market-based approach will succeed only if all participants have access to high quality science-based information on which to make their decisions. Additional science is needed to develop metrics of success and to monitor progress toward desired outcomes.

According to the President's budget demand, funding for EPA's S&T account is projected to fall in 2008, 2009, and 2010 before rebounding slightly in 2011. After adjusting for inflation, EPA R&D could fall a further 16 percent over the next five years. Even if Congress adds to the administration's request during the appropriations process, congressional add-ons may end up going to earmarked projects rather than to boost core EPA research programs, leaving most EPA research on a downward path with further cuts to come. This situation is unsustainable and should be unacceptable to this committee.

EPA's Extramural Science and Education Programs

EPA created the extramural Science to Achieve Results (STAR) program as part of a set of reforms to EPA science proposed by the National Academy of Sciences in the 1990s. STAR provides EPA an opportunity to better take advantage of the intellectual and scientific resources of the academic community and apply these resources to the challenges faced by EPA. It is EPA's principal means of getting the best environmental researchers in our colleges and universities to direct their attention to the most critical environmental problems of the Nation. STAR grants complement EPA's own scientific staff by bringing an additional independent voice and excellence in additional fields of science. STAR also provides funds for preparing the next generation of environmental scientists and engineers, both through graduate fellowships and as research assistants on grants to faculty members. We note as of January 2006, Project Investigators (PIs) from colleges and universities included in CEDD have published more than 3463 journal articles (representing 43 percent of all journal articles published by NCER funded PI's). 36 Project Investigators have been listed as highly cited (publications influential for other researchers) authors. (CEDD accounts for 41 percent of all NCER funded PI's listed as highly cited.)

As we will show, this area has born the brunt of the recent cuts in EPA's research leading to critical problems *not* being understood and new environmentally beneficial technologies *not* being produced.

The STAR program has been widely praised. The National Academies issued a laudatory report, *The Measure of STAR,* which concluded that the program supports excellent science that is directly relevant to the Agency's mission. According to the report, the STAR program has "yielded significant new findings and knowledge critical for regulatory decision-making." The report says, "The program has established and maintains a high degree of scientific excellence." It also concludes, "The STAR program funds important research that is not conducted or funded by other agencies. The STAR program has also made commendable efforts to leverage funds through establishment of research partnerships with other agencies and organizations."

The EPA STAR research program compares favorably with programs at other science agencies. According to the National Academies report, "The STAR program has developed a grant-award process that compares favorably with and in some ways exceeds that in place at other agencies that have extramural research programs, such as the National Science Foundation and the National Institute of Environmental Health Sciences."

The STAR research grants program expands the scientific expertise available to EPA by awarding competitive grants to universities and independent institutions, to investigate scientific questions of particular relevance to the Agency's mission. The National Academies report says, "The STAR program should continue to be an important part of EPA's research program."

From the standpoint of a university administrator, our ability to set priorities is greatly influenced by patterns of federal funding. Where resources are made avail-

able, academic research will flourish and new discoveries will be made. This is happening in the biomedical sciences and society is reaping the benefits of increased funding for biomedical research. In areas such as environmental science, even though there is great interest among student and faculty, it is hard for us to establish new programs and hire new faculty and take on additional students if we know that funding is not likely to be available. STAR grants that support research centers and individual scientists allow universities to make their own investments with some assurance of concurrent federal support.

Research centers funded by the STAR program at universities affiliated with NCSE are making scientific breakthroughs on topics including:

- remediation of mine waste sites
- microbial risk assessment
- remediation of volatile organic compounds in groundwater and soil
- air quality—reducing the health effects of particulate matter and aerosols
- assessment of aquatic resources
- children's environmental health and disease prevention (several centers).

Funding for the STAR program has been cut repeatedly over the past several years. The FY 2008 request for the STAR programs (including fellowships) is $61.9 million, which is approximately 45 percent below the FY 2002 level of $110 million. If the proposal is enacted, STAR will have been cut by more than $21 million or 25 percent since FY 2004. NCSE proposes that the STAR research budget be increased to $150 million, which would allow expansion of areas and scientists supported and would send a signal that Congress is serious about merit-based science for environmental decision-making.

We do commend EPA for boosting grants to $5 million for exploratory research on the environmental effects of *nanotechnology,* an emerging issue which was the subject of Science Committee hearings last year. However, even in this case, the research is trying to catch up to a genie that is already out of the bottle. NCSE cosponsored a conference with EPA's Office of Research and Development in fall 2005 on the possible benefits of nanotechnology for cleanup of hazardous wastes, such as contaminated ground water. Although, small scale field trials show considerable promise, the risks, large or small, are largely unknown. We also note with disappointment that absolutely no money is budgeted for exploratory research grants on any other subject. The nanotechnology research, as well as endocrine disruption research, originally came from the exploratory research area. The current budget leaves no money to study any new issues that emerge during the upcoming year or that have been identified but not studied.

Table 1 shows a breakdown of EPA extramural research by program area and fellowships over the past five years. It also shows a breaking down of the extramural program itself. Prior to the period shown on Table 1, the STAR program provided approximately $100 million annually in research grants from FY 2000 to 2002. The proposed budget for FY 2008 would reduce that total to $56 million—a stunning cut of 44 percent during the current Administration.

This table shows continued attrition and termination of research programs. Research grant areas *terminated* since 2004 include:

- Water quality
- Land protection and restoration
- Endocrine disruptors
- Ecosystems (formerly more than an $18 million annual investment)
- Mercury
- Pollution Prevention
- Sustainability
- Economics and Decision-making
- General exploratory research

Each of these shutdowns has real world negative consequences. I provide a few examples, but there are many more. In addition, most of the research areas presently still addressed by EPA are done so in a paltry fashion with the expenditures for research very small relative to the scale of the problem.

Consequences: Research Funding Cuts Lead to Health and Environmental Problems

Endocrine Disruption. EPA's grants for research on endocrine disruption (ED), which totaled $4.6 million in FY 2003, were terminated in the FY 2007 budget re-

quest. EPA's $10 million request in this field is down nearly 20 percent since FY 2003.

Examination of the phenomenon of endocrine disruptors (chemicals that mimic naturally occurring hormones, many of which are passed from the mother to the developing fetus and affect sexual and other types of development) provides examples of the consequences of these terminations. Headlines are raising questions about bisexual fish in rivers across the U.S. and are reporting the loss of more and more natural commercial fisheries around the world. International biomedical experts are agreeing that the growing incidence of human male reproductive organ disorders including testicular cancer, are the result of prenatal exposure to environmental chemicals. In the U.S., there has been an age-independent decline in testosterone levels in men over the past twenty years. Epidemiologists have linked unusual external genitalia development in newborn boys with plastic components in their mothers' urine during pregnancy. The Centers for Disease Control and Prevention report that one in 150 children born today has an autism spectrum disorder. The latest evidence concerning the role of environmental contaminants and reproductive health from the gene and early stages of development to the gray-haired population is extremely worrisome. Yet, despite the all evidence of growing numbers of transgenerational disorders that were rare only two generations ago, ED research at in the Office of Research and Development is declining.

In South Carolina, endocrine disruptive chemicals are used on golf courses at several locales, including Hilton Head Island, both as pesticides (e.g., Fipronil), and via treated sewage effluent that is used for irrigation (such effluent contains estradiols, birth control remnants, antibiotics, etc.), which run-off into the very productive estuarine salt marsh systems. Colleagues at the University of South Carolina and the NOAA National Ocean Science Laboratory in Charleston were funded by EPA via the endocrine disruption program to determine the effects on commercially important estuarine species. They have discovered that crustaceans (shrimp, crabs, copepods) have their reproduction shut down when exposed to these chemicals and that some fish are unable to reproduce and have both male and female characteristics when exposed. The question now is how are these chemicals passed up food chains, what is the impact on coastal fisheries yields, can humans bioaccumulate these endocrine mimics, and what are the effects? Despite these findings, present funding is now 25 percent of what was originally funded by EPA. Clearly, eliminating the endocrine disruption research grants program will not provide the data for informed decision-making related to environmental and human health.

Mercury. EPA research on mercury has been reduced to $4.3 million in FY 2008 (slightly up from 2006) from $7 million in FY 2004. Grants for mercury research were terminated in FY 2005. According to ORD's Multi-year plan (MYP): "A 1997 EPA Mercury Study Report to Congress discussed the magnitude of mercury emissions in the United States, and concluded that a plausible link exists between human activities that release mercury from industrial and combustion sources in the United States and methyl mercury concentrations in humans and wildlife. Regulatory mandates require EPA to address these risks. The Agency is developing risk management research for managing emissions from coal-fired utilities (critical information for rule-making) and non-combustion sources of mercury; risk management research for fate and transport of mercury to fish; regionally-based ecological assessments of the effects of methyl mercury on birds; assessment of methyl mercury in human populations; and risk communication methods and tools. EPA has established two long-term goals for mercury research. The long-term goals established in this MYP are:

1. To reduce and prevent release of mercury into the environment.
2. To understand the transport and fate of mercury from release to the receptor and its effects on the receptor.

However, as a result of the cuts to the already small budget, EPA is not presently studying the cycling of mercury in the environment. Thus it is hard to imagine how EPA will accomplish these goals.

Ecosystems. As recently as FY 2004, EPA was spending $108 million on ecosystem research. In FY 2005, what had been an $18 million program of grants for ecosystem research was completely eliminated from STAR. The FY 2008 budget request would further reduce funding for ecosystem research to $68 million. At this level, essentially all external participation—grants, cooperative agreements and contracts—would be eliminated. The remaining EPA researchers who were able to produce a major product every year or two would only be able to produce a major product every four to six years. Additionally, the most recent cuts will limit the participation of State and local government in the Environmental Monitoring and Assessment Program (EMAP).

The ecosystem research program is combined with human health in ORD Goal 4, so it is sometimes difficult to determine what constitutes ecosystem research. Additionally, there is some confusion about the relationship between the water quality research program and ecosystem research, although there is actually little overlap. We hope that with a new emphasis on valuation and ecosystem services, this research program will grow again.

Sustainability, pollution prevention, economics and decision-making. The suite of research efforts in pollution prevention, sustainability, and economics and decision-making are EPA's pro-active agenda to get ahead of environmental problems through prevention, development of new technology, and partnerships with State and local government and other stakeholders. The Office of Research and Development should be commended for developing a sustainability strategy that was recently approved by EPA's Science Advisory Board.

As documented at our recent national conference, the field of "green chemistry"—using products designed from nature without harmful side effects—offers great promise to reduce the need for regulation and contamination. Everything from natural, short-lived biodegradable pesticides to new energy sources can be made safer and will provide great economic opportunities as well as environmental and health benefits. Sustainability provides new partnerships as well as new technologies. Communities and other stakeholders are brought into the research program from the beginning.

Unfortunately, ORD's efforts to be pro-active and implement a new sustainability approach, as is being done in the business community is being undermined by debilitating cuts to a budget that is too small already. The very small but effective grants program in Cooperative Science and Technology is to be terminated in the FY 2008 budget. This program provided grants to states, counties and others from New York City to Puerto Rico that need science to help resolve or prevent problems.

The remaining sustainability research is largely what had been called pollution prevention. This intramural program includes key tools to support decision-making such as life cycle analysis, metrics of sustainability and flows of materials, technological assistance, including using SBIR incentive funding to develop and commercialize innovative environmental technologies needed by EPA regions and states and agency regulatory and compliance programs to protect human health and the environment. Sustainability research is planned to be cut to $ 22.5 million, a little more than half of the $42 million provided as recently as FY 2004.

Initiated in 1994 and modified in 1999, the STAR grant Economics and Decision Sciences (EDS) program supports innovative economics and decision science research. It is the only significant research effort at the EPA that addresses behavioral science research issues. EDS results have led to decreased pollution control costs, and improvements the efficiency and effectiveness of environmental policies. These practical and usable results improve understanding of polluter motivations as well as the incentive structures of policies and how people value human and ecosystem health.

According to a 2005 presentation by Kohler and Clark for the Association of Public Policy Analysis and Management, the EDS program "has established an incredible track record that has generated practical results now being used by environmental policy-makers throughout Federal, State, local and international governments." STAR EDS research is influencing the design of international and federal multi-pollutant legislative initiatives. EDS research on cost-benefit analysis "contributed to the Office of Management and Budget's recommendation that EPA not use an age-adjustment factor in its cost-benefit analyses of air quality regulations." Another important beneficial outcome of EDS research has been information that enables states to efficiently prioritize habitat protection programs. EDS research is providing local governments tools to preserve their most important local lakes, streams, and wetland. They also provide numerous examples of how this research has been used by various EPA offices and the private sector as well.

Kohler and Clark conclude, "Since its inception, funding for EDS research has amounted to $20 million over approximately 10 years, averaging two million per year. Potential savings from widespread application of economic incentives to solving environmental problems could reach $45 billion annually (Anderson and Lohof 2001). On a practical level, acid rain trading savings are at least $700 million annually. Research on the *private* benefits of R&D shows that the market value of private spending on R&D is capitalized at a rate of 2.5 to eight (with most estimates centered at five and six) (Hall 2000). By comparison the *social* benefit of EDS R&D can range up to 22,500 times the investment of public money in research, assuming that *all* average annual funding for EDS research to date can account for these potential $45 billion annual savings. However, this back-of-the-envelope calculation does not include the investment in time of policy-makers and legislators necessary

for new legislative initiatives. Assuming that only one percent of the potential savings accrued to the U.S. society are associated with EDS research would yield an annual benefits rate of 225. More specifically, funding for the Burtraw study amounted to $251,000 over two years, and can be associated with up to $700 million savings per year from trading programs—a rate of 56 times (assuming a one percent association between EDS research and public benefits), which is well above the market value of private sector R&D."

Despite these successes, this high impact, low cost $2 million grant program is scheduled for *elimination* in FY 2008.

Without these innovative approaches that underlie a preventative, flexible and market-based approach, environmental protection will be left with the same old command and control system to ineffectively minimize the number of poisons that industrialized society feeds ourselves, our children, and our fellow living beings.

Graduate Fellowship Programs

To ensure a strong supply of future environmental scientists and engineers, EPA created the STAR Fellowship program. There is considerable concern about the retirements of the baby boom generation and the need to replace the scientific and technical skills of the federal, state and private workforce. The STAR fellowship program is the *only* federal program aimed specifically at students pursuing advanced degrees in environmental sciences. According to the National Academies report, "The STAR fellowship program is a valuable mechanism for enabling a continuing supply of graduate students in environmental sciences and engineering to help build a stronger scientific foundation for the Nation's environmental research and management efforts." A majority of the STAR Fellows conduct ecological research, where the funding sources are very scarce compared with environmental health. We note that a large percentage of the STAR fellowships have been awarded to graduate students in CEDD member universities and colleges. As of January 2006, 88 of 134 CEDD institutions have been awarded NCER grants or fellowships. A total of 581 grants (including 26 centers), and 595 fellowships have been awarded to CEDD institutions for a total more than $389 million dollars.

As academic administrators of most of the Nation's environmental programs, the CEDD membership recognizes increasing student interest to "do something for (or about) the environment." There are many, many bright deserving students who want to work to make the Earth a better and safer place to live. There is also a cadre of young faculty truly dedicated to working across disciplines to affect good decision-making based on science. Increases in the STAR program are important to produce the scientists and engineers needed for the future.

The STAR Fellowship program has also been repeatedly proposed for budget cuts by this Administration, only to be restored each year by Congress. Ironically, because Congress has restored funds after this program was zeroed out by the Administration in the FY 2003 request, the EPA regards the STAR fellowship to be "an earmark." The budget for the fellowship program has been slightly under $10 million for most of its 10 year history. However, because of the unusual appropriations process for FY 2006, EPA is only adding $1.8 million to the FY 2006 request of $5.9 million for a total of $7.7 million in the soon-to-be-released EPA operating plan. Thus the program and the number of graduate students it can support is being reduced by some 20 percent this year.

The President's budget request has again has proposed cuts in the STAR graduate fellowship program to $5.9 million (an additional cut of some 20 percent). As noted in the Science Committee's Views and Estimates on the FY 2007 budget, this is "one of the most troubling decreases." The Committee stated that "the fellowship program should be funded at $10 million, the level restored by Congress in each year beginning with FY03." We thank this subcommittee under former Chairman Ehlers for its leadership and strong support to keep the STAR fellowship program alive although it is now wounded. We hope that under the leadership of Chairman Lampson and Ranking Member Inglis, you can help this program and the number of environmental scientists and professionals it produces to grow.

The STAR fellowship program is highly competitive, with only seven percent of applicants being awarded fellowships. The current level of funding is insufficient to allow all students whose applications are rated as excellent to receive fellowships and it is insufficient to meet national needs for a scientifically trained workforce. Based on the experience of NCSE staff as reviewers of the STAR fellowship applications and CEDD members as advisors for students who have applied for and have not received fellowships, we recommend doubling the funding for STAR fellowships to $20 million, which can be accomplished without any decrease in the quality of the awardees.

The lack of diversity in the environmental field, which is one of the least diverse fields of science, is also a key issue, as the demographics of America are rapidly changing. EPA has begun to address this challenge by creating the Graduate Research Opportunities (GRO) Fellowship. This program was intended to be specifically for students from ethnic minorities, but it now needs authorization to allow a focus on diversity as well as dedicated and sufficient funding. We recommend that the Science Committee authorization of EPA research in FY 2008 include specific language restoring the purpose of the GRO Fellowship to bring more minorities into the environmental field.

Office of Environmental Education

The FY 2008 budget request once again proposes no funding for the EPA Office of Environmental Education. Since 2003, the Administration has tried to zero out this office, which support the programs mandated by the *National Environmental Education and Training Act,* programs administered by this office. The Congress has seen fit to appropriate about $7–$9 million each year over the past decade. However, as with the STAR fellowship program, EPA regards it as an earmark, so its future is uncertain. NCSE strongly encourages Congress to restore funding of at least $10 million. The programs of the Office of Environmental Education provide national leadership for environmental education at the local, State, national and international levels, encourage careers related to the environment, and leverage non-federal investment in environmental education and training programs. We also request that the Science Committee encourage the Education Committee to re-authorize and strengthen the *National Environmental Education Act of 1990* (P.L. 101–619), as the funding authorization under this law expired in 1996.

EPA Libraries

Every scientist needs access to a library in order to keep current on developments in the field and to support their professional activities. EPA had an exemplary library system, where as a network, every library at EPA helped their colleagues every day in many ways to keep EPA's information services viable. The EPA Headquarters libraries and the 27 regional and laboratory libraries, staffed with experienced, professional librarians who facilitate access to information, fielded 134,000 research requests from EPA scientists and enforcement staff and others in the last year. The EPA Libraries house and catalog unique collections, including approximately 50,000 primary source documents not available elsewhere in any format, on vital environmental issues. They also serve as institutional repositories for internal documentation as well as commercially published literature about the topics agencies regulate, investigate, and research; operate public reading rooms, providing access to collections that are specifically tailored to meet the needs of constituents in their geographic region, at times specifically offering that access to comply with federal law.

Despite this, EPA is in the process of dismantling this network, with no coordination budget and at least seven locations closed, ostensibly to move to online information systems. The proposed FY 2007 budget for EPA Libraries contained a $2.5 million cut, which, according to the American Library Association has already resulted in the closure and imminent closure of some headquarters, regional and laboratory libraries and the reduction of staff at other EPA Libraries; will put the collections and services of the EPA Libraries at risk, causing essential information about the environment to be lost; would compromise the public's health and safety by making it difficult, even impossible, for the EPA staff and scientists, other scientists and researchers, the public, contractors and regulated industries, and federal, State, and local policy-makers to find accurate and high-quality information upon which to base decisions about health and safety concerns. Foremost among the critics of the EPA plans to close or reduce services and access to collections and otherwise remove information resources critical to the EPA's mission, are the EPA employees. Within weeks of implementing plans to close regional libraries and libraries and special library collections in the EPA Head Quarters in Washington, DC, the presidents of 17 union locals representing more than 10,000 EPA researchers, scientists, and support personnel, lodged formal protests against these EPA actions. *(http://www.peer.org/docs/epa/06_29_6_union_library_ltr.pdf)*

The EPA could have made a very cogent statement about their need to reconfigure the entire EPA Library Network. They could have easily justified closing some of the individual libraries. However, the complete lack of a management plan and an 80 percent cut in the budget to see such a transition through to completion leads us to question both the intent and effectiveness of the closures. With a $2.5 million increase in its budget to see that such a reconfiguration was done properly with great care given to seeing that the transition was done effectively, efficiently,

and with equity, the EPA Library Network and its managers *could* have designed one of the largest scientific libraries (or information centers) of the 21st century. We recommend that Congress direct EPA to cease the closures and prepare a management plan and a budget of sufficient magnitude to allow transition to a state-of-the-art environmental information system.

Conclusion

In order to fulfill its mission, EPA needs increased investments in both its intramural and extramural science programs, as well as such associated services as environmental education and information. The National Council for Science and the Environment and our Council of Environmental Deans and Directors urges Congress to appropriate a minimum of $700 million for EPA's Office of Research and Development (bringing it back to FY 2004 levels), including at least $150 million for EPA's Science to Achieve Results (STAR) research grants program and $20 million for EPA's STAR graduate fellowship program. We recommend a total of $900 million for EPA's Science and Technology account. NCSE also urges Congress to restore full funding for the Office of Environmental Education at a level of at least $10 million and to terminate the effort to eliminate EPA libraries absent a sufficiently funded modernization and management plan. Even these levels of funding would, for the most part, bring EPA science back to its level in FY 2004. We hope that in future years, EPA's science budget will grow to better match the Nation's needs.

In the case of EPA, there is a strong relationship between input to environmental research and education and output in terms of environmental protection. If the Nation wants more effective and efficient environmental protection, we need to make the upfront investment in science. It really is the ounce of prevention that is worth many pounds of the cure.

