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OVERSIGHT HEARING ON SCIENCE AND ENVIRONMENTAL REGULATORY DECISIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON PUBLIC SECTOR SOLUTIONS TO GLOBAL WARMING, OVERSIGHT, AND CHILDREN'S HEALTH PROTECTION

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

MAY 7, 2008

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SECOND SESSION

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OVERSIGHT HEARING ON SCIENCE AND ENVIRONMENTAL REGULATORY DECISIONS

WEDNESDAY, MAY 7, 2008

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON PUBLIC SECTOR SOLUTIONS TO GLOBAL WARMING, OVERSIGHT, AND CHILDRENS HEALTH PROTECTION,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m. in room 406, Dirksen Senate Office Building, Hon. Barbara Boxer (chairman of the full committee) presiding.

Present: Senators Boxer, Inhofe, Baucus, Klobuchar, Whitehouse, Alexander

OPENING STATEMENT OF HON. BARBARA BOXER, U.S. SENATOR FROM THE STATE OF CALIFORNIA

Senator BOXER. The Committee will come to order.

Today we will discuss the scientific integrity of the decision of the U.S. Environmental Protection Agency under the Bush administration. EPA was created by President Nixon to be an independent agency designed to protect our families, our children and our natural environment from harm.

Unfortunately, what we will hear today is that the Bush administration is discarding the best available science and instead, is seeking the advice of special interests who would benefit from weaker environmental standards.

A clear pattern has emerged at EPA. When it comes to who wins and who loses, time and time again, the polluting special interests come out on top at the expense of the health of the American people. They are forcing politics into the entire scientific process from the very beginning of the EPA's supposedly independent system for assessing health and environmental risks. We know this because the GAO report is clear. The GAO system has told us that the EPA is institutionalizing a system where scientists are thrown to the back of the room and special interests are invited to the table. That is during a process that is supposed to be pristine and is supposed to only consider what the impact is to the health of our people.

EPA has a special Children's Health Advisory Committee, because we all know that children are particularly vulnerable to the toxic effects of pollution. This important advice has been repeatedly ignored. Yesterday at our hearing on perchlorate and TCE, we put a number of documents into the record showing the deep concern of this Children's Health Advisory Committee. For example, the agency refused to follow that committee's proposal to better protect

children from smog pollution, toxic fine soot pollution, lead contamination in the air, and again, as I mentioned, perchlorate contamination of tap water, all of which are especially dangerous to children.

We must carefully scrutinize this unfortunate pattern, because it is dangerous, it has dangerous implications for children and families, and it must not be allowed to continue.

Let me recount just a few more examples of this Administration's rejection of scientific advice. There were early signs of a willingness to put politics before public health. Soon after the President took office, he suspended the Clinton drinking water standard for arsenic, which was supported by strong evidence from the National Academy of Sciences. We also learned early on that White House officials were deleting and editing scientific material in EPA reports on global warming.

More recently, on the eve of a hearing in this Committee on the public health threats posed by global warming, the White House deleted page after page of scientific findings from testimony that was about to be delivered to us by the head of the CDC. And they have still refused to provide the documents related to this incident as requested by this Committee.

EPA Administrator Johnson also recently ignored his own technical staff's advice to grant California a waiver under the Clean Air Act to regulate global warming pollution from vehicles. This would affect, is affecting up to 19 states. This advice was based on scientific information about the health and environmental threats posed by global warming. But in its place, the Administration echoed requests from the automobile industry in its final decision document.

We also see this problem in EPA's clean air program. After 30 years of closely working with its independent clean air scientific advisors, in the last few years EPA has repeatedly ignored its Clean Air Science Advisory Committee. For example, over 80 million people live in areas with unhealthy levels of toxic soot pollution, which can damage the heart and lungs and cause premature death.

Instead, the EPA Administrator ignored the scientific recommendations from the Clean Air Science Advisory Committee, CASAC, and left that standard unchanged. The scientific advisors found that "there is clear and convincing evidence that significant adverse human health effects occur" under the standard. Imagine: they set a standard and the scientists said there is clear and convincing evidence significant adverse human health effects occurred. What is the point of the EPA?

EPA's recent action on ozone or smog was similar. Over 90 million people live in areas with unhealthy levels of smog pollution, which damages the lungs and can lead to premature death. Again, EPA ignored its scientific advisors' unanimous recommendation to set the level as low as 60 but no higher than 70 parts per billion of ozone. EPA set the standard at 75 parts per billion, again ignoring the scientists.

The Government Accountability Office testified before this Committee last week, and I reference this early, that EPA's new policy for developing the risk assessments used to set levels safe to peo-

ple—let me repeat that. The GAO testified before this Committee last week on EPA's new policy for developing the risk assessments used to set safe levels of exposure to toxic chemicals. GAO found that the policy increases delays, undercuts EPA's scientific credibility by keeping interagency comments secret—this is a new thing. Not only are they doing harm, but they are keeping the meetings where they make these decisions secret. And it gives the White House and polluting agencies like DOD a privileged seat at the table, by extension, DOD contractors have a seat at the table, when scientific decisions are being made about toxic chemicals.

In the last few days, a senior EPA appointee, Mary Gade, told the Chicago Tribune she was forced to resign for aggressively pursuing the cleanup of a dioxin-contaminated site in Michigan. My colleague Senator Whitehouse, who I will give the gavel to shortly, has taken the lead in getting to the bottom of that issue. I look forward to his remarks.

The Bush administration is failing to meet its mandate to protect public health as an independent, science-driven institution. The American people are paying the price with their health. This is an unacceptable pattern, and it must be reversed.

And since I went 7 minutes, Senator Alexander, I will give you 7 minutes. I am now going to turn the gavel over to Senator Whitehouse.

OPENING STATEMENT OF HON. LAMAR ALEXANDER, U.S. SENATOR FROM THE STATE OF TENNESSEE

Senator ALEXANDER. Thank you, Madam Chairman. I don't think I will go 7 minutes, but I thank you for your courtesy.

I look forward to the testimony today and to discussing how science informs public policy. I think maybe that is the most important thing I could say in my 7 minutes, is that scientists are to inform public policy under our system, not to make public policy. The Chairman mentioned someone rejecting staff's advice. I reject my staff's advice every day. I think I know more about some things than they do. And I was elected by the people. I imagine the Chairman and Senator Whitehouse do the same.

So I think one of the most important things for us to do here today is discuss what is the role of science in making public policy. One definition of that, by Professor Jonathan Adler of Case Western Reserve University of Law, he wrote in an article called Evaluating Sciences, "Policy differences are generally not the result of a dearth of scientific information or a lack of independent analysis. Rather, they are usually rooted in disagreements about fundamental values."

So if it is simply a matter of appointed officials or Senators listening to their science advisors and saying, I am taking other considerations into account and I am coming to a different conclusion than you might if you were elected or if you were appointed, that is one thing. Another thing might be to look at the advice of science advisors and see if it is made public enough, whether all of us can see what a scientific advisor might have said and then see the reasons why the policymaker might have come to a different conclusion. That might help us, in a democracy, to understand and make sure that science is informing the making of public policy.

It is always interesting to me how much President Lincoln contributed to our society. I am reminded of a new thing every day. It was in 1863 that under the Lincoln presidency, the National Academy of Sciences was founded. They are independent, they have resources from the Federal Government. Their job was to advise us. They don't make the policy, they advise us. I worked with Senator Bingaman and many others on our America COMPETES Act, we asked for their advice. Then we made the decision.

Thinking about mercury, I think as the Administrator knows, I have been very strong on clean air. I come from an area where we have the most polluted national park, the Great Smokies in Knoxville, near my home town, which is at the top of the asthma list. So I want mercury and nitrogen and sulfur cleaned.

But let's take mercury. The question comes, do we have the ability, is it technologically possible to take 70 percent of the mercury out of the air of coal-fired power plants? Or should it be 90? The Administration decided 70. I think it ought to be 90. Should it be a cap and trade program? The Administration decided yes. I decided no, because the mercury, in my view, goes up from the power plants and comes down nearby.

Do I think that is an example of corruption in the EPA? No. I think the Administrator came to a different conclusion than I did based upon the available scientific technology. So I think it is perfectly fine for us to have a spirited argument about whether the mercury standard ought to be 70 or 90, or whether there ought to be a cap and trade or not. But I don't think that is any occasion to accuse the Administration and the EPA Director of some corrupt attitude or listening to improper people. That happens not just on the right, but sometimes on the left.

I remember how shocked I was when Camilla Benbo, the dean of the Peabody School of Vanderbilt, one of the most distinguished colleges of education and one of the most distinguished deans, had her nomination by the President held up because she had written an article one time about how gifted girls learn differently than gifted boys. That was the science, but some people didn't want to hear it, so they weren't even going to confirm her and let her be on the National Scientific Board.

Or many of us believe that we should be doing, with $4 gasoline, we should give Virginia the opportunity to drill offshore. Science has shown that there may be more seepage from the ocean floor than there is from drilling for oil and gas offshore. But one Senator may say, I don't want to see that or I don't want that to happen, another Senator may say, I do want it to happen. That doesn't mean either of us has a bad motivation, it means we simply have a different point of view.

Or the same with nuclear power. Science shows that it is clean power in terms of the four pollutants, and it produces 70 percent of our clean energy at a time when we are concerned about global warming. But many policymakers and elected officials look at all the facts and they take into other accounts. Science gives them this amount of information, but they say, but then there is proliferation and then there is the question of waste, and then there is the question of safety. And weighing all that, they come to a different conclusion.

So my hope today is to listen, listen very carefully. If there are examples where scientific advice is being mis-represented, I think that is unfortunate in a democratic society and we ought to do our best to change that and put the spotlight on it. But at the same time, I think we ought to make sure that we keep in mind the role of the scientist and the role of the policymakers. We don't elect the scientists to make the decision. We established the National Academies and we appoint scientific advisory committees. And let me be specific about the EPA's scientific advisory committee. Section 109 of the Clean Air Act directs the Administrator to appoint these committees, such as the ones who recommended the rules on ozone. And their role, it says, is advisory. So it is the job of the Administrator to take all things into account.

The EPA Administrator establishes the National Ambient Air Quality Standard based upon his or her judgment. Could be bad judgment, could be good judgment. But the science is there to inform the judgment, not to make the judgment.

Finally, Section 109 of the Clean Air Act directs the Administrator to establish the National Primary Ambient Air Quality "in the judgment of the Administrator." So I might quarrel with the Administrator about the mercury standard, but I am not going to accuse the Administrator of bad judgment, or different judgment, but if he ignores the scientists, that is his job. It is his job to consider it and his job to tell us about it if we ask about it, if we want to know why he chose to override judgments of scientists working with him.

Another thing I will be listening for, and I would be interested to know, is who are the scientists?

Senator BOXER. You have gone over.

Senator ALEXANDER. Then I will wind down. Who are the scientists? A lot of Senators think we are scientists, but we are not really. So there are scientists and there are scientists.

Madam Chairman, thank you for your courtesy on the ozone standard. We can talk about that more. I saw what the scientific community said and I want the air cleaner in east Tennessee. I also heard from the county judges who want to make sure that we can bring the auto plants, too.

So weighing the scientific recommendation with the requests of locally elected officials who are weighing that I think is a proper judgment. I welcome the hearing, and I look forward to it, and I thank the Chairman for her courtesy in giving me so much time.

OPENING STATEMENT OF HON. SHELDON WHITEHOUSE, U.S. SENATOR FROM THE STATE OF RHODE ISLAND

Senator WHITEHOUSE. If I could follow my distinguished colleague from Tennessee's thoughts for a moment, I think there are important distinctions between the policymaking function of an administrative agency and the science development function of a regulatory agency. Both potentially lend themselves to abuse. And if it should turn out that in the policymaking function, the application of the policy judgment seems over and over and over and over to the point of inevitability to come down on the side of industry and never on the side of environment and public health, it raises a significant question about whether that policymaking function is

being done legitimately, honorably, with integrity and on the merits, or whether somebody has managed to get a thumb onto the scale of the administrative process.