Program / Project	FY 2003 Enacted Budget	FY 2004 Enacted Budget	FY 2005 Enacted Budget	FY 2006 Enacted Budget	FY 2007 President's Budget	FY 2008 President's Budget
	Extramural	Extramural	Extramural	Extramural	Extramural	Extramural
Research: Particulate Matter[1]	$17.1	$13.0	$15.8	$0.0	$0.0	$0.0
Research: NAAQS[1]	$0.0	$0.0	$0.0	$16.7	$17.2	$0.0
Research: Clean Air[1]	$0.0	$0.0	$0.0	$0.0	$0.0	$17.2
Research: Drinking Water	$2.5	$3.6	$4.5	$4.4	$4.6	$4.6
Research: Water Quality	$1.2	$1.1	$0.9	$0.9	$1.0	$0.0
Research: Land Protection and Restoration	$2.2	$2.7	$0.0	$0.0	$0.0	$0.0
Research: Computational Toxicology	$2.4	$2.4	$3.4	$3.3	$3.4	$3.4
Research: Endocrine Disruptors	$4.6	$2.7	$0.0	$1.6	$0.0	$0.0
Research: Fellowships	$9.7	$9.5	$9.2	$9.3	$5.9	$5.9
Research: Global Change	$4.8	$6.7	$6.7	$6.5	$6.7	$6.3
Research: Human Health and Ecosystems	$39.5	$37.6	$27.5	$26.0	$23.6	$23.6
Ecosystems	$18.4	$13.4	$0.0	$1.5	$0.0	$0.0
Human Health	$14.5	$15.4	$18.1	$18.1	$18.6	$18.6
Mercury	$2.0	$1.8	$0.0	$0.0	$0.0	$0.0
Exploratory Grants (Nanotechnology)	$4.6	$4.0	$3.9	$3.9	$5.0	$5.0
Exploratory Grants (Non-Nanotechnology)	$0.0	$3.0	$5.5	$2.5	$0.0	$0.0
Research: Pesticides and Toxics	$0.0	$1.0	$1.0	$1.0	$1.0	$1.0
Research: Pollution Prevention[2]	$5.5	$5.2	$2.1	$0.0	$0.0	$0.0
Research: Sustainability[2]	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Research: Economics and Decision Sciences[2]	$0.0	$0.0	$0.0	$1.9	$2.0	$0.0
Total	**$89.4**	**$85.5**	**$71.1**	**$71.7**	**$65.3**	**$61.9**

1. In FY 2006, Research: Particulate Matter and Research: Tropospheric Ozone merged to form Research: NAAQS. In FY 2008, Research: NAAQS and Research: Air Toxics merged to form Research: Clean Air.

2. In FY 2006, Pollution Prevention divided into its constituent programs (Research: Sustainability and Research: Economics and Decision Sciences).

EDITORIAL

R. J. Jackson is adjunct professor of Environmental Health at the University of California at Berkeley and former director of the Centers for Disease Control and Prevention National Center for Environmental Health.

Environment Meets Health, Again

THE SEEMINGLY INSURMOUNTABLE HEALTH CHALLENGE IN THE 19TH CENTURY WAS infectious disease. In the 21st century it will be a mix of global warming, poverty, and infectious and chronic diseases. Life expectancy in the United States is now twice that of the 19th century, and environmental health—healthier food, cleaner water, better places to live (the "built environment")—has been the greatest contributor. Can environmental health address 21st-century challenges?

Environmental health in the 19th century was practiced by physicians and scientists, but, importantly, also by business people, engineers, lawyers, architects, politicians, and many others outside health and science. The primary tools for health improvement were infrastructure and sanitation. For example, it was Frederick Law Olmsted, the man behind urban landscapes like New York City's Central Park, who headed the Sanitary Commission during the Civil War that saved thousands of lives.

Over the past 50 years, environmental science and practice have become specialized but also fragmented. The U.S. Environmental Protection Agency, which was created largely out of federal health programs in 1970, focused on legal and engineering strategies related to air and water pollution, as well as species and land protection. Meanwhile, environmental health practitioners in local agencies hunkered down to enforceable and fee-supported activities like food service inspection. And environmental health scientists increasingly emphasized mechanisms of toxicity or illness within biological systems.

This separation led to decisions where a solution for one problem created unexpected collateral effects: the chemical MTBE that was added to gasoline to prevent air pollution caused groundwater contamination; flame retardants required in consumer products turned out to be human milk contaminants and carcinogens. Today, environmental health in the United States is vested in many agencies, not just those titled Environment or Health, but also Transportation, Education, Housing, Energy, Agriculture, and Defense. Each has its critical primary mandate, but each influences essential elements of the requirement to protect health and the environment. The complex challenges of the 21st century cannot be met by a set of stovepipes as disconnected as these.

Can we fix the present system? Two illustrations, one historical and the other emerging, lend hope. The first was the success of the focus on children's environmental health in the 1990s. The Food Quality Protection Act of 1996 required that children's health be the benchmark for decisions on allowable levels of pesticide residues in food, the tenet being that protecting the most exposed and sensitive in the population protects everyone. At the 10th anniversary of this Act, one-third of pesticide tolerances have been revoked. Recognizing the improvements that a children's health initiative could bring about, President Clinton ordered that all agencies develop strategies to improve the health of children, and mandated twice-yearly cabinet-level meetings to make it happen. After a cautious and questioning start, each agency recognized that it had large impacts on children's well-being, for example, Transportation in terms of safe routes to school or Housing in terms of indoor air quality. Several important efforts, including the proposal for the National Children's Study, grew out of this initiative.

The second example is more contemporary. Public health leaders are asserting—as had leaders 150 years earlier—that the built environment profoundly influences health. The focus this time is not urban tenements, but rather the fragmented and sprawling communities that foster car dependency, inactivity, obesity, loneliness, fossil fuel and resource consumption, and environmental pollution. Concern about the built environment's effects on health has caught fire, with joint health and urban-planning conferences and strategy sessions, pending legislation, and an increasing number of new scientific studies. Disciplines long estranged from health issues—planners and architects, environmentalists, even builders and developers—are becoming engaged. It's a good time to spread ownership of health and environment challenges. The challenges of the 21st century will require leadership and collaboration. It worked in the 19th century; it can work today.

-Richard J. Jackson

10.1126/science.1141968

BIOGRAPHY FOR BRUCE C. COULL

Dr. Bruce Coull is the 2006–2008 President of the U.S. Council of Environmental Deans and Directors (CEDD) a program of the National Council for Science and the Environment (*http://www.ncseonline.org/CEDD*). He leads this professional organization of deans, institute directors and environmental program administrators at more than 130 colleges and universities across the U.S. CEDD is carrying out projects to improve environmental curriculum, better prepare alumni for environmental careers, increase diversity in the field and to advance interdisciplinary education. CEDD works with partner organizations in Canada and the UK.

Dr. Coull recently became emeritus at the University of South Carolina, where as a Carolina Distinguished Professor and Dean of USC's School of the Environment, Coull led USC to approach environmental issues through multi-disciplinary research, education and community outreach. He headed the South Carolina Sustainable Universities Initiative (*http://www.sc.edu/sustainableu*), a multi-university project educating about frugal use of Earth's resources and was the architect of the greening of the University of South Carolina. He also led USC's environmental efforts in the Ukraine related to the Chernobyl nuclear accident of 1986. In his emeritus status he directs the South Carolina Lowcountry Initiative of the Chicago and New York based Center for Humans and Nature (*http://www.humansandnature.org*). This initiative aims to effect sensible use of resources in the South Carolina coastal region. Local decisions-makers are the target of this project.

Coull was educated at Moravian College and Lehigh University—both of which are located in Bethlehem, Pennsylvania. He was a postdoctoral fellow at the Duke University Marine Laboratory in North Carolina and an Assistant Professor at Clark University, Massachusetts before joining the University of South Carolina (USC) faculty in 1973. While at USC he taught over 10,000 students in Marine and Environmental Sciences and held research grants from the Environmental Protection Agency (EPA), the National Science Foundation (NSF), the National Oceanic and Atmospheric Association (NOAA) and multiple private foundations. He has directed over 60 theses and Ph.D. dissertations at USC.

He was a senior Fulbright Research Fellow at Victoria University of Wellington, New Zealand in 1981 and a Visiting Professor in Marine Sciences at the University of Queensland, Brisbane, Australia in 1994. He was President of the American Society of Zoologists, the American Microscopical Society, and the International Association of Meiobenthologists as well as advisor to the European Community on Marine Pollution. He is the author of 130 scientific papers in Ecology, Ecotoxicology and Sustainability in Higher Education and the editor of four Marine Ecology books.

He is married to Judith, a graduate of Wheaton College, Massachusetts. They have two children, Brent (Associate Professor of Biostatistics, Harvard University) and Robin (Social Worker, Brooklyn, NY) and one grandchild. Hobbies include fishing, walking, canoeing, and nature-based tourism.

DISCUSSION

THE SUPERFUND INNOVATIVE TECHNOLOGY EVALUATION (SITE) PROGRAM

Chairman LAMPSON. Thank you very much. So let us begin our questions. Dr. Gray, in EPA's fiscal year budget, the Agency indicated that it would clean up 40 Superfund sites. In the Energy and Commerce Committee hearing last week Administrator Johnson indicated that the Agency would not be able to clean up 40 sites this year and that the new estimate to clean up would be 24 sites. Is that correct?

Dr. GRAY. That Superfund is handled within a different office, but it is my understanding, I was at that hearing, and that is what the Administrator said.

Chairman LAMPSON. Okay. The Administrator indicated to the Energy and Commerce Committee that the reduction in the projected number of site cleanups this year is due to the fact that the sites remaining to be cleaned up present greater challenges, have

more complex problems, and take more time and effort to clean up. Is that your understanding?

Dr. GRAY. Yes, it is.

Chairman LAMPSON. And can you explain to the Subcommittee why if we still have complex cleanups that require more time and money to complete than the average site, the administration has chosen to eliminate funding for the Technology Development and Verification Program Congress mandated in the Superfund Law. The Superfund Innovative Technology Evaluation or SITE Program?

Dr. GRAY. Certainly. The SITE Program is a mature program that has been around for very many years. It has demonstrated a wide range of technologies and approached that have the opportunity to improve the efficiency of cleanups at Superfund sites. However, at this point this is something that is more appropriately handled in the private sector, and the SITE Program now is being closed down, and the private sector is picking up many of those technologies that were identified and verified through the SITE Program and making them available.

It is important to recognize that the Office of Research and Development continues to support the Superfund Program. We have seven technical support centers across the country in which we provide direct, both scientific and engineering support, to the program managers out there in the field, on the ground, at Superfund sites, making sure that they have access to that science and to that engineering information.

Chairman LAMPSON. Dr. Gray, is this an example of the President, again, choosing not to follow the law passed by this Congress and signed by him?

Dr. GRAY. This is a situation in which we have to make as an agency and as an office decisions about scientific priorities while making sure that we are meeting our environmental commitments. In this case we are—our commitment to help the Superfund Program through our technical support centers is something that we will continue.

LABORATORY INFRASTRUCTURE

Chairman LAMPSON. Are there plans to reduce staffing or space of EPA's laboratories?

Dr. GRAY. No, there isn't. Actually, I am glad you asked me that question, because there is some sort of—there is rumors and misinformation running around out there. What has happened is we have been asked, and ORD has been asked to take the lead on a study of the laboratory infrastructure of the EPA. We have been asked to look at the efficiency and the effectiveness of our 27, I believe, I am not sure about the number, of all our laboratory assets that are spread across this country.

The last time we did this was back in 1993, and we thought it was time to do something like this again. What we are doing is a short-term effort and a long-term effort. The short-term effort is looking for place-specific efficiencies, best practices that are happening in one laboratory that we can transfer to another. The longer-term will bring in an outside group to help us look at our laboratory infrastructure to understand that work that is being

done there and understand options we have for making it efficient and effective.

A very important thing to recognize, and this is something that the Administrator said at our House Appropriations Committee hearing is that he is not intending to shut down any laboratories, no laboratories will be shut down, and no scientists will be let go.

Chairman LAMPSON. Let me continue. I have two copies or I have copies of two memos here; one dated June 8, 2006, authored by Lyons Gray, Chief Financial Officer, and the other dated October 26, 2006, by Lek Kedeli, Deputy Assistant Administrator for ORD. They both relate to the preparation of the fiscal year 2008 budget and to some future budgets, and both discuss the development of plans to reduce costs associated with EPA's laboratories. I ask first unanimous consent that they be placed in the record for this hearing. Without objection, so ordered.

[The information follows:]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF THE
CHIEF FINANCIAL OFFICER

JUN 8 2006

MEMORANDUM

SUBJECT: FY 2008 Technical Budget Guidance

FROM: Lyons Gray
Chief Financial Officer

TO: Assistant Administrators
General Counsel
Inspector General
Regional Administrators

Thank you for the opportunity to speak with you individually and for sharing your thoughts on the difficult choices we will need to make as we develop the FY 2008 budget. I appreciate the ideas and suggestions that many of you have offered for potential savings for 2008 and beyond. As I mentioned, the FY 2008 budget presents difficult challenges for the Agency.

This memorandum provides Agency technical guidance on the next phase of the budget process. Based on our analysis, responses provided to the templates and discussions at the hearings, OCFO has developed a set of proposed disinvestments, innovations, efficiencies, and consolidations. Your written comments and responses to our proposal are due no later than Tuesday, June 20, 2006. OCFO will develop a Straw Budget, which we will share with you prior to our Senior Leadership Meeting on July 17.

APPROACH TO THE FY 2008 BUDGET PROCESS

In keeping with the Administrator's principles, our FY 2008 budget will promote environmental results and accountability, innovation, best available science, and collaboration in our work with all of our partners taking into account a very challenging budget forecast. The decisions we make will be critical, difficult, and will have long-term consequences. We must evaluate our programs across the Agency to identify priorities, reduce duplication, and identify opportunities for consolidation and streamlining. We must continue to emphasize ways to deliver our programs more effectively. We will continue to rely on performance and results information as key decision factors in developing our budget. The Agency will need to defend its budget by demonstrating past and future achievements through measurable improvements in program performance.

Attachment B

GUIDANCE FOR PREPARING NPM AND REGIONAL SUBMISSIONS

FY 2008 SAVINGS

Based on our one-on-one conversations with the AA's, discussions that will take place at the Senior Leadership meeting, and decisions by the Administrator, OCFO will issue final FY 2008 budget target levels and guidance for the OMB submission by the first week of August. Agency managers will have through mid-August to complete resource data, performance data, and justifications for the OMB submission. At that time, OCFO will work with NPMs to resolve any outstanding issues so that the budget can be submitted to OMB by the deadline of September 11, 2006.

OUTYEAR SAVINGS: FY 2008 AND BEYOND

Beginning this year (FY 2006), we will explore long term opportunities to achieve larger savings and efficiencies into the future. As budget constraints continue, our ability to link budget, performance, and results more closely will become increasingly important.

Attachment D: Template for NPM acceptance of OCFO proposal
Attachment E: Template for NPM alternative response to OCFO proposal
Attachment F: NPM and regional proposal for targeted FTE buyout/early-out
Attachment G: Regional proposal for FTE realignment

For your information, we have also included a schedule of key dates as Attachment C and a list of OCFO contacts as Attachment H.

I. Submissions for FY 2008 due by June 20th

- ***Addressing OCFO Proposals*** - Each NPM must explain how it will achieve the specific reduction OCFO has proposed by either:
  1) Accepting the OCFO proposal using the template provided as ***Attachment D***, or
  2) Providing alternative disinvestments using the template provided as ***Attachment E***. (Any alternatives proposed must meet OCFO's target.)

- ***Proposals for Targeted FTE Buyout / Early-out*** - NPMs and Regions are asked to identify FTE from GS 12 to GS 15 for proposed targeted reductions Please reference ***Attachment F*** for more information.

- ***Regional FTE Realignments*** - Beginning with the FY 2008 Budget, Regions will be responsible for determining how best to allocate their FTE. Regions still must meet performance commitments agreed to with the NPMs, but FTE shifts may be made to accommodate the priorities and needs of the Region. At this time, we would like to codify regional FTE shifts that were proposed in the hearing templates or subsequent to the hearing. Regions should complete Attachment G if they propose to make FTE shifts. Recognizing that additional FTE reductions will occur, Regions will have another opportunity to make FTE shifts during the formulation phase of the FY 2008 budget process. Please note that with this control over your resources, Regions also

will need to actively participate in the development of all justification materials and explain any changes.

- OARM is directed to develop a plan implementing grant set asides which addresses how the costs of administration will be calculated, how costs will be charged, and how the set aside will be implemented within the Agency. The proposal should specifically identify what the Agency would do with the set aside funds. OARM also should outline the advantages and disadvantages associated with this idea.

- OARM, with Region 8 and AIEO as Co-Leads, is directed to develop a plan with options to reduce tribes' administrative burden, for example through the use of block grants.

II. Exploring Outyear Savings: FY 2008 and Beyond

The Agency needs to develop a set of plans to realize long term efficiencies and savings. This process will start in 2006 and continue through the next 5 years.

Submissions for the **June 20th deadline** should include:

1) An outline of the overall process for developing the products listed, and
2) A timeline for creating the products

The Agency will consider the long term projects listed below. While the initial submission is due on June 20th, the plans will be long term, with milestones beginning in FY 2006. As needed, OCFO will provide feedback and additional guidance in the July Straw Budget. To guide your thinking, items to be included in the plans are listed in each section. Each lead office is asked to assign a senior manager as a point of contact. To save on travel costs, workgroups are encouraged to meet via teleconferencing or video conferencing.

A. Centers of Excellence Plan: OARM and the Lead Region (Region 1 in FY06, Region 9 in FY07-08), working with lessons learned from Region 7, are to develop a plan to consolidate and streamline Agency functions related to contracts, grants, and human resource work (e.g., by creating centers of excellence). Each function is to have up to three regional centers. Headquarters and other ancillary offices can be considered as centers.

The plan should include:

- Mutually agreed locations for each center.
- Facilities and equipment requirements of each center.
- Space reduction or consolidation plans, including proposals for emptied space.
- An approach for reducing or relocating necessary staff, including a FTE transition strategy.
- Expected savings and interim implementation expenses.

B. Laboratory Consolidation: - ORD will coordinate a workgroup comprised of other NPMs

and Regions to develop a plan for reducing the Agency's laboratory physical infrastructure costs by a minimum of 10% by 2009 and another 10% by 2011.

The Laboratory Consolidation Plan should outline:

- A recommendation for closing, relocating, and consolidating lab/field locations.
- An approach for relocating wet and dry laboratory equipment, personnel, and functions to localized centers of excellence, for example, by designating one location to do all micro-array work.
- An approach for reducing or relocating necessary staff, including a FTE transition strategy.
- An analysis of the cost per square foot and personnel per square foot of laboratory space before and after plan implementation.
- An implementation plan and schedule.
- Expected savings and interim implementation expenses.

C. Centralized IT Service Consolidation Implementation Plan – OEI will take the lead in developing a plan for reducing the Agency's IT/Network Services costs by consolidating servers and other mechanisms across the Agency, including small systems. The goal is to achieve at least a 10% to 15% savings. OEI will coordinate a workgroup with designated representatives from the Regions and NPMs to produce this plan. The plan may present multiple options or scenarios for achieving these reductions. OEI should utilize current inventories of IT systems.

The IT Consolidation Plan should outline:

- A recommendation for closing, relocating and consolidating agency IT projects (including small systems) and Network services such as file servers and email servers.
- An approach for relocating computer equipment, personnel, and functions to localized centers of excellence and the costs and savings associated with such moves.
- An approach for reducing or relocating necessary staff, including a FTE transition strategy.
- The implementation plan and schedule.
- Expected savings and interim implementation expenses.
- A justification that links to E-GOV Initiative.

OEI should provide savings for this effort starting in FY 2007 with significant savings in FY 2008.

D. Long Term Space Consolidations – OARM will develop a process to ensure a 90% to 95% occupancy rate for all Agency facilities by 2010. OARM should start the process by establishing the framework to address the steps required to consolidate office space in the national capital region and expand the effort to include regional and field offices. OARM should establish a workgroup with input from Regions and NPMs to ensure the plan covers all of EPA's facilities.

The Space Consolidation Plan should address:

- The process to inventory space requirements.
- The methodology used to target facilities for consolidation and/or closure.
- The process to request space changes including the approval and decision making processes.
- The implementation plan, including a milestone schedule.
- The impact and costs associated with relocating staff and reconfiguring space.
- Average costs per square foot for the various types of space (Office, conference rooms, field offices, etc.).
- Alternative solutions to keep rent/leased costs down.
- Expected savings and interim implementation expenses.

E. Energy Efficiencies: - OARM will continue its effort to establish a plan for reducing overall energy use within the Agency, including satellite offices. OARM will develop a plan for reducing the Agency's utility budget by a minimum 10%.

The Energy Plan should outline:

- A recommendation that addresses linking BTUs to the utility budget.
- An implementation plan and schedule.
- Expected savings and interim implementation expenses.

F. Voluntary programs: -OPPTS and its Lead Region are directed to develop a plan to review the Agency's voluntary programs to develop options for consolidation to maximize efficiency and results. The review also should consider severity of the environmental problems addressed and the effectiveness of the approach. The plan should include milestones and for the analysis and for the development of criteria as well as implementation options. OPPTS should form a workgroup for this effort; all NPMs are to be included except enabling/support programs.

G. Reducing Reporting Burden:

Reducing Reporting Burden: States

1. OCIR is directed to request that ECOS compile a comprehensive inventory of State reporting requirements imposed by EPA. The plan for conducting the inventory is due on June 20, 2006, and the inventory should be completed by November 2006.

2. OCIR is directed to coordinate with NPMs and Regions to compile a comprehensive inventory of EPA reporting requirements affecting the States. The plan for conducting the inventory is due on June 20, 2006, and the inventory should be completed by November 2006.