But I don't think that is so much the concern that we are addressing today. The concern we are trying to address here today is the question of whether the foundation of fact upon which those policy determinations get made is being itself polluted within the Environmental Protection Agency. Clearly, if one's intention is to put a thumb on the scales in favor of industry and in favor of polluters, rather than in favor of the environment and in favor of public health protection, it is a little bit hard to come out and do that directly. It is much easier if you can get into the science itself and pollute the very basis of the discussion, so that you give yourself cover down the road.

The question I think we face today is whether the Bush Environmental Protection Agency, under its current Administrator, Stephen Johnson, is fulfilling, in either dimension, really, its core long-standing mission to protect our environment and our health, without regard to politics or special interests and without fear or favor. The increasing weight of the evidence suggests that it is not.

We heard just recently of the forced resignation of Mary Gade as EPA's regional administrator for the Great Lakes Region, saying that Administrator Johnson's top lieutenants stripped her of her powers and told her to quit or be fired because of her aggressive pursuit of Dow Chemical in connection with dioxin contamination in waters near Lake Michigan. We don't know yet what the full story is on this, and I am going to withhold judgment, but certainly that is an alarming signal that we have seen. And it smacks of similar activities we have seen recently in the Department of Justice. I am on the Judiciary Committee, and certainly there are similarities between the eight U.S. Attorneys fired by the White House who by all accounts were well-regarded and experienced in their fields, just as Ms. Gade appears to be well-regarded and experienced in her field. They had received strong performance evaluations in positions that by all accounts are ordinarily given extremely wide latitude. Certainly they were when I was a U.S. Attorney. And Ms. Gade similarly has received strong performance evaluations, evidently, and was operating in a position where she has wide latitude. And suddenly, poof, a forced resignation in the context of a dispute with a major industry participant.

Chairman Boxer has recently held hearings that have indicated considerable concern about the pollution of the science at the EPA. The recent report from the Union of Concerned Scientists, we will hear from today, and countless previous cases raise the same concern, and that is that the Environmental Protection Agency has been co-opted by the Administration to serve special interests and has twisted the science in order to achieve the results that they wish to achieve.

Under fire like this, I think the EPA needs true leadership that will address the criticisms head-on and will give EPA employees and all Americans confidence that the important mission of this agency is being accomplished. We don't appear to have that right now. In fact, Administrator Johnson has not even deigned to appear before us today. It is not the first time he has declined the

opportunity to testify and the last few times that he did appear, he has been significantly less than forthcoming. His answers have been evasive and unresponsive, as those of Dr. Gonzales. I have seen him repeating answers that sounded, frankly, lawyer-crafted to contain more strategy than truth. I suppose that were he here today, we could expect no different. Nevertheless, it would have been nice if he had showed up.

We have heard very, very serious criticisms leveled at his agency. EPA scientists, according to the Union of Concerned Scientists, just last month, faced both suppression and distortion of scientific findings underlying the EPA's decision. Suppression and distortion, to the detriment of both science in general and the health of our Nation. Yesterday, we heard testimony from Richard Wiles about unprecedented levels of industry influence in every scientific panel and committee at the NIH and the EPA, an overall corruption of science that we have seen in this Administration. And Dr. Goldman just a few days earlier, last week, testified that the IRIS interagency process provides a back door through which industry groups can exert pressure to modify EPA's conclusions or to subject the process to endless delays that undermines the public's trust in the EPA. And this is all just in the last week or two.

Against that fire, and against what I think is legitimate public concern, Mr. Johnson has responded by deriding his critics as yammering critics. I noticed that in Mr. Gray's testimony, we will talk a little bit more further, he doesn't even mention these concerns. It is all just hunky-dory over at EPA, everybody is just doing a lovely job.

Madam Chair, I hope that this hearing will give us a clearer sense of exactly what is going on at EPA. I will close by saying that I come from a public service family. My father and grandfather were foreign service officers. I have seen first-hand in their lives the importance of people stepping into public service and taking on the duty of integrity, of honesty, and of doing your job on the merits, rather than allowing yourself to be co-opted by special interests. It is a core value, and I think it is a core value that EPA at present needs to convince the American public that it still holds.

Thank you. Senator Inhofe.

OPENING STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

Senator INHOFE. Well, for an opposing view, let me get on the record in saying that I don't believe that you or Administrator Johnson or any of the rest of them are co-opts by special interests. I think it is perfectly understandable since it is a science hearing today that Administrator Johnson would send a scientists. So that doesn't bother me a bit.

But I do think that one of our primarily responsibilities in this Committee is to ensure that regulatory decisions are based on sound science. That is something I have believed is important for a long, long period of time. Too often the environmental policy decisions that are made by EPA and other science-based agencies are driven by political or personal agendas. I think we all know that. You see these in the types of research that gets done and the types of grants that get awarded.

It is my hope that this hearing will help shed some light on how science is used by policymakers and that we can arrive at some concrete suggestions for making the process better. I believe that there are some success stories that need to be discussed today, generally speaking. Addressing lead exposure is one of the great American success stories, according to the data from the CDC and others, the immediate concentration of lead in the blood of children 5 years old and under has declined by 89 percent between 1976 and 1980.

Now, this is particularly of interest to me, Madam Chairman, because my area of Tar Creek, and you remember, when I became Chairman, I said, one thing we are going to do is what we failed to do before and had not been able to do for 30 years, is cleanup the most devastating Superfund sites. We had the highest level in the Nation of blood lead level in our kids in Northern Oklahoma.

Another example is EPA's recent changes to the Integrated Risk Information System. These changes allow the public to be involved in the risk assessment process sooner. Now, environmental groups, scientists and the regulated community can provide data, research and comments on risk assessments before they are finalized. Additionally, there is now a concerted outreach effort to members of the scientific community and more rigorous peer review. I understand that there are those in this Committee who believe that this is somehow stifling the EPA scientists. But I don't understand how someone can stand up and say they support the public right to know, the scientific community participation and transparency when an agency makes regulatory decisions, but not support those very same principles when it comes to risk assessment.

More science means better decisions and more defensible decisions. Today's hearing will also address case studies of the importance of science in regulatory decisionmaking with a focus on clean air issues and children's health. However, in the rush to try to dissect these individual cases and lay blame on whether science was adhered to properly or not, the bigger picture message gets lost. Our air is cleaner than it ever has been before. This is something that people don't understand. Since the Clean Air Amendments passed, it is. It is a real success story. Our air is actually cleaner, and nobody talks about that. The levels of the six criteria pollutants are continuing to decline. Air toxics monitoring is expanding and reductions of benzene, acid rain and haze are contributing to significant improvements in air quality and environmental health.

However, despite these improvements in the last 2 years, EPA has significantly strengthened or proposed to strengthen three of the five criteria pollutants, all driven by citizens' suits and court-ordered deadlines. And they have once again been attacked by stakeholders on both sides for doing so.

Reduction levels are now being debated so intensely and at such marginal levels, one must stop and consider if there ever will be a level requisite to protect the public health with an adequate margin of safety that will satisfy the critics. Instead, we are left with a brand new web of economic burdens that we are passing on to the States, many of which are just now beginning to make real improvements from the previous strengthening. What we have are more environmental regulations hindering environmental progress.

And I am pleased to recognize Dr. McClellan, the Past Chair of the Clean Air Science Advisory Committee, who has detailed the many flaws and questionable approaches taken in justification of the recent final ozone rule, as well as the 2006 PM rule and others. I look forward to his comments on how the science panel often no longer offers its judgment on the scientific integrity of the process, but its policy opinions. So I thank you for holding this hearing today and look forward to our witnesses and certainly beginning with Dr. Gray.

[The prepared statement of Senator Inhofe follows:]

STATEMENT OF HON. JAMES M. INHOFE , U.S. SENATOR
FROM THE STATE OF OKLAHOMA

Good morning. Today's hearing will focus on science and how it is used in environmental regulatory decisions. I have always believed that one of the primary responsibilities of this committee is to ensure that regulatory decisions are based on sound science. Too often the environmental policy decisions made by EPA and other science-based agencies are driven by political or personal agendas. You see this in types of research that gets funded or the types of grants that get awarded. It is my hope that this hearing will help shed some light on how science is used by policymakers and that we can arrive at some concrete suggestions for making the process better.

I believe that there are some success stories that need to be discussed here today. Generally speaking, addressing lead exposure is one of the great American success stories. According to data from the CDC and others, the median concentration of lead in the blood of children 5 years old and under has declined 89 percent since the period of 1976–1980, to 1.6 micrograms per deciliter in 2003–2004. Another example is EPA's recent changes to the Integrated Risk Information System. These changes allow the public to be involved in the risk assessment process sooner. Now, environmental groups, scientists, and the regulated community can provide data, research, and comments on risk assessments before they are finalized. Additionally, there is now a concerted outreach effort to members of the scientific community and more rigorous peer review. I understand that there are those on this committee who believe this is somehow stifling EPA scientists or putting politics into the scientific process. But I don't understand how someone can stand up and say they support public right-to-know, scientific community participation, and transparency when the Agency makes regulatory decisions but not support those very same principles when it comes to risk assessment. More science means better decisions—more defensible decisions.

Today's hearing will also address case studies of the importance of science in regulatory decisionmaking, with a focus on clean air issues and children's health. However, in the rush to try and dissect these individual cases and lay blame on whether science was adhered to properly or not, the bigger picture message gets lost. Our air is cleaner than it ever has been before; the levels of the six criteria pollutants are continuing to decline, air toxics monitoring is expanding and reductions in benzene, acid rain, and haze are contributing to significant improvements in air quality and environmental health. However, despite these improvements, in the last 2 years, EPA has significantly strengthened or proposed to strengthen 3 of the 6 criteria pollutants, all driven by citizen suits and court ordered deadlines, and the agency once again has been attacked by stakeholders on both sides for doing so. Reduction levels are now being debated so intensely and at such marginal levels that one must stop and consider if there ever will be a level requisite to protect the public health with an adequate margin of safety that will satisfy the critics. Instead, we are left with a brand new web of economic burdens that we are passing on to the states, many of which are just now beginning to make real improvements from the previous strengthening. What we have are more environmental regulations hindering environmental progress.

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Thank you, Madam Chairman, and I look forward to hearing from our witnesses this morning.

Senator WHITEHOUSE. [Presiding] Dr. Gray, we are ready to hear your testimony. We have your written testimony. We would ask that you confine your oral remarks to 7 minutes, so that we all have a chance to have a discussion at the conclusion of them. Because you are the solitary witness on this panel, I will give you 7 minutes. Future witnesses in panel form will get 5 minutes each.

Please proceed.

STATEMENT OF HON. GEORGE GRAY, ASSISTANT ADMINISTRATOR FOR THE OFFICE OF RESEARCH AND DEVELOPMENT, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. GRAY. Good morning. I thank you for the invitation to appear before you today. My name is Dr. George Gray. I am the Assistant Administrator for the Office of Research and Development with the Environmental Protection Agency. I also serve as the agency's science advisor.

I do want to thank you for the opportunity to discuss science, science policy and decisionmaking at the EPA, as well as our ongoing efforts to increase and strengthen the scientific integrity of all of the decisions made at the agency.

As the Assistant Administrator for the Office of Research and Development, the EPA's key scientific body, I cannot emphasize enough what a privilege it is to work with so many world-class scientists. Overall, more than 20 percent of our scientists' and grantees' publications are considered highly cited. Over 30 percent of them are published in high impact journals. Our scientists are active in many prestigious scientific organizations, where they hold positions of importance, including the presidency of organizations like the American Public Health Association, the Ecological Society of America, the Society of Toxicology and the Society for Risk Analysis, to name just a few. EPA's scientists are contributing to every part of environmental science.

In recent years, we have developed cutting edge, award-winning tools and strategies to protect public health, to test chemical effects and interactions and to develop ground-breaking reports on many issues, including the effects of climate change. So research that is conducted by our scientists and grantees provides scientific and technical information to support EPA's mission to protect human health and the environment.