3. OCIR will compare the ECOS and EPA inventories to ensure all state reporting requirements are included. OCIR will then conduct an analysis and prioritize areas where the State reporting requirements can be reduced by EPA and those that would require Congressional approval.

Attachment B

OCIR will report to the Agency's senior leadership on its findings and recommendations.

Reducing Reporting Burden: Tribes

1. The American Indian Environmental Office (AIEO) is directed to work with the Tribal Caucus to compile a comprehensive inventory of Tribal reporting requirements imposed by EPA. The plan to conduct the inventory is due on June 20, 2006, and the inventory should be completed by November 2006.

2. AIEO is directed to coordinate with NPMs and Regions to compile a comprehensive inventory of EPA reporting requirements affecting the Tribes. The plan to conduct the inventory is due on June 20, 2006 and the inventory should be completed by November 2006.

3. AIEO will compare the inventories to ensure all tribal reporting requirements are included. AIEO will then conduct an analysis and prioritize areas where the tribal reporting requirements can be reduced by EPA and those that would require congressional approval. AIEO will report to the Agency's leadership on its findings and recommendations.

Status Update: Regulatory Burden

OPEI is directed to provide an update of their review of selected rules (now underway), per a commitment to the Agency and ECOS in 2005. The update should describe the proposed approach, key milestones, and expected completion date, and is due June 20.

United States Environmental Protection Agency

October 26, 2006

MEMORANDUM

SUBJECT: Laboratory Infrastructure Review

FROM: Lek Kadeli, Deputy Assistant Administrator
Office of Research and Development

Ira Leighton, Deputy Regional Administrator
Region 1

TO: Deputy Regional Administrators
Deputy Assistant Administrators

In the U.S. Environmental Protection Agency's (EPA's) FY 2008 Technical Budget Guidance issued by Lyons Gray on June 8, 2006, an approach to exploring long-term efficiencies and out-year cost savings through a number of strategies was set forth, including centers of excellence, centralized information technology (IT) services, and energy efficiency. The Office of Research and Development (ORD) was asked to work with the other national program managers (NPMs) and regions to develop a plan to reduce the costs associated with the Agency's laboratory physical infrastructure.

ORD and Region 1, as lead region for ORD and Regional Science and Technology (RS&T), are proposing in the attached draft charter a set of guiding principles, a structure, and a timeline by which the task of identifying strategies to reduce costs, while maintaining the sound scientific underpinnings of EPA's work, can be accomplished. We have modeled this laboratory infrastructure review after the successful approach used by the regions and NPMs to address competitive sourcing in FY 2004 – 2005. The process is designed to be inclusive and collaborative in spirit, and we would strongly encourage your offices' active participation.

We have scheduled an opportunity to discuss the draft charter and seek your feedback at the November 3, 2006 meeting of the Deputy Regional Administrators and Deputy Assistant Administrators. In particular, we would appreciate your thoughts on the following questions in addition to the content of the Draft Charter:

- What additional stakeholders should be involved in the process?
- Should we involve a third party review of the process and/or decisions?
- What is the process for identifying leaders and participants in the workgroups?

- What is the sequencing of the products from the workgroups? Should certain products be on a faster track?
- How do we ensure strong coordination with other efforts to identify efficiencies and cost savings?
- What is the appropriate frequency and format of communication with senior managers (e.g., Assistant Administrators, Regional Administrators) on the progress of the study?
- What is the appropriate frequency and format of communications with EPA laboratory staff?

Our laboratories provide the science and information that drives much of the Agency's work. This laboratory infrastructure review offers us an opportunity to position our laboratories well to serve the Agency's mission for decades to come. We look forward to feedback on whether you believe we have designed an approach that will be successful.

cc: ORD Laboratory/Center Directors
RS&T Directors
Program Office Laboratory Directors

DRAFT CHARTER: LABORATORY INFRASTRUCTURE REVIEW

The laboratories of the U.S. Environmental Protection Agency (EPA) contribute important scientific support vital to accomplishing the Agency's mission to protect human health and the environment. The purpose of this Laboratory Infrastructure Review is to identify efficiencies throughout the Agency's laboratory network that will allow EPA to more effectively achieve its mission. To maximize the opportunity for cross-office efficiencies, the review will look at the broad spectrum of EPA's laboratories, including the laboratories of the Office of Research and Development (ORD), the 10 regions, and the National Program Offices. The review will consider a wide range of ideas for improved efficiency and cost savings, while ensuring EPA laboratories will continue to deliver the strong science support needed by the Agency.

This Charter sets forth the *background* of the Administrator's overall goals for the Agency, the *guiding principles* by which the review will be conducted, the *structure* by which the review will be organized, and the *timeline* for completion of the review.

BACKGROUND

This review of EPA's laboratory infrastructure is consistent with the Administrator's goals as set forth with the following themes:

- *Best Available Science.* EPA needs the best scientific information available to anticipate potential environmental threats, evaluate risks, identify solutions, and develop protective standards. Sound science helps us ask the right questions, assess information, and characterize problems clearly to inform Agency decision makers.

- *Innovation and Collaboration.* Our progress depends both on our ability and continued commitment to identify and use innovative tools, approaches, and solutions to address environmental problems and to engage extensively with our partners, stakeholders, and the public. Under each of our goals, we are working to promote a sense of environmental stewardship and a shared responsibility for addressing today's challenges.

- *Results and Accountability.* EPA is committed to being a good steward of our environment and a good steward of America's tax dollars. To provide the public with the environmental results it expects and deserves, we must operate as efficiently and effectively as possible. Accountability for results is a key component of the President's Management Agenda, designed to make government citizen-centered, results-oriented, and market-based.

GUIDING PRINCIPLES

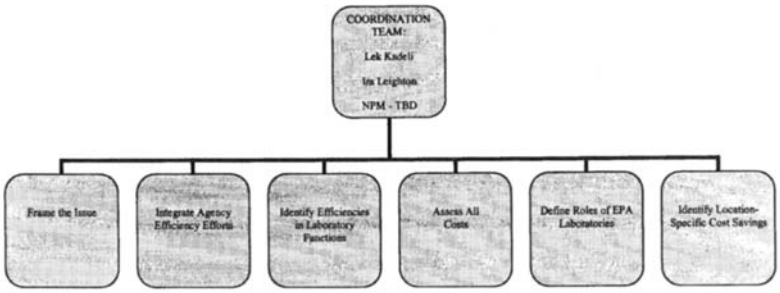
The review will be guided by a spirit of responsibility. The following principles will guide the review:

- The review will be driven by delivering the best science as cost-effectively as possible.
- The review will be conducted in an open process and transparent manner.
- The review will explore all reasonable options.
- The review will build upon the work of previous or ongoing efforts to improve efficiencies.
- The review will be conducted in a timely and concise fashion with conclusions ready by May 1, 2007.

STRUCTURE

To accomplish its mission, the review will need to gather and build upon the insights and ideas of many individuals in the laboratory community, while also remaining focused and strategic. The review would draw upon the work of several workgroups which would be charged with developing the products described below. Once combined and integrated, these work products will hopefully provide a holistic picture of the Agency's laboratories and options for increased efficiencies. As proved to be effective in devising a competitive sourcing plan, one or two representatives from the regional, ORD, and NPM laboratory community would lead each of the workgroups. Because this process has to be manageable, total membership on each workgroup will be target at approximately eight persons apiece. All information from each workgroup, however, will be shared with everyone. To the extent that workgroups identify low hanging fruit and recommendations that could be implemented immediately to realize savings, such actions should be taken.

The efforts of these workgroups will be overseen by a small Coordination Team consisting of the Deputy Assistant Administrator of ORD, the Deputy Regional Administrator of EPA Region 1, and a deputy of a National Program Office (to be determined). The Coordination Team will help the workgroups define their mission and stay focused on its accomplishment. The Coordination Team will also have the responsibility of ensuring that the effort is consistent with expectations of the Agency's Senior Managers, represented by the ORD Assistant Administrator, the Region 1 Regional Administrator, and an Assistant Administrator of a national program office (to be determined), and ultimately the Administrator.



- *Frame the Issue.* As an initial matter, it is important that the challenge facing EPA's laboratories be appropriately framed, taking into account past history of the laboratories and a thoughtful discussion of the trends in costs, mission, and outputs of the laboratories. In framing the challenge, we must recognize both the need to achieve long- and short-term savings and the need to support EPA's environmental mission with the best available science.

- *Integrate Agency Efficiency Efforts.* This review should not duplicate the work of existing efforts across the Agency (e.g., Energy and Water Use, Lab Commodities). It is critical that the laboratory efforts are aligned with other Agency efforts and should be utilized and pulled into this laboratory initiative wherever possible. Immediate involvement in these workgroups to insure maximum laboratory efficiencies in these areas is critical to completing the accountability for improvements in laboratory operations. We will also need to coordinate closely with the Office of Administration and Resource Management (OARM) and Region 9-lead efforts to identify efficiencies and cost savings throughout the Agency.

- *Identify Efficiencies in Laboratory Functions.* In the past, there have been some efforts among the regional laboratories to develop efficiencies through Centers of Excellence, which capitalize on the strengths of particular laboratories. We should build off these efforts and examine collaborative or work consolidation areas across the full range of EPA laboratories.

- *Assessing All Costs.* In order to identify potential cost saving, we will need to pull together laboratory cost information. We should consider not only the actual costs of operations, but also the avoided costs resulting from the multiple roles many laboratories play (e.g., COOP facilities, storage of field equipment, surge analytical) and the costs associated with relocating or closing a laboratory.

- *Define Roles of EPA Laboratories.* We should explore different models of providing laboratory services. We should also examine the roles of EPA laboratories and those in the private, academic, or state/tribal spheres, and determine where particular types of analytical or research work are most effectively conducted.

- *Identify Location-Specific Cost Savings.* Our laboratory network is spread throughout the United States in a very diverse array of locations that each offers their own set of opportunities. Each location should have the opportunity to evaluate its unique circumstances and to identify site specific opportunities for greater efficiency. Laboratories in close proximity should brainstorm together ideas for efficiencies across their locations. The workgroup should also encourage individual laboratories to brainstorm efficiency and cost saving measures and facilitate the distribution of these ideas to the other workgroups.

COORDINATION AND COMMUNICATION

The Coordination Team will serve as the focal point to ensure that the above work products are completed in a timely manner. Each of these workgroups will be provided a framework to collect information in a uniform way to aid in data integration and decision-making for the overall report. The workgroups developing the products will need to regularly report to the Coordination Team on their progress and present work products and recommendations as they are completed in an effort to move quickly on good ideas. The Coordination Team will convene with and provide regular updates to Regional Administrators and Assistant Administrators in order to receive input and feedback from them. Those senior managers can then be better prepared for ongoing dialogue with those involved in the decision making process, particularly the Administrator.

The Coordination Team will also produce and distribute periodic status reports to laboratory managers and staff, to keep them well-informed of the effort and to encourage the generation of additional ideas for efficiency.

TIMELINE

As with many projects, this one is no exception to having a very short timeframe of approximately six months for a very large undertaking of information gathering and proposed opportunities. A very ambitious timeline is outlined below to finalize this draft and begin the process. However, a commitment from each of the Agency's laboratories to utilize this opportunity to work collaboratively to develop efficiencies and cost savings is critical to the success of this endeavor. Critical points are identified to focus this effort towards filtering important information to the Coordination Team and senior managers to meet the end goal.

October 16	Draft Charter
October 16 – November 10	Discussions regarding Charter and Workgroup Identifications
November 15	Finalize Charter, Workgroup Leads Identified
November 15 – December 30	Workgroups Meet, Develop Work Plan, and Begin Data Collection
December 30 – April 30	Every other week Status Report from each Workgroup to the Coordination Team including Preliminary Findings or Recommendations
December 30 – April 30	Periodic Reports from Coordination Team to AAs and RAs
December 30 – April 30	Periodic Status Reports to Laboratory Managers and Staff
March 31	Final Work Product from each Workgroup
April 15	Draft Report to Senior Management
April 30	Final Report to Decision Maker

Chairman LAMPSON. The June 8 memo instructs ORD to put together a work group to develop a laboratory consolidation plan. The October 26 memo appears to be a response to this direction and invites input from deputy assistant administrators and deputy regional administrators to comment on the draft charter for the plan and asks for their responses to a series of questions. And I have some questions about those memos and this plan.

Does the Agency, agency's inclusion of stakeholders in this process include a role for Congress?

Dr. GRAY. We would certainly work with all of our stakeholders, not only our scientists but outside groups that are interested, including our union partners, and we would be happy to keep Congress apprised as we make progress here.

Chairman LAMPSON. These labs are located in Members' districts across the country. Has the Agency contacted any of these Members and informed them of laboratory review?

Dr. GRAY. This is a process that is just getting underway, and it, at this point we believe that we have to formulate our plans and understand how we are going to approach this. This is coming into view, as I said, with the short-term and long-term approach, and for that reason we have not widely contacted.

Chairman LAMPSON. Have not contacted members. Which EPA stakeholders are involved in the preparation and review of this plan?

Dr. GRAY. This plan is being reviewed and addressed. At this point there is not a plan. You have to recognize we do not have a plan. We are putting together an approach to look at our laboratory infrastructure. In the short-term we will be looking for opportunities like has been demonstrated in Region 1 where they have a certified green building, and they found ways to reduce their energy

use 19 percent. We want to find out how they did that and share it. In the long-term we will have an open process that will include many of our, all of these stakeholders that will help to bring together the data, do the analysis for a longer-term look. That, again, is something that we envision being a year or two or three down the road.

Chairman LAMPSON. Does the Agency intend to or has the Agency asked for input from the EPA Science Advisory Board on the laboratory consolidation plan?

Dr. GRAY. Again, we don't have a consolidation plan. We are—have a plan to look at our laboratory infrastructure, and at this point, as I said, there is not a plan that we can yet, that we are yet ready to share.

Chairman LAMPSON. I had the staff look through the Congressional justification for some discussion of the Agency's intention to review the laboratory infrastructure and development of some kind of a consolidation plan, whether we call it a plan or not. They didn't locate any such discussion. Did we miss it, and where in the Congressional justification is this discussed?

Dr. GRAY. I am afraid I am not as familiar with the, or I am not familiar with the Congressional justification at that level, but I would be happy to get something back to you for the record.

Chairman LAMPSON. Okay. If you would, I would appreciate that. The memo refers to a target savings of 10 percent in 2009, and another 10 percent in 2010. Do you have any idea how those targets might have been set? And what is the justification for those mandated cuts?

Dr. GRAY. I do not know how those targets were set, and the idea of our short-term effort is to look for efficiencies that might help us find ways to save some, save resources in our laboratories.

Chairman LAMPSON. Frankly, Dr. Gray, it sounds like a lot of this process used to consolidate and streamline EPA's libraries, that process was dreadful, and we are still trying to sort that out. I sincerely hope that the Agency is not going to repeat the, that process with EPA's laboratories. I will be following up with a request for more information about this plan and the process to develop it. I expect the Committee to be provided this information in a timely fashion and well prior to the plan being finalized in May as Mr. Kedeli's memo suggests.

And I ask indulgence of the Committee for my having gone over, and I recognize the Ranking Member at this time.

EMPLOYEE MORALE

Mr. INGLIS. Thank you, Mr. Chairman. Dr. Gray, Dr. Coull testified in his written testimony that EPA's ability to garner the best science for its decision-making has been hamstrung by a severe lack of resources, and I think Dr. Morgan testified about the morale. What is your response to that? Is it, do you have some rejoinder to that?

Dr. GRAY. Well, I think I have one rejoinder. This is simply anecdotal in direct response to the morale issue. The Scientist Magazine is something widely read as you might guess by scientists. Every year they do a survey of post-doctoral researchers across the country, and what is the best place to be a post doc? EPA, ORD

has made, well, we are in basketball season. We made the final four for the last three years. We were number one three years ago. We have been three and three. That tells me that the morale among our scientists, the folks, even the young ones that we are bringing in, the new ideas, the new techniques, the new talent that we are bringing into our laboratories like working for ORD. I think that we don't have at this point any kind of a morale problem. We have got a lot of very dedicated people; scientists, engineers, and the support staff to help us do what we do, that are very happy working in the Office of Research and Development.

ENDOCRINE DISRUPTER RESEARCH

Mr. INGLIS. Let me take up a case study Dr. Coull mentioned. You got my attention with this endocrine inhibiter research and maybe first before I come back to Dr. Gray to ask about that, explain, give me some background on what, how that works, particularly, you understand my great concern is Bluffton oysters and shrimp, because my brother is a hobby shrimperman, shrimper. So help me out with that.

Dr. COULL. I over-spoke on one issue and want to correct it. I did not mean to indicate that EPA had eliminated all endocrine disrupter and mercury research, only the external grants in those particular cases. So there still is that kind of research going on internally, but let me explain. Hormones that we need to live and do well are also important to other creatures in the environment. Hormones are necessary for reproduction. Hormones are necessary for nervous function, and these chemicals, various chemicals interfere. They are called, endocrines are one kind, interfere with these endocrines. And, therefore, in studies done on shrimp, crab, and copepods, which are another small kind of crustacean, very tiny but very basic to the food chain, and essentially the basis of a good part of the food chain and all those salt marshes we have in South Carolina and in throughout the Gulf Coast, the reproduction is shut down when these animals are exposed to these particular chemicals.

Now, this particular research is relevant because it relates to ecosystems, which is, how does an ecosystem work? That salt marsh ecosystem outside of Bluffton is one of the most productive natural ecosystems on earth next to coral reef before they all started getting bleached by warming climate. That is an aside. And tropical rain forests. So these are important aspects of the ecosystems. Those systems are the nursery grounds for all of those shrimp that are either being caught on the South Carolina coast or the Texas coast or the Louisiana coast, all right, up to about Cape Haderous, North Carolina, all right, and all the way around to Corpus Christi. Those systems are where it happens. Those are the nursery grounds. And if we continue to pour nasty chemicals to interfere with the reproductive rate and the behavior of those particular organisms, we have a problem.

The Extramural Program in the fiscal year 2008 budget for endocrine disrupter research in the data that we have does not exist.

Mr. INGLIS. And so, Dr. Gray, what is your response to that, the cutoff of external funding?

Dr. GRAY. Well, first, I want you to recognize that endocrine disrupting compounds is an important part of the ORD research portfolio, and I am glad that Dr. Coull was able to let you know that, in fact, it is one, well, he didn't let you know, it is one of areas of this budget where we actually ask for an increase from the fiscal year 2007 budget. It is an area that we take very seriously where we are doing work not only to help the program offices to better identify and, to identify and prioritize these compounds, including pesticides and other compounds, but we are also doing work that is directly relevant here. A situation in which we are working on the recent discovery of inter-sex fish in the Potomac River. You remember seeing questions about fish that appeared to have endocrine alterations or some sort of alterations of their secondary sexual characteristics, and we are working with our state partners, our regions to help work on that particular issue.

Mr. INGLIS. Now, what is, the Chairman is showing me some numbers here. He is showing a four percent reduction in endocrine inhibiter research.

Dr. GRAY. In the fiscal year 2007 President's budget we asked for $9.1 million. In the fiscal year 2008 President's budget we are asking for $10.1 million, a $1 million increase in EDCs.

Chairman LAMPSON. This is the last, or it is a four percent decrease from the last enacted budget. According to our numbers here, this chart that I have indicates a four percent——

Dr. GRAY. We work from President's budget to President's budget, and in that case we actually are asking for $1 million more this year than we did last year.

EXTERNAL AND INTERNAL RESEARCH

Mr. INGLIS. Oh, I see. Okay. So that is based on the request, the President's request. I got you. Okay. So talk to me a little bit about the—I know I am over time but the difference between internal and external. Dr. Coull is a proponent of external research, and you are apparently preferring internal here in this case.

Dr. GRAY. Oh, no. First of all, I will tell you the research that we do, ORD is made up of about 1,900 people. At least 1,000 of them are scientists and engineers who are doing acts of science every day. And they are talented people. They are smart people.

Dr. COULL. And they are very good, many of them, they are wonderful people. They do very good work.

Dr. GRAY. And they have a lot to do, and we do a lot of our science inside. We also do work with our partners in universities, our STAR Program that has been mentioned several times, Science to Achieve Results Program, is a very important way in which we take advantage of some of the best brains in the country to work on science that helps advance EPA's mission.

Even in these fiscally-challenging times, we work hard, for example, to leverage that work. We are doing research in nanotechnology through our STAR Program, and we have actually, in that case we have partnered with other federal agencies, with the National Science Foundation, the National Institute of Occupational Safety and Health to increase the size of the pot that we can have for our STAR Programs. So it is a situation in which we have a very rigorous, very competitive system that brings in some of the

best ideas from the universities around the country, and whenever we can, we look to leverage those funds to make sure that we have the greatest opportunity we can to draw on the kinds of smarts that Dr. Coull and his friends and colleagues and students can bring to us.

Mr. INGLIS. Thank you. Thank you, Mr. Chairman.

Chairman LAMPSON. The numbers that I was sharing was from the document, this document that you all handed us, and in '06, the budget for—that was enacted by Congress was 10 million, $10.5 million, and the request is $10.1 million. So you, what you are basing yours on is what the President requested in '06, I guess, but what was actually enacted by Congress indicates that those numbers are different. So just for clarification.

DATA SOURCES AND CONCERNS

If you will bear with me just one minute, let me get a couple questions in, and then we will go to you. Dr. Sass, in your testimony you refer to free or cheap data provided by regulated industries, several laws, Pesticide Law, Toxic Substances Control Act, are set up to mandate the provision of data by a regulated industry. EPA has the authority to require the production of data under those statutes. Should these systems be changed, or is this a problem of inadequate EPA staffing to review the quality of these data and sufficient peer review of the data provided?