During the past several years, EPA has taken a number of steps to maintain a program of sound scientific research to inform agency decisions without allowing regulatory objectives to guide or to distort our scientific findings or analyses. These steps include open, transparent and peer-reviewed research planing, competitively awarded extramural grants, independent and external peer review of our scientific studies, publications and analyses, and rigorous evaluations of EPA's research laboratories and centers. Science informs and provides a basis for EPA's regulatory decisions.

At the same time, it is very important to recognize that what often appears to be a purely scientific question or an assessment generally involves both science and science policy considerations. Similar to other Federal agencies that are required to produce both scientific assessments and make regulatory decisions, EPA views the relationship between science, science policy and decisionmaking

as a continuum. To start, science is conducted by individuals or teams working in our laboratories, out in the field or in academic institutions across the Country. Their work is reviewed by subject matter experts in accordance with EPA's highly regarded peer review process and our information quality guidelines. These scientists are encouraged to publish and otherwise communicate their findings. Our scientists and grantees publish hundreds and hundreds of studies every year.

Science policy is also an integral aspect of the science to decisionmaking continuum. Because the scientific method encourages critical thinking and frankly, professional disagreement, it does not often lend itself to a bright line that decisionmakers can use as a reference point. By their very nature, scientific studies involve varying degrees of uncertainty. So there is rarely a best answer that we can use in decisionmaking.

Therefore, we rely on science policy processes when we synthesize and assess a range of scientific opinions and data points. These science policy decisions may involve filling in knowledge gaps with default assumptions, using weight of the evidence approaches to make scientific inferences or choices. The science policy work draws on expert insights from multiple scientific disciplines and is further strengthened by agency, interagency and public review.

Decisionmaking is the third aspect of the continuum. Science informs and guides our regulatory decisions, but it cannot be the only factor in formulating national policy. Technical feasibility, local autonomy versus Federal control, justice, equity and implementation costs are among the considerations that need to be factored into EPA's decisions when that is appropriate under the statutes. These other considerations also affect our quality of life and well-being.

To ensure that we have made good choices to achieve our mission, we use scientific and technical means to monitor the effectiveness of agency decisions, and we update those decisions as appropriate.

In conclusion, EPA has a proud history of producing science that has informed decisions to protect human health and the environment. We are committed to using the best available science and to constantly evaluating our science policy choices to achieve our strategic goals and fulfill our mission. From the lab bench to the Administrator's desk, we follow a science to decisionmaking continuum, in common with other Federal agencies that rely on both science and science policy considerations in decisionmaking.

Thank you to the members of the Committee for this opportunity to describe EPA's critical scientific work. I look forward to answering any questions that you may have.

[The prepared statement of Mr. Gray follows:]

TESTIMONY OF

GEORGE GRAY, PhD
ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON PUBLIC SECTOR SOLUTIONS TO
GLOBAL WARMING, OVERSIGHT, AND CHILDREN'S HEALTH PROTECTION
UNITED STATES SENATE

May 7, 2008

Good morning, Madam Chair and Members of the Committee. My name is Dr. George Gray, and I am the Assistant Administrator for Research and Development (ORD) at the Environmental Protection Agency (EPA). I also serve as the Agency's Science Advisor. Thank you for this opportunity to appear before the Committee to discuss science, science policy, and decision making at EPA, and our ongoing efforts to strengthen the scientific integrity of all decisions made by the Agency.

EPA conducts research that provides scientific and technical information to support our mission to protect public health and the environment. Our scientists conduct research independent of political influence, publish results in peer-reviewed journals, present findings at scientific and technical conferences, and speak openly with the public about their work.

We are committed to using the best available science and the most defensible science-policy choices to achieve our strategic goals and fulfill our mission. Science informs, and provides a foundation for, EPA's regulatory decisions. At the same time, it is important to recognize that what often appear to be purely scientific questions or assessments generally involve both "science" and "science-policy" considerations. For

example, developing risk values requires many decisions, choices, and assumptions that are generally guided by Agency science policy.

While it is important to integrate our scientists' research and development products with the Agency's regulatory needs, it is also vital that the research itself is independent, objective, transparent, and of the highest quality. During the past several years, EPA has taken a number of steps to maintain a program of sound scientific research to inform Agency decisions without allowing regulatory objectives to guide or distort scientific findings or analyses. These steps have included open, transparent, and peer-reviewed research planning; competitively awarded extramural research grants; independent and external peer review of our science publications, assessments, and documents; and rigorous evaluations of EPA's research laboratories and centers.

EPA's science program is at the leading edge in many areas of science and technology. With our focus on high-quality, relevant support for the Agency's activities and decisions, we are well-positioned to address the challenges of the 21st century. We constantly look for ways to build on our strengths so that EPA's decisions and actions continue to be informed by the best available science and the most defensible science-policy choices.

EPA's Scientific Staff

As the Assistant Administrator of EPA's Office of Research and Development (ORD), the Agency's key scientific body, I cannot emphasize enough what a privilege it is to work with so many world-class scientists. A substantial percentage of publications by our scientists and grantees achieved "highly cited" and "high-impact" status in our most-recent analysis using Thomson Scientific's *Essential Science Indicator*s. Overall, over 20 percent of our publications are "highly cited" and over 30 percent are published in "high-impact" journals.

Our scientists are also active participants in many scientific organizations, including the American Public Health Association, Association for Practical and Professional Ethics, Geological Society of America, American Geophysical Union, Ecological Society of America, Air and Waste Management Association, Society for Risk Analysis, International Society of Exposure Analysis, Society of Toxicology, and more. Many of our scientists hold leadership positions in, and have received prestigious awards from, major scientific organizations such as the Intergovernmental Forum on Chemical Safety, International Commission on Radiological Protection, and Society of Toxicology, as well as major research universities.

Considering the scientific and technical talent in our organization, and our experts' clear commitment to public service, it is my aspiration to have ORD be the premier environmental-science organization in the federal government. We have demonstrated positive momentum toward this goal with many achievements, such as:

- Award-winning tools and strategies to protect public health developed by our National Homeland Security Research Center;
- Cutting-edge models to test chemical effects and interactions developed by our National Center for Computational Toxicology;
- Ground-breaking reports on the effects of climate change to inform national and international dialogues developed by our Global Change Research Program; and
- Grants awarded to scientists across the nation to research environmental challenges and develop innovative solutions through our National Center for Environmental Research.

Science Planning and Science Management at EPA

EPA's first priority is "doing the right science." A number of sources, both internal and external to the Agency, provide information and guidance on how EPA can prioritize its research. EPA's Strategic Plan serves as the first organizing principle for EPA's research agenda. Next, EPA's Program and Regional Offices communicate their

science needs based on their unique policy and regulatory responsibilities. EPA's Office of the Science Advisor also provides critical input. The Agency must incorporate into its research planning Congressional mandates, the priorities of the Administration and other agencies, as well as advice from external advisory committees. Other research stakeholders, including non-governmental organizations and industry, may voice their priorities. EPA management and directors of ORD research take input from these various sources into account when setting the research agenda.

"Doing the science right" by promoting effective management and implementation of ORD's research strategies is an equally important responsibility and serves to strengthen scientific integrity. It is vital that EPA strive for the highest quality and credibility in its activities and decision-making processes if the American public is to have confidence in our decisions. To this end, EPA scientists, managers, and union representatives jointly developed the EPA *Principles of Scientific Integrity* under the auspices of the National Partnership Council. To ensure that management and staff understood the importance of scientific integrity at all levels of the organization, the release of this document was followed with online training. The Principles include the following:

Honesty - EPA employees are responsible and accountable in all aspects of their science.

Accuracy - Employees represent their work, and the work of others, fairly and accurately.

Recognition - The intellectual contributions of others are recognized and acknowledged.

Freedom from conflicts - All science is conducted in an atmosphere free of conflicts of interest.

Knowledge of statutory authorities - Know and understand the statutes and regulations that guide EPA's work.

Responsibility - Breaches of these principles must be promptly reported when discovered.

Open-mindedness - Differing views and opinions on scientific and technical matters are a welcome part of the scientific process.

To monitor performance, ORD requests feedback from EPA Program and Regional Offices on the timeliness and quality of its research. ORD research programs also undergo formal performance evaluations by the Office of Management and Budget by way of OMB's Performance Assessment Rating Tool (PART). Additionally, the Board of Scientific Counselors, Science Advisory Board, National Academies of Science, and other advisory panels provide program evaluations that facilitate continuous improvement and ensure ORD is advancing the state of the science in key areas. Members of EPA's advisory boards are non-EPA scientists, engineers, and economists, and other social scientists who are recognized experts in their fields. They come from academia, industry, government, research institutes, and non-governmental organizations throughout the United States. EPA chooses them for their demonstrated ability to examine and analyze environmental issues with objectivity and for their interpersonal, oral and written communication, and consensus-building skills.

In sum, ORD's research is guided by strategic directions and stakeholder input, adjusted according to annual budget decisions, evaluated to ensure effective and efficient management, and ultimately applied to inform environmental decision-making.

The Science to Decision-Making Continuum at EPA

Similar to other federal agencies that are required to produce both scientific assessments and make regulatory decisions, EPA views the relationships between science, science-policy, and decision-making as a continuum—from science and science-policy to official Agency decision-making.

To start, EPA science is conducted by individuals and teams working in our laboratories or in the field. All of their work is reviewed by subject-matter experts in accordance with EPA's highly regarded peer-review process and information-quality guidelines. Once an EPA scientific product meets scientific standards of quality and credibility, scientists are encouraged to publish and otherwise communicate their findings. Note that these independent, scientific findings do not necessarily represent official Agency policy positions, as national policies must also take other factors into account.

Science policy is an integral part of the continuum. Because the scientific method encourages critical thinking and professional disagreement, it does not commonly lend itself to a "bright line" that decision-makers can use as a reliable reference point. A range of reasonable and scientifically defensible options or decisions are usually available, and there is rarely a single "best answer" for use in decision-making. Scientific assessments also entail varying degrees of uncertainty and many decisions, choices, and assumptions must be made based on science-policy considerations.

To meet our statutory requirements, we often cannot wait for independent scientific findings to converge on a solution—this would cause long delays in environmental decision-making. Therefore, we rely on science-policy considerations, which often entail synthesizing and assessing a range of scientific opinions and data points. This process also involves filling in knowledge gaps in the body of technical information, and where necessary, using weight-of-evidence approaches to make scientific inferences or assumptions. The scientific models that inform most national policies require this kind of give and take. This work draws on expert insights from multiple scientific disciplines, and it is further strengthened by Agency, interagency, and public review.

Decision-making is further along the continuum. Science, however, is but one aspect of EPA's regulatory decisions. Other important considerations need to be factored into EPA's decisions without compromising scientific integrity, the Agency's mission, or statutory mandates. These considerations include technological feasibility, implementation costs, local autonomy versus federal control, justice, and equity. The impacts or limitations of these non-science factors, as well as the current state of the science, will influence how scientific considerations are brought to bear on environmental decisions facing the Agency.

Administrator Johnson and his leadership team give serious weight to science and science-policy choices in developing options for national policy. Nevertheless, the science to decision-making continuum does not end with regulation and rules. Every Agency decision feeds back into science and science-policy considerations as we monitor the effectiveness of our national policies and use updated information about changes in the quality of human health and the environment to adjust our policies over time.

Peer Review

An important and practical way to ensure the integrity of scientific programs and products is through independent and external peer review—i.e., the evaluation of programs and products by outside experts. EPA has a very strong peer-review program to ensure that only high-quality science is released and/or used by the Agency. Hundreds of Agency products undergo peer review each year, and nearly 90 percent are reviewed by independent experts who are not affiliated with the Agency.

EPA's Science Policy Council maintains our Peer Review Handbook—a "how-to" manual that is used by staff across the Agency. In addition, external stakeholders often refer to the Handbook as a model of good peer-review practices, which include: peer

review by experts who are independent of the Agency and have no conflicts of interest; public review and comment as appropriate; and maintenance of transparent, public records of scientific products at key stages of development. Our updated Peer Review Policy (2006) and 3rd edition of the Peer Review Handbook (2006) benefit from insights gained by implementing the program over the last decade. The 2006 Handbook clarifies ethical standards, improving understanding and compliance on the part of staff and management.