Dr. SASS. I mean, that is a good point. What you are saying is there are programs, particularly in the pesticide office, actually, where the regulated industry is obligated to supply data on the toxicity of its products and also under TOSCA the industry is obligated to provide any information it has, be it its own or not its own.

No, I mean, I think that is great. I think the regulated industry should be contributing both its funds and its technical power to develop that kind of data and submit to the agencies. Our concerns are what you suggest, which is, A, when the Agency can't provide appropriate oversight, either because it doesn't have the internal resources, staff or time, or when it doesn't have the ability to actually get to the underlying data and really do a data quality check on that submitted data. Our other concern is that EPA in many cases, and the pesticide office is an example of this, relies wholly or predominantly on that submitted data, sometimes without really scrutinizing and incorporating more publicly-available data often from the peer-reviewed literature and sometimes from its own sister agencies.

So, for example, with atrazine, the pesticide office right now is relying on data that it has requested and been waiting for from the manufacturer, Cingenta, on water monitoring, but it isn't incorporating data from USGS on water monitoring of pesticides.

Chairman LAMPSON. Thank you very much. Mr. Diaz-Balart, you are recognized.

PROGRAM ASSESSMENTS

Mr. DIAZ-BALART. Thank you, Mr. Chairman. Thank you for this very important hearing. Dr. Gray, one of the issues that I con-

stantly run into is, you know, government has a tendency to judge results by how much money we spent, not on actual results. One of the things that always comes to mind in a number of hearings that we have had in this Subcommittee and elsewhere is, for example, some of the Inspector General reports where they will come back, and they will tell us about EPA, particularly in some of the outside grants in a bunch of different areas where they really frankly don't have, EPA doesn't have a good handle as to if we are getting any results at all. We are spending the money for good-sounding things, but frankly, there is no way of telling, I am sure there are ways of telling, but we don't have any good data that tells us that we are actually paying for this, the actual studies as opposed to just good-sounding studies, and we are not getting the results.

A couple of questions based on that. Is there a way for the EPA to get other players, your other partners and do you get other partners coming back to you with recommendations of where EPA can save money and can be more efficient? Is there a way to do that? Do you have a way that you can get that source? Does the, I don't know, the Science Advisory Board, come to you and tell you, hey, look, these are, there are some areas here that we think we can find some efficiencies, or is that something that is not accepted by the EPA? It is not solicited, or it is just not, you just don't get a lot of that, and that would be my first question.

Dr. GRAY. Well, within the Agency we are always looking to make sure that we are getting results for the resources that we are putting out, and I think that it is a place, especially if you look at the Office of Research and Development, one where we are pretty confident that the way in which we run our Grant Program, the way in which we integrate it into our intramural research program so that there is alignment between the work that we are doing and the work that we are asking folks in the university community to do, actually does come together and help us make a difference in the science that is used by the Agency.

A great example of this is looking at National Ambient Air Quality Standards. We write what is called a, used to be called a criteria document. We now call it a science assessment for ambient air quality standards. The last one that was done for particulate matter, over 40 percent of the citations, the science that was used to support the ultimate decision that was made, came from work that was done by us or supported by us. So I am quite confident that, in fact, we do a good job.

On these areas of efficiencies I will tell you that I don't know the exact name. The agency, in addition to its Science Advisory Board, does have a Financial Advisory Board, and these are folks from outside of the Agency who are there to help us think about the way in which we run the business of EPA, how can we do things well, how can we be more efficient. I could get you more information about that if you would like for the record.

Mr. DIAZ-BALART. Actually, I would, and if you have, if there is something that you have that kind of shows, you know, some results in different areas, I would like to have it. If it is something that even members of Congress can understand, it would be obviously helpful.

Dr. Sass, you mentioned, for example, the clean air and mercury rule in your testimony and your concern over the Agency's ability to implement the CAMR adequately to lack of, and I don't know if I am misquoting you, you know, credible or reliable data. Should we wait to implement that or not because we don't have the reliable science or the reliable data? And should we work, should we not, should we wait, should we not wait?

Dr. SASS. Well, I mean, my hope is that EPA is going to go ahead on the best data that it has. The complication of that is that the EPA plan is sort of a Cap and Trade Plan, and Cap and Trade makes the assumption that the pollutions are shared or distributed evenly. So if you remove it over here, you are really helping, you are reducing the whole pot of pollution let us say. Without being able to do sampling to look at whether there is mercury hotspots, particular areas that are particularly vulnerable because they have high exposures, for instance, around cold-fired power plants that release mercury, EPA is not going to know whether its Cap and Trade Program is actually effective. If you are reducing it in one area but on population is taking all the risks, then your National risk may go down, but your environmental justice issues, your populations at higher risk, remain at higher risk.

So EPA should move ahead with the data it has, but it needs to do that hotspot monitoring so that it can measure the efficacy of its programs.

Dr. MORGAN. Do you mind if I—the other issue is that mercury, I mean, what was just said is absolutely correct. There are hotspots. But mercury is also a global pollutant, and a significant amount of the mercury that we see in this country comes from natural sources around the world and from power plants in China and similar sorts of things. And unfortunately, while the Agency does have a program to look at local and regional mercury issues, it doesn't have resources to try to understand the global mass balance of mercury, that is where it comes from, how it moves through the environment, where it ends up. And without that sort of fundamental scientific understanding, there is limits to just how far you can go and even to knowing whether the enormous amounts of money that power plants are going to be called upon and are being called upon to spend will always necessarily get the improvements we want. None of this is to say we shouldn't take action. It is to say, however, that there are important fundamental science issues that one really needs to underpin the development of regulation. Because absent that you could do things that were inefficient or counterproductive.

Mr. DIAZ-BALART. Mr. Chairman, if I may, thank you, sir. Thank you for your indulgence. I am not quite sure, but, I mean, am I hearing that we should or should not wait to implement? I am not quite sure if with that answer you are saying that we should wait to implement or we should not wait to implement. I am not quite sure.

Dr. SASS. We should move forward with the data we have and then continue to collect the data we need.

Mr. DIAZ-BALART. And Mr. Morgan, let me just ask you this, because you pointed something about other countries. Is the United States the first country to require reduction of mercury emissions?

Dr. MORGAN. Well, mercury issues are serious all around the world, and I can't tell you in detail what the regulatory environment across the EU is, but I know there are similar concerns. But the other point is that one needs to differentiate between a scientific standard, I mean, in science you don't publish until you have, I mean, you try to avoid false positives, that is to suggest things that aren't there. But regulation is essentially a public health issue, and there you need to move when there is strong suggestive evidence, even if it isn't definitive because the point there is to be protective of human health. And so there is a clear difference between, you know, whether I should say something definitively scientifically, that is whether I can get it published in a journal, and whether the Agency should move on something when the evidence is sufficient to suggest there is a problem. Then it behooves the Agency to be protective.

Mr. DIAZ-BALART. I understand that, Mr. Morgan, but obviously, you know, that can sometimes be very, very, very controversial because there is always a cost associated with that but I understand where you are coming from.

When I was listening to the Chairman, and I tend to agree with him about making sure that, Mr. Chairman, I am not paraphrasing what you said, about making sure that, you know, that there is input as much as possible, and again, I am not going to put words in your mouth, but I tend to agree with that, tends to be where you come from in a lot of cases.

INTEGRATED RISK INFORMATION SYSTEMS (IRIS)

Let me ask you in regard to the IRIS process, Dr. Sass, and again, I don't want to put your words in your mouth either, but you seemed to be, I guess, a little bit frustrated for the lack of finalized assessments in the recent past and point to more opportunities for public comments as kind of like, I guess, you know, further slowing the pace. Could you explain if you are not in favor of more opportunity for public comment in that context, because I kind of, again, you know, with an open caveat there, tend to be a little bit apprehensive about not having as much open comment and, again, on a separate issue that I think the Chairman mentioned which is totally unrelated, but I just want to know what your comments are on that. Did I read that right? Did I understand that correctly?

Dr. SASS. Especially, you might be confused because I am the one that is always commenting, too, so why wouldn't I want opportunities to comment. The IRIS Program, which is very important, I mean, it gets hits every month, it gets thousands of hits every month. I think 50,000 hits a month the last time I looked from almost 100 counties in the world every month, down actually in July and August, I have noticed. So it is incredibly important that, and the IRIS database is, does provide quantitative estimates of toxicity or hazard, and then you use that site specific in places to estimate exposure. And then when you know the toxicity and you know the exposure, you can do a risk assessment. So it is incredibly valuable all around the world. They are considered one of the gold standards of the world to be used. In the last few years they have only done somewhere between two and five finalized assessments every year. They have ongoing reviews and assessments, but they finalize only

two to five. In the budget they actually promise finalizing eight a year. I don't know how they are going to do that, but I have talked to EPA staff who tell me they should be finalizing about 16 a year. What is the difference between 16 and two to five? The difference is the delays that happen because of interference. I don't think it is oversight. I think it is interference. The reason why is there are built-in opportunities for public comment and for oversight, and there is built-in opportunities for OMB review, early and late, and there is built-in opportunities for interagency review already.

In addition to those, they would now have, I think it is about three more rounds of this, and each one of those will add on about six months to a year or extend the process by six months to a year.

Mr. DIAZ-BALART. Mr. Chairman, will you indulge me in one last one? I thank you. You have been very generous.

Chairman LAMPSON. Help yourself.

Mr. DIAZ-BALART. Thank you. When you mention, now, again, there is obviously a difference between input and interference. I understand that, and you are saying now three more opportunities or layers of interference, not of input, not of comment?

Dr. SASS. At this point since everybody has had an opportunity to comment early, including OMB and the agencies and they get an opportunity later, then I would say the intervening several opportunities just become delay.

Mr. DIAZ-BALART. I think I would like to get an idea of what those are. If I, I don't know if Dr. Gray, if you can kind of get back with me or whenever, I mean, whoever can do that, it would be nice.

Dr. GRAY. Yeah. We are very proud of the process we use to develop our IRIS assessments. It is one of the reasons as Dr. Sass said, they are gold standard around the world, and we can get something to you.

Mr. DIAZ-BALART. Great. Thank you. And, again, thank you, Mr. Chairman, for——

Chairman LAMPSON. You are very welcome.

Mr. DIAZ-BALART.—allowing me to go way over. Thank you, sir.

Chairman LAMPSON. That is okay. Thank you. I did myself awhile ago, so I am glad I could pay you back. Mr. Lipinski, you are recognized.

FUNDING REDUCTIONS FOR GREAT LAKES RESEARCH

Mr. LIPINSKI. Thank you, Mr. Chairman. I am very glad that you all went over so much so I could get here in time to ask these questions.

I want to start by talking about the Great Lakes and certainly the, over the last 20 years the discharge of toxic substances in the Great Lakes has been reduced, but we still have those high concentrations of contaminants in the bottom of the lakes and, you know, surrounding areas. And, of course, there are great concerns about this. As you know, there is advisories against fish consumption in most locations throughout the Great Lakes. Now, in order to address this problem, in 2002, Congress passed and the President signed into law the *Great Lakes Legacy Act.* My concern in this budget is that the budget request represents a reduction of $14 million from last year, from $49.6 million to $35 million for this,

and I am concerned that the program is going to be significantly impacted by this decrease. So what is the reason for this significant cut?

Dr. GRAY. I assume that is a question for me.

Mr. LIPINSKI. Yes.

Dr. GRAY. What I—and this question that you raise, for example, cleaning up sediments, is actually one of the priority areas for our, what we call our land research area. It is one of those things that were recognize is an ongoing question. It is not just in the Great Lakes. It is in a variety of parts of the country, both in fresh waters and marine waters. So this is something that we take very, very seriously, and we want to be part of the solution. The Office of Research and Development is about being part of the solution. We not only do the science to help identify potential problems as we have heard. We also do the science to find the solutions. We have a great group of engineers that helps us to get to the place where we can help clean up these situations.

In the case of our budget, we are in a situation in which we have to set priorities, and we have before us a budget that helps us, that funds the high priority science that the Agency needs.

Mr. LIPINSKI. So this is not a high priority then?

Dr. GRAY. No. We are funding it. I said this is one, this is something that we consider a high priority.

Mr. LIPINSKI. You do consider it, and then, but a $14 million cut is a significant amount from $49.6 million to $35 million. Is this correct?

Dr. GRAY. I am honestly not sure what numbers you are talking about. Not knowing the budget I don't want to get numbers wrong, so I would be happy to get back to you.

Mr. LIPINSKI. Okay. All right.

Dr. GRAY. For the record.

NANOTECHNOLOGY RESEARCH

Mr. LIPINSKI. Very good. Well, one thing that I am pleased to see is the ninety-one percent increase in the research on environmental implications of nanotech. I certainly have seen a lot and talked to a number of researchers. I believe that nanotech, it could possibly really be the next industrial revolution as it is, as the proponents say that it is. And so I am happy to see that we are putting more funding into researching the environmental implications of nanotech. I, you know, I don't know if there is any really negative environmental impact here, but it is something that I think we need to do more research on to know for sure and also so that the public, the public has some concerns over nanotech, and I think that also needs to be put to rest, if indeed it should be put to rest.

Now, Dr. Gray or anyone else who wants to elaborate on this, talk about the current research agenda that the EPA has regarding nanotech.

Dr. GRAY. Well, I would certainly be happy to start there. I think this is a situation that is a great example of the way in which the Agency identified something kind of out on horizon, used our STAR Grant Program to begin research back in 2001. We were funding research on nanotechnology back in 2001. As it has become more clear that this is an issue that we have to look at both from an ap-

plication side, how can we use nanotechnology to clean up the environment, to make processes cleaner, to reduce waste, but also the implications. That is, are there potential health affects. We have increased our efforts here, and in fact, the funding that we asked for in this present budget is to bring some research in-house, to use our in-house scientists to help to address some key issues. And here what we have done, the National Nanotech Initiative across the Government is spending lots of money on nanotechnology. We have worked very hard to identify where it is that there is a nitch for EPA where our knowledge and our expertise can make a difference and where people aren't doing this research. And what you will see here is that our focus is on, for this, for the 2008 budget, on the fate and transport of nanomaterials in the environment. That is, what happens to them when they get out? We know that in some cases in some kinds of media, in water, they can glom up and become no longer nanomaterials. And then there are different kinds of risks. In other cases they may say dispersed, they may be able to travel long distances, and we are trying to understand that.

In our STAR Program we continue to fund work in universities around the country looking at potential health implications of nanotechnology so that we can understand whether there are risks of this technology that we need to manage to get some of those benefits that you described.

Mr. LIPINSKI. Thank you. Anyone else have any comments on that?

Dr. MORGAN. Yes. The SAB, the Science Advisory Board looked at this new program and is quite positive about it. It has made significant progress since we looked at it last year, and I would agree that understanding fate and transport is really quite important. At the same time we also expressed a concern, which is that if one approached the regulation of nanomaterials in the same way that we have approached say the regulation of chemicals, that is with extensive toxicological tests for each new particle type, we are going to get swamped. I mean, we have already been swamped with chemicals, because you can make new chemicals faster than you can run the toxicological studies, and if you think that is bad, material scientists can make new nanoparticles even more rapidly, and you know, if the molecule sticks out there or sticks out here, it can have very different toxicological properties.

So the one thing we would hope the Agency starts doing as well is trying to figure out some new ways to frame and think about the regulatory problem, because the simple notion that every time I come forward with a new particle I am going to have to run the full set of animal toxicity tests and so on, I mean, that isn't going to work. And so while we are very positive about the fate and transport issue, it is a critical first step. There is an important second step that we have urged the Agency to take, and I think they have heard us but so far, you know, it is still a nascent program.

Dr. COULL. The first research as I remember in nanotech in the EPA and nano environment came out of a program called Exploratory Research. This was an external extramural-funded program out to universities and colleges around the country. And it was from there as I remember that we saw the first implications and studies in this. The entire program in Exploratory Research, that

is what kind of ideas are out there in this academic, intellectual, and or consulting world that are looking ahead in the future and seeing issues that are going to occur. I think the first, I am trying to remember the dates, and I don't have them exactly in my head, but it was in the late '90s where we saw nano-research, and then we now have an initiative on that, and that is great, and I am really supportive of that, and I think that is really important for us to do.

But the whole concept of Exploratory Research, what is the problems? What are the problems in 2015, that we are going to be looking at, would be a really nice thing to see to let the intellectual, bright, young minds of the future have an input into these kinds of things. And we don't have that anymore at the ORD at EPA per se. It is all sort of prescribed and defined within certain categories; endocrine disrupters, nano, et cetera, et cetera.

Mr. LIPINSKI. Thank you.

Chairman LAMPSON. Mr. Inglis.

Mr. INGLIS. I want to follow up on Mr. Lipinski's line of questioning there about nanotechnology. In particular, Dr Coull, you mentioned earlier it is either the, you said the PCB of the future or the world saver. So back up and tell me a little bit about that so that I can understand how it could be the PCB.

Dr. COULL. I think others have spoken to that issue. It is at what are the environmental consequences of this.

Mr. INGLIS. Right.

Dr. COULL. And we don't know. Right? But are we going to make major breakthroughs and have stints that we can put, made out of nanoparticles that are going to save our lives from having heart attacks and things? We are starting to know about those things, but we don't know a lot about them either. And that is why I made that comment, is that those who are interested in nanotechnology to make new products to sell on the market are telling us that this is the best thing since, you know, traditionally sliced bread. But, you know, those of us who are concerned with the environment, where are those? You know, are they going to wind up in the sediments of the Great Lakes like the PCBs have done or in Charleston Harbor of the future, and I don't know the answer to that. And that is why I think we need research to look at what is the effect of these. There are colleagues, again, at USC and at the National Fisheries Lab looking at the effects of nano-tubuals on attracting contaminants and sediments. That is all I can tell you, and I don't know the results of their research, and that is funded by the STAR Program also.

Mr. INGLIS. Dr. Morgan, you had——

Dr. MORGAN. Yes. If I could just add something. I mean, we all talk about nanomaterials as though they are some uniform set of things. In fact, of course, it is an enormous heterogeneous bunch of stuff, and if I have put nanoparticles in paint on a new car to make it shiny, it is probably not going to pose any significant health risk because it is all bound up in a paint matrix. On the other hand, if I am producing mono-disperse sub-micron material that can penetrate the blood brain barrier to take a medication to the brain, then I have to worry a bit about whether it might do other things as well. And so it is a very complex domain, and you

know, we need to be careful not to think about all of these topics as though they are exactly the same. I mean, I don't worry too much if it is embedded in the matrix of a paint, and I worry quite a bit if it is mono-dispersed, but as Dr. Gray said, one of the things you have to quickly understand is how these things behave in the environment. I mean, very fine particles in the atmosphere, this room is full of them, quickly adhere to larger ones, and so, you know, does the particle then retain its same properties when I inhale it? We don't know the answer in many cases, and that is why some basic research is important in this field as well as some applied research to support regulation.

Mr. INGLIS. Yeah, and Dr. Gray, you mentioned in your testimony, I believe, that you are comfortable with the research budget for the, I guess precisely what Dr. Morgan was just mentioning.

Dr. GRAY. Yeah. This budget gives us the resources we need in this case to look at nanotechnology and really to do it in a multi-pronged approach. We are still, much of your early research focused as several people have mentioned, on some of the potential environmental applications of nanotechnology, and there are some great examples. There are things being demonstrated using, in fact, at Carnegie Mellon, using zero valiant nanoparticles of iron to clean up chlorinated solvents that are contained in ground water. A great use of it. What we have done more and more is to focus on implications. That is, how do we understand what might be happening, what might be some adverse affects. We have had STAR Grant studies looking at the absorption through skin of these nanoparticles to help address some of these questions that Dr. Morgan raised, and then what we are doing now is bring some of this research in-house to use our smarts. We have got great engineers who are very excited about this area, to understand what it means when these materials get out into the environment, how people might be exposed.

So this budget gives us the resources we need to really get a great start on that.

NEAR ROAD POLLUTANTS

Mr. INGLIS. Yeah. One other question, Dr. Gray. You mentioned the Air Pollution Near Roads Initiative. Tell me a little bit more about that. That is particular significant for those of us who have a non-attainment issue.

Dr. GRAY. This is something that, again, came out of some of the research that we have supported, primarily in the area of particulate air pollution. One of the big areas of focus in our clean air effort, one of the big parts of our STAR Program are particulate air pollution centers that we fund at universities across the country. And one of the things that has come out of some of the epidemiology there are hints that there may be differential risks around roadways, and so what we are doing is making sure that we start focusing our research, both the folks that we have got in ORD and the research that we are doing in our particle centers, to think about this near roadway exposure.

And also then to think not only about how it happens but what the health affects might be and back to one of the things I think

is important to remember that ORD does, what are some solutions that we might have.

Mr. INGLIS. Thanks, Mr. Chairman.

EPA BUDGET REQUEST

Chairman LAMPSON. Dr. Morgan, does the SAB find the EPA's annual budget presentation to Congress to be straightforward? Does the presentation provide a clear picture of what funds the Agency is requesting and the programs that are receiving increases and decreases?

Dr. MORGAN. We have trouble unscrambling the numbers from time to time as I suspect you may also. We got probably one of the better briefings this year from the Agency that we have had in quite awhile. We asked them to show us, and I think you held up the presentation that we got, where the budget had undergone significant decreases and increases. But, you know, there are, particularly this year with operating under a continuing resolution and the fact that it is really hard to know how in the current fiscal year the money is going to get allocated within or across programs, it has been a bit of a struggle.

Chairman LAMPSON. Anyone else want to make a comment? I got a couple more questions but——

Dr. SASS. I actually did my best analysis of the budget by looking at the presentation of ORD to the Scientific Advisory Board because there is no numbers associated with the different programs.

Chairman LAMPSON. Dr. Coull.

Dr. COULL. We had trouble understanding the budget.