Our peer-review program fits within the context of a larger, Agency-wide quality system. EPA's quality system is the means by which we manage our scientific information in a systematic, organized manner and it provides a framework for planning, implementing, and assessing EPA's scientific work. Our peer-review policies also incorporate the provisions of the Office of Management and Budget's (OMB) Final Information Quality Bulletin for Peer Review. This Bulletin contains provisions for conducting peer review at all federal agencies in order to enhance transparency and accountability and applies to "influential scientific information" and "highly influential scientific assessments." OMB's Information Quality (IQ) Guidelines, together with our own IQ guidelines, are important elements in our quality system.

EPA's Principles of Transparency further support the Agency's scientific quality by providing explicit information about our research-planning process, as well as the process for developing science and science-policy assessments that are used for regulatory decision-making. The Principles were written so that any reader would understand all the steps, logic, key assumptions, limitations, and decisions in the assessment process, and also comprehend the supporting rationale that led to the outcome. EPA's 2000 *Risk Characterization Handbook* provides a number of transparency goals that we try to consider during the risk-characterization process. Specifically, the *Handbook* states that transparency achieves full disclosure in terms of:

The assessment approach employed;

The use of assumptions and their impact on the assessment;

The use of extrapolations and their impact on the assessment;

The use of models *vs.* measurements and their impact on the assessment;

Plausible alternatives and the choices made among those alternatives;

The impacts of one choice *vs.* another on the assessment;

Significant data gaps and their implications for the assessment;

The scientific conclusions identified separately from default assumptions and policy calls;

The major risk conclusions and the assessor's confidence and uncertainties in them; and

The relative strength of each risk assessment component and its impact on the overall assessment (e.g., the case for the agent posing a hazard is strong, but the overall assessment of risk is weak because the case for exposure is weak).

Along with adherence to the Principles of Transparency, individual scientific studies and scientific assessments follow a rigorous peer-review process. The peer review of assessments, which often synthesize multiple scientific studies, may include a number of steps: internal peer consultation, EPA review, interagency review, and external review. For example, to enhance the quality and transparency of assessments in EPA's Integrated Risk Information System (IRIS), each report undergoes peer review as follows:

Internal Peer Consultation: Internal (EPA) peer reviewers are selected to provide detailed scientific feedback on the draft assessment.

EPA Review: The draft assessment is reviewed by a standing group of senior health scientists representing EPA's Offices and Regions and by selected senior health scientists with scientific expertise relevant to the substance under review.

Interagency Review: The revised draft assessment is distributed through the Office of Management and Budget for review by scientists in other federal agencies.

External Peer Review: EPA obtains external peer review, typically via a panel meeting that is open to the public. At this time, the draft assessment is posted on the internet for public comment. EPA may submit more challenging assessments to high-level advisory panels, such as the EPA Science Advisory Board or National Academies of Science.

Peer review is also conducted at a higher level of planning and management. The Science Advisory Board, among other bodies, reviews EPA's research program. Science Advisory Board reviews provide critical cross-Agency perspectives as we establish research priorities. EPA also ensures systematic, external peer review of its ORD research programs by the Board of Scientific Counselors and others. Each ORD research program undergoes a detailed review approximately every four years, with a mid-cycle review after two years.

Additionally, all grants awarded by ORD's Science to Achieve Results (STAR) program are selected through a rigorous peer-review process, whereby panels of independent researchers review all the proposals for their scientific quality. The STAR program's commitment to scientific quality earned accolades from the National Academies' National Research Council in a 2003 report, "The Measure of STAR." Dr. Harold Mooney, the chair of the committee that wrote the report, concluded, "The STAR program has established and maintained a high degree of scientific excellence. It has provided EPA with independent analysis and perspective that has improved the agency's scientific foundation. By attracting young researchers, this program has also expanded the nation's environmental science infrastructure."

Conclusion

EPA has a proud history of producing science that has informed decisions to protect the environment and human health. Our scientists and engineers are among the

finest and most productive in the Federal government, and they share a deep commitment to public service. Our personal and organizational commitment to scientific integrity is further strengthened by EPA's Principles of Scientific Integrity, Principals of Transparency, our peer-review guidelines, independent advisory committees that oversee our work, and other elements of the EPA information-quality system. From the lab bench to the Administrator's desk, we follow a science-to-decision-making continuum in common with other federal agencies that rely on both science and science-policy considerations in decision-making. However, science rarely provides a "bright line" that directly translates into a decision. Making decisions in a timely manner requires that science be taken into consideration with other legal, technical, and economic concerns.

Thank you, Chairwoman Boxer and members of the Committee for this opportunity to describe EPA's critical scientific work. I look forward to answering any questions you may have.

Senator WHITEHOUSE. Thank you, Dr. Gray.

If what you say in your testimony is true, why is it that 889 scientists answered the Union of Concerned Scientists' study and said that they had personally experienced at least one incident of political interference in their work during the past 5 years? Eight hundred and eighty-nine is not a fluke. That is a lot of people.

Mr. GRAY. I think the first thing we have to do here is be careful about those numbers. You are right, that is a large number of responses. But we have to recall that this report provides useful information, it is based on individual opinions and anecdotes that really are not a statistically appropriate view of EPA, as is acknowledged in that report.

But I will say that even that number of responses——

Senator WHITEHOUSE. Setting aside the statistics, or percentages or any conclusions you might draw, just the raw data point of 889 scientists who work for your organization who say that their work has been interfered with politically——

Mr. GRAY. I will say that 889 is a number that is unacceptable to me as the head of the agency's Science and Technology Office and as the agency's science advisor.

Senator WHITEHOUSE. Why is it that your testimony doesn't reference this in any way? And it is not just the Union of Concerned Scientists. We had, in the last two hearings, enormous criticism about the way in which the science has been manipulated at EPA and the way in which folks like OMB have been stuffed into scientific calculations. Even from the very get-go in the IRIS process of deciding what chemicals to even look at. And then they get the last bite at the apple before it comes out.