Chairman LAMPSON. Okay. A number of years, 10 years ago as a matter of fact I created the Congressional Caucus on Missing and Exploited Children. I have a lot of interest in children and child safety and issues, and while this doesn't have to do with a child abduction issue, it does have something to do with children's health and safety. Protecting the health of our children is important. It is an important part of EPA's mission.

In your testimony, Dr. Gray, you state that EPA's "Human health research funding will allow us to conduct research regarding the health risks of susceptible populations." But, in fact, the President is proposing to cut the funding to help protect children and the elderly by seven percent. Is that correct?

Dr. GRAY. Again, sir, I don't know exactly which line you are speaking to, so I don't know. If you have a more precise question, I would be happy to get back to you with budget and with the exact numbers.

Chairman LAMPSON. It appears to me that it goes from $61.5 million to $56.8 million, which is a decrease of $4.7 million.

Let me ask Dr. Coull. In Dr. Gray's testimony he argues that, "At EPA we are good stewards of our environment and good stewards of our nation's tax dollars." However, in your testimony you discussed many emerging new environmental threats including avian influenza, episodic diseases such as cholera, toxicants such as arsenic and mercury. Without additional research, could these emerging threats be expensive for the U.S. Government to address or contain? If we under invest in environmental research, are we

being good stewards of our taxpayers' dollars, because will it not cost of through the nose in the future?

Dr. COULL. Absolutely. Money spent upfront to know things is better than having to spend it after the gates. I mean, that, in the environmental world we call this the precautionary principle. We would like to have precaution on certain things that may be brought about by environmental change. Are we going to have palm trees in Maine? You know, that is not the same level of issues that you are talking about, but are we going to have malaria in Florida? And these are environmental issues related to global climate change.

So certainly EPA cannot afford to do them now under the budget that I have seen for the last several years and the present budget. So that is, it will cost us more later than now to do this.

Chairman LAMPSON. That is a huge concern. It should be a huge concern to all of us, and I hope it is to you as well, Dr. Gray, and I made my comments strongly earlier, and I feel very strongly about them. This is an agency that the people of the United States of America rely on, and we need to see that same kind of care and concern and particularly when our Congress, and these budgets have been pushed forth by a Republican Congress prior and signed by our Republican President. It is not about partisanship. I don't know whether my kids are going to grow up to be Democrats or Republicans, but I know that I want them to grow up to be healthy. And we do have that obligation. We are the stewards of their future. I don't feel like we are honoring that. So I would beg you to please go look again and do what Congress asks. That is why we have a procedure. And then if you don't agree with it, then come back and bring realistic information to us. I think it is a catastrophe for us to see the kinds of things that are happening right now and putting us in huge jeopardy for our future.

And with that I will turn to the Ranking Member again.

Mr. INGLIS. I have no further questions, Mr. Chairman, and I thank the witnesses, though, for appearing.

Chairman LAMPSON. Likewise. I thank you for your tolerance this afternoon, all of you for taking the time and for bringing your information up here. Your testimony indeed is helpful, and if there is no objection, the record will remain open for additional statements from Members and for answers to any follow-up questions that the Committee may ask of the witness. Without objection, it is so ordered, and we are now adjourned. Thank you all very much.

[Whereupon, at 3:50 p.m., the Subcommittee was adjourned.]

Appendix 1:

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by George M. Gray, Assistant Administrator for Research and Development, Environmental Protection Agency

Questions submitted by Chairman Nick Lampson

EPA LABORATORY STUDY

Q1. With respect to EPA's study of the laboratories infrastructure, you indicated in your response that ". . .no laboratories will be shut down, and no scientists will be let go." The Congressional justification indicates the Administration is proposing to cut Total Work-years for Science and Technology from 2,433 in FY 2006 to 2,406 in FY 2008. Where are the cuts to the Science and Technology workforce coming from? Are there plans to reduce the administrative support staff of the laboratories? Is the Administration making plans to offer buyouts to any of the senior management, support, or scientific staff of the laboratories over the next two years? Please provide the section/s and page number/s in the Congressional Justification and/or the Strategic Plan that describes and discusses the Agency- wide study of EPA's laboratory infrastructure.

A1. The 27 work-year decline between FY 2006 and FY 2008 represents a one percent decline in workforce levels overall to the S&T account. A portion of the decline has occurred in each of the Agency's five strategic goals and in both the programmatic and administrative areas. The plan is to achieve all reductions through attrition, and a portion of the reductions in the administrative area reflects expected efficiency improvements. The study is briefly discussed in the Justification on page 82 of the Appendix.

Q2. You mentioned the Agency is looking for opportunities to increase efficiency at the laboratories and used the Region One laboratory as an example. You indicated that the Region One laboratory found ways to reduce their energy use by 19 percent. Over what time period did the Region One laboratory achieve this reduction in energy use? What changes did they make to achieve these savings?

A2. The reduction in energy use of 19 percent cited in my testimony before the Committee reflected reductions achieved by the EPA Region One laboratory between fiscal years 2005 and 2006. If one looks at the reductions in energy use over a two year period, from fiscal years 2004 to 2006, the reduction is an even more impressive 28 percent.

When opened in 2001, EPA New England's laboratory received a LEED Gold Rating for its green design, in recognition of its energy efficient design, its active and passive solar power, its use of recycled materials in construction, and its environmentally-friendly landscaping. However, the laboratory has worked to do even better.

Over the last two years, the EPA Region One laboratory in Chelmsford, Massachusetts reduced its energy consumption from 25,154 million British thermal units (mmBtu) in fiscal year 2004 to 18,107 mmBtu in fiscal year 2006, for a total reduction of 28 percent. The laboratory reduced its energy consumption by 11.2 percent in fiscal year 2005 (compared to 2004 levels) and an additional 18.9 percent in fiscal year 2006 (compared to 2005 levels). Using an average mmBtu cost of $26.60, the cost savings from these reductions were $187,451 in fiscal year 2006 alone.

The Region One laboratory implemented a variety of building modifications and operational changes to achieve these reductions in energy use. The largest physical modification to the building was installation of 23 fan powered units, which were necessary to correct temperature imbalances in the building. This modification was funded entirely by the building owner, after pressure from EPA. This modification had no direct cost to EPA. The fans enhanced heat distribution in the perimeter offices, improving both temperature and energy efficiency.

EPA did pay $41,372 for other modifications to the HVAC system. EPA had two goals in modifying the laboratory's HVAC system. The first priority was to assure availability of HVAC redundancy for the computer room, telephone switch room, and the UPS room. The second priority was to increase building efficiency. This was accomplished by connecting the primary facilities HVAC system to the previously mentioned rooms and using the original less efficient units for redundancy, in an emergency, should the house system fail.

The Region 1 laboratory instituted several other changes in operation which did not have significant cost. During a routine operations maintenance audit in 2005, the laboratory discovered that its gas boilers were wasting energy by operating more

pumps and motors than required to meet the building heating demands. The lab found that defective sensors were the problem and replaced them to increase system efficiency. In June 2005 the facilities staff began working with new on-site management to monitor HVAC performance on a daily basis and make adjustments to system set points according to outdoor air temperatures, actions which continue to improve efficiency and save energy.

The facility manager worked closely with the property manager to modify the operation of the building in other energy-saving ways, including:

- Expanding night/weekend hours when lab and office temperatures and air volumes are moderated in order to save heating and cooling;
- Identifying analytical equipment and processes which can be shut down when not in use and/or batch processed when constant operation is not necessary;
- Manually adjusting chiller/heat supply temperature and humidity controls relative to the demand due to seasonal ambient temperature and humidity loads;
- Reducing illumination levels in common areas by utilizing emergency and natural lighting only in building hallways; and
- Conducting daily "end of day" laboratory and office walk-throughs manually closing fume hoods and shutting lights.

EPA hopes to achieve further energy savings at the Region One laboratory. In March 2007, EPA embarked upon a feasibility study to site a wind, solar or geothermal generation project at the laboratory.

Q3. Has the Agency funded any workshops or meetings to solicit input to EPA's work in developing guidance or test protocols with the academic, public health, or public interest community similar to the International Life Sciences Institute sessions described by Dr. Sass in her testimony? If so, please provide a list of these meetings funded over the past five years and the amounts of funding provided for each meeting.

A3. EPA's professional staff takes full responsibility for drafting scientific guidelines, risk assessments, and similar documents. They draw on their professional training, the experience gained at EPA, advice from other professional colleagues, and publicly available scientific literature. EPA does not customarily organize meetings with external groups to solicit input on the development of its scientific guidance documents outside of the accepted Federal Advisory Committee Act (FACA) process. However, EPA has occasionally funded outside organizations to hold meetings on scientific topics that are related to the development of guidelines and risk assessment methodologies used in its programs. For example, EPA has supported:

Drinking Water Scientist-to-Scientist Meeting

EPA invited representatives from other federal agencies, academia, industry/trade organizations, and environmental advocacy organizations to attend a meeting concerning the effects of drinking water treatment on organic pollutants. The meeting afforded participants the opportunity to describe current and planned research and models. The participants also discussed the direction of future drinking water treatment research, as well as how to use study results in the pesticide program's drinking water exposure assessments.

AOAC International

AOAC International is a widely recognized, nonprofit standard setting organization. Among other efforts AOAC publishes methods related to testing the efficacy of antimicrobial pesticides; EPA requires studies using these methods to support applications for registration of antimicrobial pesticides with public health uses. The pesticides program has provided funding to AOAC to coordinate workshops, symposia, and roundtable discussions with interested stakeholders on modifications of existing methods and the development of new methods. In addition, AOAC has coordinated the recent, ten laboratory Three Step Method (TSM) validation to evaluate a new quantitative method for determining the efficacy of sporicides (for Homeland Security purposes).

International Life Sciences Institute (ILSI)

ILSI is a nonprofit worldwide foundation whose mission is to improve public health through scientific advances. EPA has funded work through ILSI to develop science papers on issues related to human health. ILSI used the funds to support expert workshops that included scientists from federal agencies, international organizations, drug and chemical companies, academia, and nongovernmental organizations to review public literature and other available information on selected sci-

entific topics. ILSI has focused on particular issues related to toxicology testing, exposure assessment, and identifying mechanisms of action, and on developing new tools and methods for risk assessment. The results of these efforts are a series of publications that appear in the peer reviewed literature. These projects are not done specifically for the benefit of EPA but are done to benefit the area of health broadly and are widely used nationally and internationally. ILSI does not work on specific chemical risk assessments or on regulatory policy papers for OPPTS.

Anthrax Interagency Expert Panel

The panel comprises technical experts from numerous government agencies (DOD, FDA, EPA, etc.) who provide technical insight and advice on research goals related to test method development for select biological agents (anthrax and others). EPA provided funding to Tetratec for logistical meeting support (not technical support), including the compilation of meeting minutes, maintaining a webpage, etc.

World Health Organization (WHO) Workshop on Setting Acute Reference Doses

Along with other donors, EPA provided funding to the WHO to support the development of guidance concerning the derivation of benchmarks reflecting safe acute (one day or shorter) exposure levels for pesticides. The WHO formed a Working Group of senior scientists from various national pesticide regulatory organizations who met repeatedly to develop detailed guidance on the performance of acute risk assessments. The Working Group's efforts resulted in a lengthy document that eventually appeared as a publication in peer review literature.

Joint Meeting on Pesticide Residues (JMPR) Annual Meeting

Along with other donors, EPA funds the World Health Organization portion of the annual meeting of the JMPR. The JMPR is an international expert scientific group jointly administered by the UN Food & Agriculture Organization and the World Health Organization. The annual JMPR meetings recommend Maximum Residue Levels (MRLs), i.e., the amount of a pesticide residue in food to which people may safely be exposed. Published information can be accessed through: *http://www.who.int/ipcs/food/jmpr/* Although EPA independently determines safe levels of pesticide residues in food and sets tolerances that apply to food and feed products in the United States, EPA considers relevant MRLs recommended by JMPR in its tolerance-setting process.

The EPA High Production Volume (HPV) Challenge Program Conference

EPA funded a cooperative agreement with the Northeast Waste Management Officials' Association (NEWMOA) to conduct a National Conference on Characterizing Chemicals in Commerce: Using Data on High Production Volume Chemicals. The purpose of the conference, which took place December 12–14, 2006, was to educate a wide variety of stakeholders including federal/State agencies, international organizations, NGOs, academia, and industry about the EPA High Production Volume (HPV) Challenge Program, as well as other sources of chemical toxicity and environmental information; to share experiences of key stakeholders about the use of data made available by the EPA HPV Challenge Program, and to develop ideas on how to make sources of HPV chemicals information and other data user friendly, accessible, and relevant to a diverse audience. As a result EPA has received many comments and suggestions about EPA review of data quality and setting priorities for further work, and about making the HPV Information System easier to use.

The Perfluorooctanoic Acid (PFOA) Meetings

In 2003, EPA initiated an enforceable consent agreement (ECA) process under section 4 of the *Toxic Substances Control Act* (TSCA) to generate information on the sources of perfluorooctanoic acid (PFOA) in the environment and the pathways leading to human and environmental exposures (68 FR 18626; April 16, 2003). Fifty-one organizations and/or individuals registered as Interested Parties to participate in the public negotiation process leading to the development of testing under ECAs that EPA signed with individual companies. A series of 16 public meetings ranging from one to three days in length were held at EPA Headquarters from June 2003 through June 2006 to provide a forum in which all the Interested Parties, including industry, environmental groups, government agencies, public utilities, public health groups, and others could participate in the drafting of two ECAs for incineration testing on fluorotelomers (70 FR 39624; July 8, 2005: available online in docket number EPA–HQ–OPPT–2001–0001 via "Advanced Search" on *http://www.regulations.gov*) and fluoropolymers (70 FR 39630; July 8, 2005; docket number EPA–HQ–OPPT–2003–0071); provide input on the creation of two voluntary Memoranda of Understanding (MOUs) between EPA and industry for environmental sampling and monitoring at two fluoropolymer manufacturing facilities (EPA–HQ–

OPPT–2004–0112 and EPA–HQ–OPPT–2004–0113); and participate in discussions on method development and study design for telomer biodegradation and telomer and fluoropolymer aged article testing. The meetings were held in EPA Headquarters meeting space. The only cost concerned meeting support in the form of an EPA contractor recording the meetings for the purpose of preparing meeting summaries, which were entered into the PFOA ECA docket, EPA–HQ–OPPT–2003–0012, and distributed via e-mail to all meeting attendees, Interested Parties, and others expressing interest in following the topic. The initial meeting included the preparation of a full meeting transcript. Information on the meetings is available on the EPA's PFOA website at *http://www.epa.gov/opptintr/pfoa/meetings/meetings.htm* and *http://www.epa.gov/opptintr/pfoa/meetings/pfoarchive.htm,* and in the online PFOA ECA docket, EPA–HQ–OPPT–2003–0012. The information obtained through the PFOA ECA process and through voluntary activities initiated as a result of this process will contribute to the EPA's ongoing risk assessment work on PFOA. EPA will seek SAB review on any final PFOA risk assessment document.

NPPTAC Nanoscale Public Meetings

On June 23, 2005, EPA held a public meeting to solicit input on the potential development of a stewardship program to address various issues related to nanoscale materials under TSCA. This meeting was funded by the Office of Pollution Prevention and Toxics (OPPT), and included an electronic docket for submission of comments.

As a result of the public meeting, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC) was asked to develop possible courses of action for OPPT to address the potential issues related to nanoscale materials under TSCA. At their June 30, 2005 meeting, NPPTAC established an Ad Hoc Work Group to take up the request. The Work Group held a public meeting September 29, 2005 to solicit comments on a potential voluntary program. In addition, the full NPPTAC held a public meeting October 13–14, 2005 as well as a public teleconference November 17, 2005 to finalize a document outlining elements of a voluntary program. This document was officially forwarded to EPA on November 22, 2005.

On October 19–20, 2006, OPPT held a public scientific peer-consultation to receive input on the risk management practices elements of the stewardship program being developed in response to public and NPPTAC input. Two more meetings—a public scientific peer-consultation on materials characterization and a public meeting on the stewardship program as a whole—are being planned for summer, 2007. EPA typically seeks public input from all interested stakeholders including FACAs.

Toxicology Excellence for Risk Assessment (TERA)

This project, under a cooperative agreement with TERA, is the backbone of the Voluntary Children's Chemicals Evaluation Program (VCCEP): it provides a mechanism for peer consultation on VCCEP chemicals in which technical experts representing all stakeholders in VCCEP have an opportunity to discuss and comment on proposed risk assessments for chemicals of concern to children.

Q4. Were any of the products of these meetings—guidelines or recommended research protocols—subject to review by the Science Advisory Board? What is the review process for the materials that emerge from these meetings?

A4. EPA works carefully to ensure that our documents and regulations are supported by strong, peer reviewed science, and we typically solicit input from our stakeholders, the public, and other federal agencies as we develop our materials. EPA has institutionalized formal mechanisms for reviewing its scientific work and evaluating it against the highest professional scientific standards and integrity. For example, the most influential scientific products are subject to independent, external peer review. These external peer reviews by experts like the Science Advisory Board in the various subject areas help ensure that EPA's science and research achieve defensible scientific results and quality.

In addition, EPA welcomes any comments that are intended to strengthen the scientific underpinnings of the documents we disseminate. While EPA often solicits external expert advice on scientific issues and draft work products, EPA retains the responsibility for final determinations on risk analyses and other scientific findings, and their use in Agency decisions.

Q5. GAO released a report in February 2005 in response to a request by Rep. Udall and Rep. Johnson of this committee. The report recommended that EPA "develop formal policies for evaluating and managing potential conflicts of interest when entering into research arrangements with non-governmental organizations, particularly those that represent regulated industry." Please provide EPA's formal

policies for evaluating and managing potential conflicts of interest produced in response to the recommendations by GAO in this report.

A5. EPA's formal policies for evaluating and managing potential conflicts of interest produced in response to recommendations made by GAO in their February 2005 Report are included as Attachment A.

Q6. In your testimony, you indicated that the President's FY 2008 request of $754.5 million for science and technology (S&T) is a significant increase over the 2007 enacted funding for science and technology programs. Does the $754.5 million figure include funding to support operations and maintenance for S&T facilities? If so, what is the amount of funding from the $754.5 million total that is allocated to this category of spending? Does the FY 2006 enacted total for S&T of $731 also include the funding to support operation and maintenance for S&T facilities? If so, what is the amount of funding from the $731 million that was allocated to this spending category in FY 2006?

A6. Yes, the $754.5 million FY 2008 President's Budget Science & Technology (S&T) request includes $65.1 million for rent, security and utilities. Prior to FY 2007 direct laboratory rent, security and utilities for S&T-funded personnel were paid for through the Environmental Programs and Management (EPM) appropriation. Starting in the FY 2007 budget, EPA proposed shifting these resources from EPM to S&T to more accurately account for the overall costs for S&T personnel. EPA's overall funding is not changed, nor are any S&T programs reduced by this change. The restructuring is being phased in the FY 2007 Enacted budget ($23.6 million) and would be fully implemented in the FY 2008.

Environmental Protection Agency (EPA)
Science and Technology Appropriation Information
(Dollars in Millions)

	FY 2006 Enacted	FY 2007 Enacted	FY 2008 President's Request
S&T Total Appropriation Level	$730.8	$733.4	$754.5
Rent, Security and Utilities	$0.0	$23.6	$65.1

Q7. The National Academy of Sciences' report, Assessing the Human Health Risks of Trichlorethylene: Key Scientific Issues, was released in July 2006. The Committee found: ". . .Thus the committee recommends that federal agencies finalize their risk assessment with currently available data *so that risk management decisions can be made* expeditiously." *[emphasis added]*

It has been nearly one year since the NAS issued this report.

When is EPA going to issue new health-protective standards for trichloroethylene under the Safe Drinking Water Act *and other appropriate statutes that mandate containment and clean up of toxic substances?*

A7. Pursuant to requirements in the *Safe Drinking Water Act,* EPA is currently reviewing existing national primary drinking water regulations for TCE and 72 other regulated contaminants. As part of this review, EPA analyzes new scientific and technological data and information on health effects associated with each regulated contaminant. If the Agency identifies a potential health or technological basis for a revision to the drinking water regulation, this would necessitate a series of follow-up analyses for potential regulatory revision. For example, EPA would need to conduct occurrence and exposure analysis, and evaluate available economic information to determine if changes to the standard are needed. EPA currently anticipates completing this review after the final revised risk assessment for TCE is complete.

The final revised risk assessment for TCE represents a key piece of information that is needed for the Agency to complete its review of the drinking water regulation. EPA is considering the NAS report, along with previously submitted Science Advisory Board (SAB) and public comments and newly published research, to pre-

pare a new draft TCE assessment. This draft assessment will be released for peer review as well as additional public review and comment and then finalized.

INTEGRATED RISK INFORMATION SYSTEM REVIEW PROCESS

Q8. During the hearing Dr. Sass indicated that finalizing chemical assessments for inclusion in the Integrated Risk Information System (IRIS) data base was very slow and that it has become slower due to additional review procedures.

Q8a. Please provide the current procedure for informal and formal reviews of a chemical assessment from the point where the initial DRAFT assessment is produced until the assessment is finalized. Include all opportunities for internal, external (e.g., formal peer review and public comment), and interagency reviews that are now part of this process.

A8a. EPA's current process for developing chemical health assessments that ultimately are posted to EPA's IRIS database consists of: (1) an annual *Federal Register* announcement of EPA's IRIS agenda and call for scientific information from the public on selected chemical substances; (2) a comprehensive search of the current scientific literature; (3) development of draft IRIS health assessments utilizing EPA's risk assessment guidelines and state-of-the-art scientific methods; (4) review within EPA; (5) interagency review; (6) independent external peer review and public review and comment; (7) public external peer review meeting; (8) preparation of final IRIS documents based on independent expert review and public comment; (9) interagency review; (10) final EPA review and clearance; and (11) posting of completed IRIS assessments on to the database.

EPA is continuing to build and update the IRIS database by addressing the foremost user needs, as expressed within EPA, by other federal agencies, and by the public. EPA will also work toward updating the assessments in the IRIS database where new scientific information is sufficient.

Q8b. Indicate which of the steps is constrained to a specific time period (e.g., public comments for 60 days).

A8b. At this time, the only step in the health assessment development process that is constrained to a specific time period is public review and comment. EPA's current process calls for at least one opportunity for public review and comment on each draft health assessment. This comment period, which is announced to the public via a *Federal Register* notice, ranges from 30 days to 60 days depending on the complexity of the assessment and the level of stakeholder interest in what is recognized as a high profile assessment. Generally, EPA times the end of the public comment period so that it ends one to two weeks prior to the peer review meeting. Then, prior to the peer review meeting, all comments submitted to the Agency by the close of the public comment period are provided to the members of the peer review panel for their pre-meeting review.

Q8c. Indicate the agencies that are involved in any interagency review process and the nature of their role in the process.

A8c. The agencies involved in any interagency review process for any particular chemical depends on the chemical itself and an individual agency's interest in that chemical. The Office of Management and Budget (OMB) coordinates and participates in the interagency review process. The interagency group may consist of representatives from the: Office of Science and Technology Policy (OSTP), Council on Environmental Quality, Department of Health and Human Services (HHS) [including representation from the Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), National Institute for Environmental Health Sciences (NIEHS), National Institute for Occupational Safety and Health (NIOSH) and Food and Drug Administration (FDA)], Department of Defense (DOD), Department of the Interior (DOI), Department of Labor (DOL), National Air and Space Administration (NASA), Department of Energy (DOE), Department of Transportation (DOT) [including representation from the Federal Aviation Administration (FAA)], Department of Agriculture (USDA), and the Consumer Product Safety Commission (CPSC).

Q8d. Indicate the points in this process that the Office of Management and Budget, the Office of Science and Technology Policy, and any other White House office or committee are involved in the formal or informal review of the assessment and the nature of their role in the process.

A8d. OMB is involved in steps 5 and 9 of the review process described in the response to question (a) above. In step 5, EPA provides to OMB the draft health as-

sessment and the draft charge to the external peer reviewers. OMB distributes these draft documents to the others in the interagency group for review and comment. EPA then revises the draft health assessment and charge, as appropriate, to respond to the comments. After interagency review is completed, the draft assessment is released for public comment and begins independent peer review. In step 9, after peer review is complete and EPA has addressed comments from the independent peer reviewers and the public, OMB and the other federal agencies are again provided the draft assessment for review. This provides an opportunity for OMB and the other federal agencies to review any changes by EPA arising from external peer review comments. After step 9 is completed, the final assessment is publicly released by inclusion on IRIS.

Q8e. What is the maximum, minimum, and average time required to complete this review process for a chemical assessment?

A8e. EPA, in cooperation with an interagency group, is reviewing the Agency's development process for health assessments that will be posted on IRIS. Thus, the review process is evolving. The current process, however, as described above, in which EPA sends draft health assessments for interagency review at two points in the process [prior to external peer review (Step 5) and before posting on IRIS (Step 9)] has been followed for over a year. As this review process has developed, several assessments (e.g., toluene, n-hexane, and phosgene) were completed and posted on IRIS. EPA will be happy to provide updated information as more assessments are finalized. In addition, the Agency has developed annual goals of completing 16 health hazard assessments of high priority chemicals for interagency review or external peer review and posting eight finalized assessments on the Internet.

HUMAN HEALTH

Q9. The Agency's proposed budget in FY 2008 for human health risks of susceptible populations is reduced by $4.7 million as compared to the FY06 enacted funding. What specific research projects or activities will be eliminated to accommodate the proposed reduction in funding for research in this area?

A9. The reduction includes a redirection of some resources to support higher priority research in several areas, such as Clean Air, Human Health Risk Assessment (HHRA), and Sustainability. While no major programs will be eliminated by the reduction, some lower priority research will be impacted. EPA will continue to fund critical core research to address health risks of susceptible sub-populations, (such as mechanistic work, aggregate and cumulative risk assessments, and the Children's Environmental Health Centers) and will meet critical performance commitments.

INTEGRATED RISK INFORMATION SYSTEM

Q10. In her testimony, Dr. Sass listed several types of information that are not being included in the current postings of chemical assessments on the IRIS data base listed within the past year or two: acute risk values and summaries of the assessments. Dr. Sass also indicated that EPA's supplemental cancer guidelines providing for consideration of children's exposure has not been applied to the posted assessment on ethylene oxide. Dr. Sass attributes these features of recently posted chemical assessments on the IRIS data base to decisions of the Office of Management and Budget.

Q10a. Why have acute risk values been excluded from the recent IRIS assessments?

A10a. Acute risk values have not been part of traditional IRIS assessments. The IRIS database is focused on health effects from longer-term exposures. Other federal agencies, such as the Agency for Toxic Substances and Disease Registry (ATSDR), develop values for less-than-lifetime exposures. EPA also supports the development of Acute Exposure Guidance Levels or AEGLs (*http://www.epa.gov/opptintr/aegl/pubs/process.htm*) and Provisional Assessment Levels or PALs (*http://www.epa.gov/NHSRC/news/news062906.html*) for short-term exposures. Additionally, EPA began a pilot effort in 2003 to evaluate the application of methods, procedures, and resource needs for deriving less-than-lifetime exposure duration values. This effort focused on some "pilot" chemical as part of this methods development effort.

Q10b. Why don't the recently posted chemical assessments on the IRIS data base contain summaries?

A10b. When an IRIS assessment is completed, EPA's practice is to post the final toxicological review document and IRIS summary after external peer review is completed.

In addition, EPA is in the process of enhancing the IRIS system by employing new electronic technologies, making the system more useful to users. The current format for IRIS is dated and relies heavily on text instead of an integrated and interactive approach to displaying the risk information in IRIS. The direction we're heading is to move the IRIS database into the 21st century by revising the format of the summaries to utilize hot links to the appropriate discussions in the toxicological review documents. This will enhance the information transfer to users and eliminate redundancy in the current system.

Q10c. Have the supplemental cancer guidelines providing for consideration of children's exposure been followed in the preparation of the IRIS listing for ethylene oxide in the toxicological review and in the summary assessment? If not, why not?

A10c. The external review draft of the Evaluation of the Carcinogenicity of Ethylene Oxide (EPA, August 2006) follows the Agency's 2005 *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens.* The assessment draft concludes that "Because the weight of the evidence supports a mutagenic mode of action for EtO carcinogenicity, and in the absence of chemical-specific data on early-life susceptibility, increased early-life susceptibility should be assumed and, if there is early-life exposure, the age-dependent adjustment factors (ADAFs) should be applied, as appropriate, in accordance with EPA's *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. . .*" (p. 2, line 18–23).

Q10d. What information does the Agency use to decide when and how the supplemental cancer guidelines providing for consideration of children's exposure will be applied in the development of chemical assessments posted on the IRIS data base?

A10d. The Agency considers chemical-specific data (from humans or animals) demonstrating increased early-life susceptibility to cancer. If no such data are available but the chemical has been determined to be carcinogenic by a mutagenic mode of action, then the default factors supplied in the Supplemental Guidance are used to estimate risk corresponding to children's exposure.

Q10e. What role has OMB played in determining the type and scope of information to be included in chemical assessments included in the IRIS data base?

A10e. EPA is the author of chemical assessments included in the IRIS data base and EPA determines the type and scope of information that will be included in the assessments. However, EPA does make revisions to draft documents based on public comments, peer review comments, and comments from interagency review, including comments from OMB.

Questions submitted by Representative Ralph M. Hall

BOARD OF SCIENTIFIC COUNSELORS

Q1. I understand that in addition to working with the Science Advisory Board (SAB) you also work closely with the Board of Scientific Counselors (BOSC). Please describe the BOSC and how it assists with improving the efficiency of your efforts.

A1. The BOSC was established by the U.S. Environmental Protection Agency (EPA) in 1996 to provide advice and recommendations about the Office of Research and Development (ORD) research program. It is one of approximately 25 Federal Advisory Committees at EPA. Since the BOSC is a Federal Advisory Committee, it must comply with the *Federal Advisory Committee Act* (FACA) (5 U.S.C. App. C) and related regulations. Consequently, the BOSC has an approved charter, which must be renewed biennially, announces its meetings in the *Federal Register,* opens its meetings to the public, and provides opportunities for public comment on issues before the Board.

The BOSC members constitute a distinguished body of scientists and engineers who are recognized experts in their respective fields. The BOSC currently has 14 members, and they meet three to five times each year. BOSC members are Special Government Employees (SGEs), and are required to complete ethics training and an extensive confidential disclosure form (3110–48) that is reviewed for potential conflicts of interest, and approved by the Designated Federal Officer (DFO) and Des-

ignated Agency Ethics Official prior to commencing any work for the BOSC. The BOSC provides advice and recommendations to ORD on:

- science and engineering research, programs and plans, laboratories, and research-management practices of ORD
- ORD's program development and progress, ORD's research planning process, and research program balance
- peer review, including evaluation of ORD's peer review policies, and review of ORD Offices, National Laboratories and Centers, and research plans and products
- human resources planning, such as scientist career development and rotational assignment programs, and the appropriate scope and design of training programs for environmental research professionals.

With the approval of EPA, the BOSC Executive Committee establishes subcommittees for any purpose consistent with the BOSC's charter. Subcommittees have no authority to make decisions on behalf of the BOSC, nor can they report directly to EPA. Subcommittees may not work independently of the chartered Executive Committee, and must report their recommendations and advice to the BOSC Executive Committee for full deliberation and discussion. ORD has been implementing periodic independent expert retrospective/prospective reviews of the relevance, structure, performance, quality, scientific leadership, coordination and communication, and outcomes of each of its research programs since 2004, and is using BOSC subcommittees as the independent expert review mechanism for these reviews.

An ORD representative serves as the DFO for the BOSC Executive Committee and each Subcommittee, coordinating all of their activities and related administrative activities. Current BOSC members, activities, and copies of BOSC meeting minutes and reports are available at *www.epa.gov/osp/bosc*.

Although the "efficiency" of ORD research is not explicitly addressed by the BOSC reviews of ORD programs, it is implicitly addressed by asking the BOSC to comment on whether ORD is doing the right science, doing the science right, satisfying client/stakeholder needs, and achieving needed outcomes in its reviews. The BOSC recommendations help ORD to: plan, implement, and strengthen its programs; compare the program under review with programs designed to achieve similar outcomes in other parts of EPA and in other federal agencies; make research investment decisions over the next five years; prepare EPA's performance and accountability reports to Congress under the Government Performance and Results Act; and respond to evaluations of federal research, such as the Performance Assessment Rating Tool.

Between 2004 and 2006 the BOSC conducted program reviews and issued reports for the following ORD research programs: drinking water, particulate matter and ozone, ecology, human health, endocrine disrupting chemicals, water quality, land, and global change. Each of these reviews has provided valuable advice for improving ORD research. ORD plans to continue periodic retrospective/prospective analysis of its research programs at intervals of four to five years, and sees the BOSC reviews as an important feedback mechanism for how well ORD is conducting its research, responding to client needs, and achieving outcomes.

NEAR ROAD ENVIRONMENT RESEARCH

Q2. You mentioned in your testimony vehicle emissions in the near road environment. What are your plans with near road environment research and how do you plan on reducing public exposure to air pollution?

A2. A growing number of health studies have identified an increase in the occurrence of adverse health effects, including respiratory disease, cancer, and even mortality, for populations living near major roads.[1] These initial reports have raised concerns about the siting of schools near roadways, the quality of indoor air in existing schools near roadways, and the general health impacts on people living near roads. Additionally, recent studies assessing the health impacts of airborne particu-

[1] For more details, see:

Peters A, von Klot S, Heier M, Trentinaglia I, Hormann A, Wichmann HE, Lowel H. (2004). Exposure to traffic and the onset of myocardial infarction. *N Engl J Med.* 351(17):1721–30.

Kim JJ, Smorodinsky S, Lipsett M, Singer BC, Hogdson AT, Ostro B. (2004) Traffic-related air pollution near busy roads: the East Bay Children's Respiratory Health Study. *American Journal of Respiratory Critical Care Medicine* 170:520–526.

Gauderman WJ, Avol E, Lurmann F, Kuenzli N, Gilliland F, Peters J, McConnell R. (2005) Childhood asthma and exposure to traffic and nitrogen dioxide. *Epidemiology* 16(6):737–743.

late matter have shown a source signal (e.g., copper, nitrogen oxides, or engine or brake metals) associated with roadway traffic.

EPA plans to evaluate the impact of roadways on health risk by conducting research following the paradigm of "source to ambient air to exposure to health outcome" in an attempt to rank this medium in the hierarchy of emission sources associated with air pollution. Comprehensive studies are planned in collaboration with the Federal Highway Administration over the next four years in Las Vegas, Detroit and Raleigh—each representing distinct, representative meteorological and topographical environments and traffic situations. Initial studies will include: near-road emissions (diesel and gasoline), distance from road measurements, development of local-environment dispersion models, and assessment of low-cost mitigation strategies in indoor school environments. This effort will expand beginning in Detroit to include the broader significance of near-road emissions in the context of multiple other sources and more specific personal exposure assessments on people and potential health impacts. In addition to assessment of roadway exposures as a health risk, specific information as to potential measures for mitigation of exposures (through the use of barriers and horticulture, changes in building ventilation, etc.) and tools for addressing the problem (through models that suggest altered traffic flow or road and urban design) will be developed.

EPA Libraries

Q3. In her testimony, Dr. Sass, from the Natural Resources Defense Council, mentioned that EPA had not finalized digitizing documents housed in EPA libraries on schedule. Please clarify the current situation in regard to the libraries and digitizing of documents. Also, please describe any plans (including timelines) EPA has for closing its libraries.

A3. The Agency has met its commitment to digitize all unique EPA documents held by the Regions 5, 6, and 7 libraries and the OEI-run Headquarters Library by January 31, 2007.

EPA plans to complete digitization of unique EPA documents in other libraries by the end of fiscal year 2008.

EPA has no plans to close other libraries.

Questions submitted by Representative Daniel Lipinski

Q1. The Administration's FY 2008 budget request for the Great Lakes Legacy program represents a reduction of $14 million from FY 2006 enacted funding (from $49.6 million to $35 million). I believe this cutback will hamper efforts to address persistent high concentrations of contaminants in the bottom sediments of rivers and harbors that represent a risk to aquatic organisms, wildlife, and humans. Two of these "areas of concern" (AOCs) are located near the Chicagoland area and my district. What degree of contaminated sediment remediation has been accomplished by this program since it became law five years ago? What is the anticipated date that remediation of these areas will be completed? How will the program be impacted by this proposed budget cut? What activities will be discontinued to achieve the $14 million reduction in funding for this program?

Q1a. What degree of contaminated sediment remediation has been accomplished by this program since it became a law five years ago?

A1a. The program first received funding in FY 2004. Since then, the program has remediated 250,000 cubic yards of contaminated sediments at three completed sites in three Areas of Concern. Project Agreements have been signed for two additional sediment remediation projects which are expected to remediate an additional 640,000 cubic yards of contaminated sediments (Ashtabula River, Ohio, and Tannery Bay, Sault Ste. Marie, Michigan). These two projects are underway and are scheduled to be completed by the end of 2007.

Q1b. What is the anticipated date that remediation of these areas will be completed?

A1b. U.S.EPA has received proposals for Legacy Act funding for remediation of sites within Waukegan Harbor and Grand Calumet River Areas of Concern. We will be able to estimate a remediation date for projects in these Areas of Concern if the projects score favorably and are selected for funding, in accordance with the *Great Lakes Legacy Act* implementation rule. The Great Lakes Program works with the full gamut of enforcement and regulatory programs in the 30 remaining Areas of Concern (including the Waukegan and Grand Calumet AOCs), along with the *Great Lakes Legacy Act* to find solutions to addressing the remaining problems in the AOCs. Specifically, we are working closely with the Illinois EPA, the Illinois DNR,

the Indiana Department of Environmental Management, and the Indiana DNR to find solutions to the remaining problems at Waukegan and the Grand Calumet River.

Q1c. How will the program be impacted by this proposed budget cut?

A1c. If the President's budget is enacted, the Legacy Act program will actually receive an increase of about $5 million over the FY06 enacted level, for a total of $35 million.

Q1d. What activities will be discontinued to achieve the $14 million reduction in funding for this program?

A1d. See #1c. If the President's budget in enacted, no activities will be discontinued.

Attachment A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 7, 2006

OFFICE OF
RESEARCH AND DEVELOPMENT

POLICIES AND PROCEDURES MANUAL CHAPTER 4, SECTION V.D.4

SUBJECT: Memoranda of Understanding (MOU)

FROM: George Gray ***/s/ George Gray***
Assistant Administrator (8101R)

TO: ORD Laboratory/Center/Office Directors
ORD Laboratory/Center/Office Deputy and Associate Directors for Management
ORD Laboratory/Center Associate Directors for Ecology and Health
Associate Director for Science, OSP

POLICY STATEMENT

The Office of Research and Development (ORD) supports the Agency's environmental management philosophy to encourage collaboration with outside organizations. This policy memorandum revises and updates ORD's MOU guidance to: (1) include Conflicts of Interest (COI) considerations; and (2) clarify steps for coordinating with the Office of General Counsel (OGC) and the Office of Grants and Debarment (OGD). Agreements within a MOU may not form the basis for sole source acquisition or assistance justifications. The use of mandatory language in this policy is intended to improve the internal management of ORD by providing recommended procedures and does not create or confer legal rights or impose any legally binding requirements on ORD or the Agency.

POLICY RECISION

This policy supersedes previous ORD policy on this subject:

(1) Policies and Procedures Manual (PPM) Chapter 4, Section V.D.4., "Memoranda of Understanding," dated May 10, 1999.

(2) ORD Policies and Procedures Manual (PPM) Chapter 4, Section V.D.4., "Memoranda of Understanding," dated December 29, 2004.

REFERENCES

(1) EPA Delegations Manual 1200 TN 542, 1-11, Interagency Agreements, dated February 22, 2002, http://intranet.epa.gov/rmpolicy/ads/dm/index1.htm

(2) Section 103 of the Clean Air Act, 42 USC 7403 http://www.gpoaccess.gov/uscode/index.html

(3) Section 104 of the Clean Water Act, 33 USC 1254 http://www.gpoaccess.gov/uscode/index.html

(4) Section 8001 of the Solid Waste Disposal Act, 42 USC 6981 http://www.gpoaccess.gov/uscode/index.html

(5) Section 102(2)(F) and (G) of the National Environmental Policy Act, 42 USC 4332(2)(F) and (G) http://www.gpoaccess.gov/uscode/index.html

(Note: Section 102(2)(F) authorizes cooperation in international efforts to protect the environment; Section 102(2)(G) authorizes EPA to provide advice and information to a broad array of stakeholders to restore, maintain and enhance the environment.)

(6) Federal Advisory Committee Act , 5 USC App.2 http://www.gpoaccess.gov/uscode/index.html

(7) Freedom of Information Act, 5 USC 552 http://www.gpoaccess.gov/uscode/index.html

(8) Office of General Counsel, Ethics Web Site http://intranet.epa.gov/ogc/ethics.htm

BACKGROUND

EPA has broad authority to cooperate with federal and non-federal parties to encourage, coordinate, and accelerate environmental research under several statutes including Section 103 of the Clean Air Act, 42 USC 7403; Section 104 of the Clean Water Act, 33 USC 1254; and Section 8001 of the Solid Waste Disposal Act, 42 USC 6981.

ORD uses the term MOU to describe unfunded agreements between ORD and other entities. These agreements, which establish a *non-binding general* framework for cooperation, including planning for collaboration, may often contain binding clauses, such as clauses regarding the use or disposition of intellectual property rights. A MOU specifies the type of effort to be undertaken and accomplished, and sets forth the responsibilities of all parties to the agreement. Some sections that may be appropriate, are: Purpose/Objectives/Goals, Background, Authorities, Roles and Responsibilities, Limitations, Proprietary Information, Intellectual Property, Points of Contact, Modification, and Duration/Termination provisions.

MOUs may be entered into with a broad range of parties including:

Other EPA organizations	Other federal agencies
Educational institutions	Non-profit entities (e.g., Hospitals)
Not for-profit entities (e.g., Research Institutes)	For-profit entities (e.g., Corporations)[1]
State, local and tribal governments	Individuals

International Entities (contact the Office of International Activities (OIA) & OGC)[2]

PROCEDURES

Conflicts of Interest (COI)

Each Laboratory/Center/Office (L/C/O) is responsible for ensuring that COI are identified and addressed (e.g., avoided, mitigated, or neutralized). The COI Assessment Form (Exhibit 1) must be completed and routed with the MOU for review and approval in accordance with the procedures and delegations outlined below.

Provided below are some principles that should be considered before entering into a MOU. None of these are determinative, but are points to be considered in weighing the pros and cons of entering into a relationship to be documented by a MOU.

- Exercise particular care when entering into MOUs with a for-profit organization to ensure that the MOU does not create the appearance that EPA/ORD is giving the for-profit organization a commercial advantage.

- Has there been an assessment of other business practices or organizational activities of the potential partner that may represent or suggest a direct or indirect conflict to ORD's mission and policies?

- Does the partnership conflict with current administrative practices and procedures (e.g., funding priorities, scientific review, grants administration practices)?

---

[1]Use of EPA facilities by for-profit organizations, unless covered by a Cooperative Research and Development Agreement (CRADA), are governed by 42 USC 4370, which requires EPA charge fees for use of EPA facilities. See ORD PPM 3.6, Outside User's Agreement (OUA) for ORD Research and Test Facilities, dated November 6, 2000. Located at http://intranet.epa.gov/ord/orma/htm/policies.htm

[2]OIA must review and concur on all MOUs that will be performed outside of the United States.

- Are there defined oversight mechanisms that can be used to gauge progress and identify potential or emerging conflicts during the partnership?

Additional Considerations

- Are the goals of the MOU explicit and consistent with ORD's mission?
- Are the activities of a sufficiently high priority such that they might have been implemented entirely with appropriated funds, if such funds had been available?

Review and Approval

Because funds are not exchanged via MOUs, the need for review outside of the responsible parties is dependent upon the nature of the understandings contained in the MOU. MOUs must not be implemented until they are approved by the appropriate parties and have received the necessary concurrences.

All MOUs must be reviewed by OGC's Finance and Operations Law Office and Cross-Cutting Issues Law Office. OIA must review and concur on all MOUs that will be performed outside of the United States.

Many ORD MOUs involve the use or creation of intellectual property, ranging from the creation of a copyrightable journal article to the development of a patented process. Before entering into an agreement with another party, the proposed MOU activities and objectives must be carefully reviewed to determine whether any intellectual property will, or even may, be created. The review may show that a MOU is not the appropriate type of agreement for the activities and objectives contemplated. For example, CRADAs are appropriate for EPA to accept funds, in addition to in-kind resources, from CRADA partners, which goes directly to the lab in support of the CRADA. If a MOU is appropriate, great care should be taken when considering the terms ORD would prefer regarding the disposition of intellectual property, as it is much easier to include provisions in the original agreement. For example, ORD may want a copyright license to articles or software created jointly, or want works to be placed in the public domain and be free of charge to anyone.

All MOUs that may involve the use of or creation of copyrighted works, trademarks, the Agency seal and/or identifier, or patents, must be reviewed and concurred on by OGC's Intellectual Property Law Practice Group.

All MOUs must be reviewed by an Extramural Management Specialist (EMS) in order to determine the required approval levels. The EMS will also determine whether the activity is subject to the Federal Advisory Committee Act[3] and consult with OGC as needed. All MOUs

[3]The Federal Advisory Committee Act applies when EPA establishes or manages and controls a group that provides collective advice to EPA or another federal agency.

must be entered into OMIS/IRMS for tracking purposes. In the case of multiple ORD organizational involvement, one EMS shall be appointed as "lead EMS" for review purposes and for entering the MOU into OMIS/IRMS.

Depending on the impact, the MOU could be approved by the EPA Administrator, AA/ORD, L/C/O Director, L/C/O Deputy Director for Management, or Division Director.

MOUs with Agency-wide impact: For example, in 2004, EPA and the Department of Energy entered into a MOU to expand Research and Computing Collaboration, including the linking of two national supercomputers. http://www.epa.gov/ord/WebPubs/DOEMOU.pdf

MOUs with ORD-wide impact: For example, a MOU between ORD and another program office (e.g., Office of Solid Waste and Emergency Response) to establish the framework for a rotational exchange program.

MOUs with L/C/O-wide impact: Apply to multiple divisions within the L/C/O. For example, a MOU between a L/C/O and the U.S. Department of the Interior to establish a visiting scientist program.

MOUs with Division-wide impact: For example, a MOU between the Western Ecology Division and the U.S. Department of Agriculture for use of specialized research facilities for U.S. Forest Service experiments.

Regardless of the approval levels, **a signed copy of all MOUs must be forwarded to the Office of Resources Management and Administration (ORMA)**/Research and Management Support Staff (RMSS). ORMA/RMSS will forward copies of all MOUs signed by the EPA Administrator to the Office of the Executive Secretariat upon execution.

A template with sample language is included as Exhibit 2; specific paragraphs should be included as appropriate.

Instructions for Preparing the Signature Package and Obtaining Approval are included as Exhibit 3.

Waivers: The delegatees listed below may waive any procedural requirement with the exception of the authorities reserved to the Grants Operations Branch B (GOBB) under EPA Delegation 1-11 (Reference 1). With the concurrence of the MOU approval official, the EMS may request that GOBB waive its approval requirement.

DELEGATIONS

MOUs with other federal agencies, state, local, and foreign governments fall under Section 1.a.2 of EPA Delegation 1-11, Interagency Agreements, which states that they "Set forth basic policies and procedures governing their relationships on matters of mutual interest and responsibility under which no exchange of funds occurs."

The AA/ORD has redelegated the items listed below. All potential redelegations are also listed. Potential redelegations are not to be interpreted as a redelegation of this authority and must be made in writing by the authorized delegating official.

Item	Approval Required	Redelegated To	Potential Redelegation	ORD Source
MOUs with Agency-wide impact	AA/ORD	N/A	N/A	This ORD PPM Chapter 4.D.4 on the date approved.
MOUs with ORD-wide impact	AA/ORD	N/A	N/A	This ORD PPM Chapter 4.D.4 on the date approved.
MOUs with L/C/O-wide impact	AA/ORD	L/C/O Director	L/C/O Deputy Director for Management	This ORD PPM Chapter 4.D.4 on the date approved.
MOUs with Division-wide impact	AA/ORD	L/C/O Director→ L/C/O Deputy Director for Management	Division Director	This ORD PPM Chapter 4.D.4 on the date approved.

After a MOU is approved by the ORD officials above and has been signed by all parties, the EMS may obtain the concurrence of the ORD approving official to request that GOBB waive its approval requirement.

Item	Agency Delegation	Redelegated To	Potential Redelegation	EPA Source
MOUs with other federal agencies, state or local governments, and foreign governments	AA/OARM & RAs	OGD→ Grants Administration Division (GAD)	GAD Branch Chief or equivalent (e.g., GOBB)	EPA Delegations Manual 1200 TN 542, 1-11, 1.a.2, 2/22/02

cc: ORMA Management Team
ORD Policy Coordinator (RMSS)
ORD Policies and Procedures Coordinators
ORD Extramural Management Specialists
ORD Extramural Management Network
ORD Management Integrity Coordinators

US EPA Office of Research and Development

EXHIBIT 1

ORD MOU CONFLICT OF INTEREST (COI) ASSESSMENT FORM

1. Are funds or other resources being provided to parties, who are not signatories, in support of this MOU? ☐ No ☐ Yes
If yes, attach a full description of the facts and, if applicable, a programmatic rationale and/or steps taken to avoid, mitigate or neutralize any potential conflicts.

_____
_____
_____
_____
_____

2. Are any of the parties, either direct partners of ORD or partners in the MOU through an intermediary, being given any special treatment or access due to their status as a partner? Examples of special treatment could include, early access to data, images or materials; or, involvement in ORD decision-making, such as positions on steering committees and involvement in review procedures. ☐ No ☐ Yes
If yes, attach a full description of the facts and, if applicable, a programmatic rationale and/or steps taken to avoid, mitigate or neutralize any potential conflicts.

_____
_____
_____
_____
_____

3. Do any of the parties, given their organizations missions, pose an organizational COI, either real or perceived, with that of ORD? For example, organizational COI could occur or be perceived or give the appearance as possible with organizations that are part of a regulated industry. ☐ No ☐ Yes
If yes, attach a full description of the facts and, if applicable, a programmatic rationale and/or steps taken to avoid, mitigate or neutralize any potential conflicts.

_____
_____
_____
_____
_____

4. A copy of the proposed MOU is attached for review and approval.

Other Agency/Org. Logo

EXHIBIT 2

MEMORANDUM OF UNDERSTANDING

ON (INSERT SUBJECT)

BETWEEN THE

U.S. ENVIRONMENTAL PROTECTION AGENCY

AND THE

(INSERT NAME OF OTHER ORGANIZATION)

I. PURPOSE/OBJECTIVES/GOALS

The purpose of this MOU is to _____. In general, the parties intend to focus on _____.

II. BACKGROUND

(Insert a background statement.)

III. AUTHORITIES

EPA enters into this MOU pursuant to Section ____ of the _____ Act.

IV. ROLES AND RESPONSIBILITIES

Each party intends to _____. EPA intends to _____.
The (name of other party) intends to _____.

V. LIMITATIONS

A. All commitments made in this MOU are subject to the availability of appropriated funds and each party's budget priorities. Nothing in this MOU, in and of itself, obligates (name of other party) or EPA to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or other financial obligation. **(Name of other party) agrees not to submit a claim for compensation for services rendered to EPA or any other federal agency for activities it undertakes in carrying out this MOU.**

B. This MOU is neither a fiscal nor a funds obligation document. Any endeavor involving reimbursement or contribution of funds between the parties to this MOU will be handled in accordance with applicable laws, regulations, and procedures, and will be subject to separate subsidiary agreements that will be effected in writing by representatives of both parties.

C. Except as provided in Section V. paragraphs (A) and (B) and Section VII. INTELLECTUAL PROPERTY, (list any other section/provision intended to be binding), this MOU is not legally binding and does not create any right or benefit, substantive or procedural, enforceable by law or equity against (name of other party) or EPA, their officers or employees, or any other person. This MOU does not direct or apply to any person outside (name of other party) and EPA.

D. *If applicable, include the following language:* The Parties agree that use of EPA/ORD research and test facilities, and the presence of outside users at the EPA/ORD facilities by non-government entities or individuals, will be properly documented and approved in a separate Outside User's Agreement if the use is appropriate and in the public interest.

E. *If the MOU involves cooperative use by EPA of laboratory or other equipment owned or controlled by the other party to the MOU, identify the equipment in the MOU or a separate attachment and include the following language:* "(Name of other party) expressly waives, now and forever, any charges to EPA for use or claims against the Agency associated with the use, including any damage whatsoever, of the equipment identified below [or in an Attachment]."

F. The (name of other party) may make factual statements to the public which describe its cooperation with EPA. However, nothing in this MOU allows EPA to endorse the purchase or sale of (name of other party) products or services. The (name of other party) agrees not to make statements to the public in news releases, product brochures, on web sites or in any media that imply EPA endorsement of (name of other party) products or services.

VI. PROPRIETARY INFORMATION

To carry out the joint work resulting from this MOU, (name of other party) may need to disclose proprietary information to EPA. For the purpose of this MOU, proprietary information is defined as information that an affected business claims to be confidential and is not otherwise available to the public. (Name of other party) agrees to clearly identify as such confidential information disclosed to EPA in writing; and to clearly memorialize in writing, within a reasonable time, any confidential information initially disclosed orally. EPA agrees not to disclose, copy, reproduce or otherwise make available in any form whatsoever to any other person, firm, corporation, partnership, association or other entity information designated as proprietary or confidential information without consent of (name of other party) except as such information may be subject to disclosure under the Freedom of Information Act (5 U.S.C. § 552), and EPA's regulations at 40 C.F.R. Part 2, or as otherwise authorized by law.

VII. INTELLECTUAL PROPERTY *(If intellectual property is anticipated, OGC must review whether a MOU is appropriate and whether the following paragraphs need to be tailored to address the particular situation.)*

The parties agree that any copyrightable subject matter, including but not limited to journal articles, training, educational or informational material or software, created jointly by the parties from the activities conducted under the MOU may be copyrighted by (name of other party). (Name of other party) hereby grants to the government a royalty-free, nonexclusive, irrevocable right to reproduce, distribute, make derivative works, and publish or perform the work(s) publicly, or to authorize others to do the same on its behalf.

The parties agree that any patented invention created by (name of other party) pursuant to the terms of this MOU will be jointly owned by the parties regardless of inventorship, unless an alternative agreement indicates otherwise.

VIII. POINTS OF CONTACT

The following individuals are designated points of contact for the MOU:

U.S. Environmental Protection Agency:

(Insert name, organization, mailing address, e-mail address, phone and fax numbers)

(Name of Other Party):

(Insert name, organization, mailing address, e-mail address, phone and fax numbers)

IX. MODIFICATION/DURATION/TERMINATION

This MOU will be effective when signed by all parties. This MOU may be amended at any time by the mutual written consent of the parties. The parties will review this MOU every ____ (insert time period) to determine whether it should be revised, renewed, or cancelled. This MOU may be terminated by either party at anytime by one party notifying the other party in writing 90 days in advance of the termination date.

X. APPROVAL

(Name of Other Party)	U.S. Environmental Protection Agency
_____	_____
(Signature Block)	(Signature Block)
_____	_____
Date	Date

EXHIBIT 3

INSTRUCTIONS
FOR PREPARING THE SIGNATURE PACKAGE AND OBTAINING APPROVAL

MOUs that require AA/ORD (or higher) approval:

1. The signature page should only contain signature blocks (and no other text).

2. Print two color copies of the MOU; print an 'Official File Copy' yellow concurrence page.

3. Place a plastic Executive Correspondence cover sheet on the first page of the MOU; attach "Sign Here" tabs where appropriate.

4. Place a copy of the OMIS/IRMS entry screen on left side of the blue signature folder. If the party to the MOU is not on the OMIS/IRMS list of institutions, contact your respective OMIS Representative to add this information to the database.

5. On the ORD Extramural Package & Routing Transmittal Checklist (located at http://intranet.epa.gov/ordintra/orma/htm/extmlmgmnt.htm)

- insert a space (after the L/C/O Director) for OGC concurrence;

- insert a space (after the ORMA Director) for ORD Communication Officer concurrence;

- if the MOU will be performed outside of the United States, insert a space (after the ORD Communication Officer) for OIA concurrence;

- if parties to the MOU are other federal agencies, state or local governments, or foreign governments, insert a space (after the AA/ORD) for OGD/GOBB concurrence;

6. When concurrence is made by email, place a copy of the email behind the yellow concurrence page.

7. Forward the signature package (and e-mail the file) to ORMA/RMSS (Mail Code 8102R).

8. Upon receipt, ORMA/RMSS will: (1) log MOUs into the Lotus-Notes Extramural Tracking System (the letters, "MOU," will be used as an extension of the tracking number); and (2) route the package for signature (and update the Tracking System as appropriate).

9. When the MOU is signed by the AA/ORD, ORMA/RMSS will update the Tracking System and return a signed hard copy (and electronic copy) to the originating L/C/O EMS.

10. If higher approval (e.g., the Administrator) is required, ORMA/RMSS will forward the signature package to the Office of the Executive Secretariat (OEX) Records Specialist (Mail Code 1105A) and update the Tracking System.

11. When the MOU is signed by all parties, ORMA/RMSS will update the Tracking System and return a signed hard copy (and electronic file) to the originating L/C/O EMS. The originating L/C/O EMS will update OMIS/IRMS to reflect the date signed and any other pertinent information (e.g., Active, Inactive, Complete). Completed or expired MOUs shall **not** be deleted from OMIS/IRMS.

ANSWERS TO POST-HEARING QUESTIONS

Responses by M. Granger Morgan, Chair, Environmental Protection Agency Science Advisory Board

Questions submitted by Chairman Nick Lampson

Q1. You indicated in your testimony and in response to subsequent questions that EPA's proposal for increased research on nanomaterials was improved and that a focus on fate and transport research is important. Last year the Wilson Center released a report indicating that there are already a number of products on the market that contain nanomaterials, and EPA has made some determinations under the Toxic Substances Control Act *(TSCA) that several nanomaterials are substantially similar to existing chemicals and therefore has not required testing of these substances. Did the SAB evaluate the nanomaterials research program in relation to its ability to deliver information to support decisions that EPA is now making under TSCA and future decisions the Agency may be required to make under other environmental statutes? Is the proposed level of funding and the scope of the program sufficient to support both EPA's regulatory mission and an exploration of future questions that may arise related to nanomaterials?*

A1. As indicated in my testimony, and our written report on this issue, this year, the SAB focused on a strategic review of ORD's research program. Thus, we did not look at the details of each ORD research program, for example, the nanotechnology research program in relation to TSCA. Thus, our responses reflect what I believe to be strategic advice to EPA on its research programs, especially as its program components relate to each other and become parts of an integrated overall research program. My response to this question, and the other questions below, should be considered in recognition of this larger view.

It is tempting to think of nanomaterials as just another form of chemical substance that needs to be evaluated with classic toxicological testing before it is used in settings that might involve exposure to people or the environment. However, for several reasons it is not appropriate to think about most nanomaterials in this way.

Nanoparticles may undergo substantial transformations once they have been introduced into the environment. For example very small (sub-micron) particles rather quickly stick to larger particles. In addition one must ask:

— What sorts of chemical and physical transformations might the material undergo?

— What will happen to any "external coatings" that may be applied?

— What will be the degradation processes and what sorts of other materials will result from those processes?

— How will the electrical properties of some particles impact living cells?

When we said we were pleased to see EPA/ORD undertaking research on fate as well as physical and chemical transformation in the environment (and presumably in the future in living organisms), it was because without an adequate understanding of the answers to such questions, it will be difficult for EPA to develop an appropriate science-based approach to the regulation of these materials.

However, if the agency were to apply classical toxicological testing to evaluate nanomaterials it seems likely that those classic toxicological testing procedures would rapidly become overwhelmed. Existing laboratory capacity is already overtaxed by such testing for chemicals and the situation for nanomaterials could be far worse. For example, it is entirely possible that without changing the chemical properties of a particle, minor topological changes (for example, whether a specific string of molecules protrudes on the left or right side) could have profound toxicological or other effects.

I believe that in addition to its work on fate and transport, we face an urgent need to develop new thinking about how to approach the task of regulating such materials. To date, there has been little progress made by EPA, or anyone else, on this issue. The problem is probably best addressed by broadly engaging the thinking of many smart people both inside, and especially outside, the Agency.

You specifically asked:

— Did the SAB evaluate the nanomaterials research program in relation to its ability to deliver information to support decisions that EPA is now making under TSCA and future decisions the Agency may be required to make under other environmental statutes?

— Is the proposed level of funding and the scope of the program sufficient to support both EPA's regulatory mission and an exploration of future questions that may arise related to nanomaterials?

The answer to the first part of your question is that with the program's very limited scope and funds, even if it were to focus entirely on assessing the toxicity of specific new products or materials now under regulatory review, as is the common practice under TSCA, it would never be able to develop the more fundamental insights and understanding needed to support development of efficient science-based regulation in the longer-term. If one wants the program in ORD to do both, then a substantially expanded level of support will be needed.

The answer to the second part of this question is "no." While the current funding supports a modest program of research to improve our understanding of the fate, as well as the physical and chemical transformation of these materials in the environment, it is far too small to address all the important issues, and it does not currently support the broader extramural effort I suggest above that is needed to develop new and efficient ways to address the regulatory challenges these materials pose.

Q2. Dr. Morgan, was the SAB briefed by the Agency on any plans to study, reduce funding for, or consolidate EPA's laboratory personnel, operations or infrastructure? Was the SAB ever asked by EPA to consider or evaluate their plan to consolidate EPA's libraries and restructure their service delivery to Agency employees and the public?

A2. The SAB was not briefed on any plans to consolidate EPA's laboratory infrastructure. However, it has been clear for over 20 years that EPA's research funding was at best flat and as I stated in my testimony this year and last, the EPA research budget is now being significantly decreased. The Agency has been open about these cuts but has maintained, as it must in budgeting, that it can still do important research. Our current and past comments recognize that continuing cuts to research resources, coupled with a desire to maintain an intramural staff of EPA experts, will diminish the resources associated with those things actually needed to conduct research (i.e., equipment, supplies, and appropriate laboratory facilities).

The SAB was not briefed on EPA's library plans, though the issue was raised by SAB members during the FY 2007 research budget review meeting. ORD representatives noted at that time that libraries were managed outside their office and thus were not in their control.

Q3. In your testimony you state that it is important to consider land use, soil and water issues related to development of biomass as an energy source. Is EPA factoring these considerations into their research on biomass energy?

A3. The materials provided to the SAB to support its review of EPA's strategic research directions and the EPA FY 2008 research budget suggest that biomass energy is just beginning to make its way onto the research agenda. The SAB stated on page 8 of its report of March 13, 2007:

> "Many of the responses to global change may also have impacts that should be studied so that they can be understood and plans can be made to manage them appropriately before they arise. For example, while biomass fuel holds the potential to drastically limit future net CO_2 emissions to the atmosphere, it will require vast amounts of land and may have important impacts on ecosystems, on soil degradation, and on water quality and water demand. These fuels can also yield different combustion products that will present changing concerns for air quality. While some of these issues now appear to be on the agenda of the new sustainability initiative, they have yet to be addressed in a serious way, or integrated with the global change research program."

Q4. The FY 2008 Budget again proposes to eliminate funding for its technology verification programs, the Superfund Innovative Technology Evaluation (SITE) program and the Environmental Technology Verification (ETV) program at EPA. Should EPA continue to have these programs or is this something the private sector can do on its own as Dr. Gray suggested in his testimony?

A4. Dr. Gray's assessment of the need for future federal support of these programs seems to reflect the difficult choices that ORD must make in allocating scarce and declining resources to develop the scientific knowledge to support EPA's mission. I have consulted on this issue with Dr. Michael McFarland, Chair of the SAB's Environmental Engineering Committee, and we offer the following personal opinion based on what we know of SITE and ETV.

The Agency plays a critical role as an honest broker in both the SITE and ETV programs. Environmental technology evaluation and verification can, in principle, be conducted within the private sector. However, results from these activities are often fraught with consumer concerns including the possibility of technical inaccuracies, unbalanced testing methods, inadvertent or deliberate bias and possibly even outright fraud.

The overt presence of the Agency within the technology evaluation/verification process lends an important degree of credibility to the marketplace. In other words, we believe that consumer confidence is much higher when the Agency is known to be involved with the development, implementation and assessment of environmental technology evaluation processes. It is important to recognize that the Agency does not choose technology winners or losers in either the SITE or the ETV programs. The Agency merely provides the marketplace with the assurance that the technology evaluation process was conducted as advertised.

The appropriate level of Agency involvement with the development, implementation and assessment of technology evaluation processes (and methods) is arguably the most relevant question and, of course, how those activities should be financially supported. From our evaluation of the SITE and ETV programs, we would strongly argue that the Agency needs to maintain an explicit (and transparent) role in SITE and ETV to ensure that the processes (and methods) used to evaluate environmental technologies are scientifically sound and applied in a balanced way.

Although the private sector has a clear interest in financially supporting environmental technology evaluation and verification processes, it is not entirely obvious how competing demands on private sector resources will influence the development, implementation and/or assessment of technology testing procedures. Explicit Agency involvement provides a means of ensuring vital standardization in technology testing.

Of course, with declining federal budgets, it is clear that increasing financial support for the SITE and ETV programs will be difficult to achieve. However, consideration should be given to maintaining these programs at a level sufficient for them to engage in meaningful discussions with private trade groups and testing organizations (e.g., American Society of Testing Materials—ASTM) to assure the marketplace and the general public that environmental technology claims are supported by scientifically sound and fully documented procedures.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Jennifer Sass, Senior Scientist, Health and Environment Program, Natural Resource Defense Council

Questions submitted by Chairman Nick Lampson

International Life Sciences Institute (ILSI) contracts and projects with EPA

Q1. Was NRDC or any other public interest group invited to participate or observe any of the workshops or meetings funded under these contracts?

A1. No. However, if NRDC or any other public interest group had been invited to participate, this would have still left the public interest overwhelmingly under-represented in a highly technical debate. The public relies on its publicly-supported federal agencies to represent the public interests, and expects its products to be available for public scrutiny by all interested parties. It would be unreasonable to expect the public and public interest groups to provide adequate technical representation during a long, drawn-out process of workshop proceedings. Rather, we expect the final products of such events to be disclosed as corporate/industry work products, submitted to federal agencies during appropriate stages in the regulatory process, available for public scrutiny, and treated with the same consideration, and no more, as all public submissions.

Q2. What is the nature of NRDC's concern about these workshops and meetings?

A2. The ILSI, like any trade group or industry, has the right, and is even encouraged to conduct scientific inquiries (research or analysis) regarding the risks associated with its member's products. Such inquiries should be welcomed as submissions to the regulatory agencies for their review and consideration. When conducted through the proper channels, such submissions are available for public scrutiny, and are submitted to the agencies during appropriate times in the regulatory process. For example, pesticide registrants are required to submit safety data on their products as a prerequisite for registration[1], and are required to submit adverse effects information as it becomes evident during the products commercial use.[2] While the registration of new chemicals does not require safety data, all chemical manufacturers, importers, processors and distributors are required to submit all available information on the risks of their products.[3] The difference between these industry-submissions and the ILSI–EPA activities is that the latter are conducted in a manner that parallels, manipulates, and even co-opts the Agency's activities, so that a final work product represents the corporate response to regulatory needs, but without the disclosure that it is a corporate work product, without the limitations placed on a public submission, and without the participation of public advocacy groups. ILSI describes itself as, "bringing together scientists from academia, government, and industry."[4] While it is expected that ILSI will sponsor research, conferences, workshops, and publications to increase awareness of its scientific research and viewpoints, it is of great concern that government officials from regulatory agencies participate in and even sponsor many of these efforts, influencing government policy positions while by-passing federal requirements for balance of perspectives and transparency such as those embodied in the *Federal Advisory Committee Act* (FACA).[5]

For the reasons above, at a meeting in January, 2006, the World Health Organization (WHO) took action to limit the participation of ILSI in its activities, specifically preventing ILSI from participating in "normative activities," defined as setting chemical or contaminant levels for food and water. This decision followed a public letter from NRDC, Environmental Working Group, United Steelworkers of America

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[1] The data requirements for registration of pesticides are intended to generate data and information necessary to for EPA to assess the identity, composition, potential adverse effects and environmental fate of each pesticide. EPA's requirements for data are listed in the Code of Federal Regulations, Chapter 40, Part 158. *http://www.epa.gov/pesticides/regulating/data.htm*

[2] Section 6(a)(2) of the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA) requires pesticide product registrants to submit adverse effects information about their products to the EPA. *http://www.epa.gov/pesticides/fifra6a2/*

[3] Section 8(e) of the *Toxic Substances Control Act* (TSCA) requires U.S. chemical manufacturers, importers, processors and distributors to notify EPA within 30 calendar days of new, unpublished information on their chemicals that may lead to a conclusion of substantial risk to human health or to the environment. *http://www.epa.gov/opptintr/tsca8e/*

[4] *http://www.ilsi.org/AboutILSI/*

[5] 5 U.S.C. Appendix 2.

and 15 other health, environmental and union groups calling on the WHO to sever all official ties with ILSI. In response to the WHO decision, an e-mail from Craig Barrow of Dow Chemical to ILSI leadership pledges the support of Dow to, "work with ILSI to develop and implement a proactive strategy" to prevent "further discredit to industry and ILSI in the U.S."[6] As the Dow e-mail demonstrates, the interests of ILSI are the interests of its corporate members.

Many ILSI workshops result in recommendations for more scientific study by raising uncertainty and doubt regarding existing science. This technique often serves to stave off liability and health-protective regulations, as described in the now-famous 1969 tobacco memo as follows: "Doubt is our product since it is the best means of competing with the 'body of fact' that exists in the mind of the general public."[7] Similar misinformation campaigns have been used by ILSI members representing asbestos, beryllium, lead, mercury, vinyl chloride, chromium, benzene, and other toxic chemical and pharmaceutical agents.[8,9] This strategy (calling for more research while avoiding meaningful action) also has been the hallmark of global warming opponents, who have misrepresented the scientific consensus, resulting in a decades-long delay in U.S. efforts to curb global warming emissions; a delay that may prove costly indeed for the American people.[10]

EPA is finding itself spiraling into an increasingly weaker scientific state. It has been dealt a decreasing budget for providing scientific infrastructure and resources, despite an increasing need for robust data to support human health and environmental protective policies and regulations. The result is that EPA is increasingly under pressure to make regulatory and policy decisions with no data, inadequate data, or poor-quality data. NRDC recommends that EPA support and expand its use of in-house scientific and technical experts. These people represent the Nation's brain-trust, and their work products should be publicly available. The Agency's own technical experts have to be enabled to investigate and disclose what dangers we truly face from environmental pollutants, despite myriad influences of business interests. With the current cuts to the EPA budget, and under current EPA leadership, grievous and irreversible damage is being done to this Agency's capacity to protect human health and the environment.

Questions submitted by Representative Daniel Lipinski

Nanotechnology

Q1. What is your opinion of the EPA's current research agenda regarding nanotech?

A1. While it focuses on collecting much needed information about nanomaterial toxicity, it fails to either take advantage of existing authority to require the generation and submission of certain information or to explain how this information will inform or support regulatory action, and the nature of regulatory action that EPA plans to take. Thus, EPA's current agenda is missing a vitally important element: a commitment to "develop and enforce regulations that implement environmental laws enacted by Congress"[11] to protect human health and the environment. EPA should use existing authorities to require safety testing of nanomaterials and to prevent exposure to or release of untested or unsafe nanomaterials. In short, EPA is failing to develop new regulations, or amend existing regulations, to adequately address the dangers that potentially toxic nanomaterials may pose to human and the environmental.

Q2. What is your opinion of the efficacy of the EPA voluntary pilot program on nanotech?

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[6] E-mail from Barrow, Craig (CS). Sent: Monday, January 30, 2006 8:32 AM. To: Holsapple Mike (Holsapple, Mike); Gibson Jim (work), (Gibson, Jim (work)); Goodman Jay (Goodman, Jay). Cc: Bus, Jim (JS). Subject: WHO Bans ILSI Participation

[7] Burgard, JW. Executive at Brown and Williams. August, 1969. Available at the Legacy Tobacco Documents Library, University of California, San Francisco. Bates number 680559702. Available at *http://legacy.library.ucsf.edu/tid/wjh13f00*

[8] Michaels, David. Doubt is their product. *Scientific American* June, 2005. pp. 96–101

[9] Special Issue. The Corporate Corruption of Science. Eds. D Egilman, S Rankin-Bohme. *Int J Occup Env Health,* Vol II, No 4. October-December, 2005. *http://www.ijoeh.com/*

[10] White house white-washes global warming data. June 8, 2005. A top White House environmental official—and former oil industry lobbyist—repeatedly manipulated government reports to downplay the threat of global warming. Available at NRDC Bush Record: *http://www.nrdc.org/bushrecord/2005_06.asp*

[11] *http://www.epa.gov/epahome/aboutepa.htm* (statement and explanation of EPA's mission).

A2. A voluntary pilot program now under consideration by the EPA will request that industry participants submit data on material characterization, toxicity, exposure potential, and risk management practices.[12] While this program may help to fill the regulatory breech, it will only involve those companies that volunteer to participate, and will gather data regarding only those products that participating companies choose to disclose. Companies with the riskiest products, as well as those with poor business ethics—that is, those most likely to need government oversight—are least likely to participate. A coalition of more than 20 public interest groups including NRDC, Friends of the Earth, Greenpeace, Sierra Club, and ETC Group insist that a voluntary program without a mandatory regulatory component will not be able to address potential risks.[13]

As a result, the pilot program may generate *some* useful data, but it falls well short of what is need to ensure that we can identify and address significant potential health threats *before* they cause widespread damage.

Despite its shortcomings, the *Toxic Substances Control Act* (TSCA), enacted by Congress in 1976 to gather information about chemical substances and control those deemed dangerous to the public or the environment, is the most obvious candidate for regulating nanomaterials. NRDC and other public interest groups urged the EPA to identify all engineered nanomaterials as "new chemical substances" under TSCA because they meet the standard of "organic or inorganic substance[s] of a particular molecular identity."[14] This would trigger TSCA section 5 pre-manufacture notice ("PMN") reporting requirements prior to the commercial manufacture or import of nanomaterials.[15] The U.S. Patent and Trademark Office issued more than 8,600 nanotechnology-related patents in 2003, suggesting that at least one arm of the government already considers these materials to be new.

In addition to pre-manufacture (PMN) reporting, the EPA has authority to issue test rules under TSCA section 4, and may waive the regulatory production volume thresholds that otherwise would not be triggered by the miniscule product volume of most nanomaterials.[16] EPA also has authority under TSCA section 6 to prohibit or limit anyone manufacturing, importing, processing, distributing in commerce, using, or disposing of a chemical if there is a reasonable basis to conclude the chemical presents, or will present, an "unreasonable risk of injury to health or the environment." EPA has not taken advantage of these authorities to address the risks that nanomaterials pose. Indeed, the EPA has failed to regulate *any* new chemical using the TSCA's section 6 authority since that provision was gutted by the U.S. Court of Appeals for the Fifth Circuit in the 1991 case *Corrosion Proof Fittings v. EPA,* rejecting the EPA's application of the TSCA's section 6 to asbestos).[17] The court's decision and subsequent problematic EPA interpretations of that decision make it extraordinarily difficult for the agency to adopt regulations under TSCA's section 6.

In the end, EPA's current agenda leaves the American public virtually unprotected, the *de facto* guinea pigs of the nanotechnology industry. While NRDC believes that requiring pre-manufacture notice, issuing test rules, and promulgating regulations under TSCA may ultimately be insufficient to protect public health and the environment, EPA's current agenda fails even to identify how it will use these authorities reduce the risk associated with nanomaterials. As a result, legislative action by Congress, the states, and potentially the courts will be necessary to ensure that concerns regarding nanomaterials are adequately addressed.

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[12] National Pollution Prevention and Toxics Advisory Committee (NPPTAC). Interim Ad Hoc Work Group on Nanoscale Materials, Overview of Issues for public discussion and consideration by NPPTAC. U.S. Environmental Protection Agency, September 21, 2005.

[13] J. Sass, NRDC comments on EPA proposed voluntary pilot program for nanomaterials, July 20, 2005, Docket: EPA–OPPT–2004–0122–0013.

[14] *Toxic Substances Control Act* ("TSCA") § 3(2)(A); 42 U.S.C. § 2602(2)(A).

[15] TSCA § 5 authorizes the EPA to review activities associated with the manufacture, processing, use, distribution in commerce, and disposal of any new chemical substance before it enters commerce, and requiring pre-manufacture notice ("PMN") reporting prior to commercial manufacture or import under § 5 and 42 U.S.C. § 2604.

[16] TSCA § 4(a) states that where there are insufficient data to assess the effects of the manufacture, distribution, processing, use or disposal of a chemical substance, and testing is necessary to develop such data, the TSCA provides that the EPA shall promulgate regulations requiring manufacturers and/or processors of such substances to develop new data that are needed to assess potential risks to human health and the environmental if the administrator finds: (1) that manufacture, distribution, use, and disposal practices may present an unreasonable risk of injury (§ 4(a)(1)(A)(i)); or (2) that the chemical will be produced in substantial quantities and that it enters or may be reasonably anticipated to enter the environment in substantial quantities or that there is or may be significant or substantial human exposure to the substance, § 4(a)(1)(B)(i)).

[17] Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

Q3. Is the EPA research plan designed to support Agency decisions and key questions about potential risks?

A3. This is an important question, and one that is difficult to answer, since the EPA research strategy is not clearly coordinated with identified regulatory needs. In other words, the research does not identify what question it is designed to answer, and what regulatory action may be associated with that answer. For example, Section 3.3.5 of the White Paper (Feb 2007; EPA 100/B–07/001) provides some general discussion of the important issue of "bioavailability and bioaccumulation of nanomaterials," and then later in Section 5.1.3, identifies the need for research on the extent that nanomaterials used in environmental remediation may themselves be persistent, bioaccumulative, and/or toxic. This extremely limited view fails to identify the critical need for this research on all nanomaterials, whether in remediation applications, commercial products, or industrial processes. Moreover, the White Paper fails to make recommendations about regulatory actions based on this information. If a nanomaterial is shown to be persistent, bioaccumulative, and toxic, what is EPA to do? The failure of our regulatory agencies to identify and regulate persistent bioaccumulative toxics represents a failure of public health prevention, and an abdication of responsibility from our publicly-entrusted federal agencies to the private realm via voluntary agreements.

An array of good stewardship approaches to nanotechnology development would increase public confidence and market stability. In public comments on the EPA external review draft nanotechnology white paper, NRDC and other public interest groups and public health experts requested that EPA do the following:[18]

- take immediate action to prevent uses of nanomaterials that may result in human exposures or environmental releases, unless reasonable assurances of safety are demonstrated beforehand;
- label products that contain nanomaterials, or are made with processes that use nanomaterial;
- publicly disclose information on potential risks;
- include toxicity information on nanomaterials for worker protection on material safety data sheets;
- increase safety testing conducted by independent or government laboratories subject to "sunshine laws" that allow public access;
- conduct comprehensive assessment of the environmental and human health concerns that may arise across the life-cycle—including production, use, and disposal—of nanotech products.

The potential of nanotechnologies to transform the global social, economic, and political landscape makes it essential that the public participate in the decision-making regarding the introduction and management of these new technologies to ensure that public values and preferences inform the development of this transformative new technology. It is essential that such public participation directly inform public policy development and nanotechnology decision-making, rather than limiting public 'engagement' to a one way process in which government and the scientific community 'educate' the public. Public preferences should also inform the allocation of public funding for nanotechnologies' research and development; commercially-oriented research should not be at the expense of public interest research. Consideration of nanotechnology's broader social implications and ethical issues should occur at each stage of the development process. Social impact and ethical assessment, alongside the expression of community preference, should guide the allocation of public funding for research; new nano-products should be subject to a social impact and ethical assessment process as part of the regulatory approval process prior to their commercialization; and social science analysis of nanotechnology's implications should take place in real time alongside that of the toxicological sciences. Meaningful public participation will require transparency of both scientific and social issues, and will require rapid public access to credible information.

[18] NRDC comments on the US EPA external review draft nanotechnology white paper. January, 2006. Docket ID: EPA–HQ–ORD–2005–0504

Appendix 2:

Additional Material for the Record

STATEMENT OF THE AMERICAN CHEMICAL SOCIETY

The American Chemical Society (ACS) would like to thank Chairman Bart Gordon and Ranking Member Ralph Hall for the opportunity to submit testimony for the record on the Environmental Protection Agency (EPA) science and technology programs for fiscal year 2008.

ACS is a non-profit scientific and educational organization, chartered by Congress, representing more than 160,000 individual chemical scientists and engineers. The world's largest scientific society, ACS advances the chemical enterprise, increases public understanding of chemistry, and brings its expertise to bear on State, national, and international matters.

As Congress and the Administration consider funding priorities for FY 2008 in a tight budgetary environment, ACS urges policy-makers to support the important work carried out by the Environmental Protection Agency's Science and Technology Program. In reviewing the President's budget request, ACS has identified four areas of focus for EPA:

1. Growing the EPA Science & Technology account and increasing support for scientific research supported by the Agency, particularly through the Office of Research and Development (ORD).
2. Restoring important programs that build the talent pipeline for the environmental sciences, such as the Science To Achieve Results (STAR) fellowships.
3. Increasing support for green chemistry and engineering programs and reversing the short-sighted decision to eliminate the Technology for Sustainable Environment research program.
4. Reforming the management structure for science at EPA.

We look to science to understand environmental challenges and to develop more intelligent, less burdensome solutions. Over the past two decades, demand for more scientific evidence—whether it's to set or improve regulations—has grown substantially. The amount of research envisioned in EPA-related authorizations also has increased. Nevertheless, appropriations for EPA science programs have not kept pace with the need for more and better science.

Over the last 20 years, the EPA S&T account, which includes the ORD and research programs in other EPA Offices, has fluctuated between seven and ten percent of the Agency's total budget. In order for EPA set science-based national environmental standards, conduct research and environmental monitoring, and provide technical assistance to states, local governments, and businesses, the S&T account needs to increase as a percentage of the Agency's total budget, ultimately to a stable ten percent level. The President's budget request is $755 million, a roughly 3.3 percent increase over FY 2006 (final FY 2007 spending levels from H.J. Res. 20 are not available); however, with the expiration of the Superfund tax, previously funded Superfund support activities now come out of the S&T account and cancel out any nominal increase in account funding. ACS recognizes the tight fiscal situation the country faces, but strongly believes that substantial constant-dollar decreases in funding for the S&T account will only hinder the ability of EPA to achieve its mission.

For FY 2008, ACS recommends the ORD account should receive $646 million, consistent with its 2004 funding high point. This represents an increase of 8.6 percent relative to FY 2006 funding levels. ACS recommends that the additional funds be applied to the following priority areas:

- Provide $10 million for the STAR fellowships.
- Increase overall STAR programmatic funding to $110 million.
- Increase funding of green chemistry and engineering to advance the development and use of innovative, environmentally benign products and processes.
- Invest in EPA's ability to recruit, develop, and retain an effective scientific workforce.
- Continue investing in federal research and technology development to reduce or avoid greenhouse gas emissions and address the potential impacts of global climate change.
- Support innovative and high-risk research that may help identify and explore future environmental problems and develop new sets of technologies to solve existing problems.

The FY 2008 budget request continues a pattern of declining support for science at EPA for the Office of Research & Development, which is the largest part of the S&T account. The Administration requested $540 million for ORD for FY 2008. This

represents a minus nine percent cut in ORD resources over FY 2006. The $55 million decrease in ORD accounts from FY 2006 threatens ORD's mission to carry out world class environmental research, further damaging the government's ability to provide top notch research on behalf of the American taxpayer and ensure America's policy-makers use sound scientific advice in decision-making.

The Administration's proposal to continue the dramatic reductions in the STAR fellowship program is a good case in point. This program is the only federal program dedicated to graduate study in environmental sciences at colleges and universities across the country. The STAR fellowships are part of a cohesive effort to characterize critical or emerging environmental problems and create solutions to address them. EPA designed this extramural research grant program to work in cooperation with a fellowship program. Together, they provide ideas, information, new discoveries, and new researchers. Today's STAR fellows will become tomorrow's environmental experts working for industry, government agencies like EPA, and academic institutions. The loss of this program's resources will further erode the Agency's capability to attract an excellent workforce and will reduce the amount of scientific information available to inform agency decisions.

ACS supports increased funding for green chemistry and engineering programs to advance the development and use of innovative products and process, reducing or eliminating the use of hazardous substances. Because chemistry and chemical products fuel the economy of every industrialized nation, the tools and strategies chemists and chemical engineers develop will be instrumental in meeting the dual challenges of protecting the environment and strengthening the economy. The elimination of the Technology for Sustainable Environment research program under STAR was an unfortunate decision that hobbles the Agency's ability to work creatively with industry and others to carry out the mission through cost-effective technology substitution as opposed regulatory burdens.

Finally, ACS remains concerned about broader management issues raised by the long-term decline in support for EPA science and technology programs. ACS understands the often confrontational nature of the regulatory process; however, EPA's organizational structure reinforces this tension by housing the Agency's main scientific functions in an office that is:

- Inadequately funded;
- Not budgeted independently or separately by-lined in the annual appropriations process;
- Not often given specific authorizing legislation;
- Forced to compete with its own internal offices—its principal customers—for attention and resources; and
- Often criticized for the quality of its science and its inability to apply this science to environmental decisions.

In previous Congresses, the Science Committee passed legislation addressing many of these issues; unfortunately the situation today is even more important and urgent. The ability of the government to marshal scientific expertise and resources in the wake of the terrorist attacks has been tested severely. New issues also have arisen, such as the need to assure that access to government information does not provide tools to terrorists and the need for stronger data quality standards within government agencies. ACS endorses the creation of a Deputy Administrator for Science and Technology, as suggested by the National Research Council's report in 2000, *Strengthening Science at the U.S. Environmental Protection Agency*. A Deputy Administrator for Science and Technology would add considerably to an effective and efficient EPA response to these challenges.

ACS is a long-term advocate for increased attention to research programs at EPA, both in budgetary and in management terms, and our enthusiasm for these programs remain strong. We also appreciate the Science Committee's support for EPA Science and Technology programs and look forward to working with the Committee, Congress, and the Administration to ensure their future vitality. ACS thanks the Committee for this opportunity to submit testimony and would be happy to answer any questions.