It strikes me that these are fairly serious people who are raising this challenge. It is a very frequent and commonly made challenge. We are hearing it over and over and over again from different quarters. There appears to be significant support for these concerns, when you actually look behind them and look at the data, look at what happened and look at the process.

And yet you act as if none of this was going on. And the Administrator says there is nothing to this but yammering critics. Is that really the EPA's position about the public concern about the integrity of its science, there is nothing going on here but yammering critics?

Mr. GRAY. It is important to recognize that this agency relies upon the best available science in making its decisions. In making those decisions, it is important to recognize also that science does not give us a single or precise answer. We take scientific information, we combine it with our science policy judgments and choices and that leads ultimately to a decision. What is very important to me and something we are working very hard on that will address some of these concerns is that we are very transparent in the way that we do things. We want people to understand how it is that we arrive at a decision, what are the choices that we have made, so that we can have scientific input. We have a very rigorous peer review process that looks at the way in which we have used our science. We will have scientific input about the choices, about the data, about the information that we have used that can ultimately lead to strong decisions by this agency.

Senator WHITEHOUSE. How are the secret meetings we have just heard about this week with OMB, with your science advisors, how does that jive with your claim that this is done transparently? What could be less transparent than a secret meeting with OMB?

Mr. GRAY. Transparency is key to the way that we do our assessments. It has always been the case that discussions that we have within our agency about science and science policy and that we have with the rest of the Federal family about science and science policy are kept deliberative to help encourage a free and frank exchange when those scientists are discussing things.

But the important thing to remember is at the end, in that IRIS process——

Senator WHITEHOUSE. Is it your——

Mr. GRAY [continuing].—strong peer review that says that that assessment must pass. There is not room for monkey business, there is not room for shenanigans when the outside, independent scientists are reviewing our work.

Senator WHITEHOUSE. Is it your testimony that the input from OMB in these secret meetings is limited to purely scientific discussion? And if so, could you compare for me the qualifications of, say, chemists within OMB with the chemists involved in making scientific conclusions for EPA?

Mr. GRAY. As I discussed in my testimony, the development of scientific information in EPA, and IRIS assessments are a very clear example of this, include not only scientific considerations but science policy considerations. Those are some of the discussions that happen within our agency. Those are discussions that happen with the other agencies and they are part of moving the scientific process forward.

But at the end, again, the decisions we make are transparently described and reviewed by independent, outside scientists.

Senator WHITEHOUSE. My time has expired, so I will yield to the Senator from Tennessee. But I do want to put into the record, we just heard the other day from the GAO, which said that the OMB interagency reviews lack transparency. Transparency is especially important, because agencies providing input include those that may be affected by the assessments should they lead to regulatory or other actions.

So you seem to have a bit of a disagreement with other parts of Government.

Senator ALEXANDER.

Senator ALEXANDER. Thank you. Thank you, Mr. Chairman.

Mr. Gray, how many scientists work at the EPA or are employed by the EPA?

Mr. GRAY. We have scientists not only in my office——

Senator ALEXANDER. The number.

Mr. GRAY. It is estimated to be somewhere right around 7,000 scientists.

Senator ALEXANDER. Around 7,000. All right. Let's take an example. The recent ozone decision that was made, how many of these scientists would be formally involved in that decisionmaking process, roughly?

Mr. GRAY. Throughout the agency, multiple tens, up to a hundred or even more. In fact, if we look at the scientific work that forms the basis of our assessments, it could be even larger.

Senator ALEXANDER. So maybe 100 or 200 out of several thousand?

Mr. GRAY. Correct.

Senator ALEXANDER. And the scientific advisory committee, according to law, made a recommendation to the Administrator which was only advisory, is that correct, about ozone?

Mr. GRAY. Yes, that is what is required under the Clean Air Act.

Senator ALEXANDER. And there might be a couple of hundred scientists, roughly speaking, involved in that. The recommendation was that the ozone standard should go down to between .06 and .07, is that right?

Mr. GRAY. That is correct.

Senator ALEXANDER. And the Administrator decided that it ought to be a little higher than that .075?

Mr. GRAY. That is correct.

Senator ALEXANDER. Do you think it is possible that those couple hundred scientists would say that that decision represented political interference in their scientific conclusion?

Mr. GRAY. I think that there may be scientists who would disagree with the choice.

Senator ALEXANDER. Well, but if asked the question, that was a political appointee making a decision that was different than the scientific board, do you think a scientist, one of those 200, might have answered that question to say yes, my recommendation was interfered with by a political decision?

Mr. GRAY. I suppose that could happen.

Senator ALEXANDER. I would think so. So what you are saying is that maybe 6,800 or 7,000 scientists who work for EPA were not a part of that process, that maybe a couple of hundred were. And that all of them, if they agreed with the recommendation of the scientific board, could say that some non-science person made a decision which represented political interference, and if they hadn't interfered, in my view, then you would have accepted no standard greater than 0.07.

What conclusions led the Administrator, what factors caused him not to accept the recommendation of the scientific advisory board?

Mr. GRAY. I can't speak for all of the things that the Administrator considered. He knows that he has the decisionmaking authority and what is required.

Senator ALEXANDER. So you don't know?

Mr. GRAY. I know that he takes very seriously the advice that he gets from our various advisory committees.

Senator ALEXANDER. I know. But you don't know why he didn't?

Mr. GRAY. It had to do with how he weighed the science and he ultimately——

Senator ALEXANDER. But you don't know why, what the factors were. Well, I know what some of the factors were, because I had a lot of people in Tennessee saying to me, a lot of county mayors saying, we don't want it changed at all, because we won't get auto jobs in our State because they can't meet the Clean Air standards, that is much too aggressive. So might he have considered the effect

of a more severe rule on the economy of an area? Might that have been a factor?

Mr. GRAY. No, he would not have done that. By law he is not allowed to consider costs.

Senator ALEXANDER. What could be another factor?

Mr. GRAY. The big factor is, going back to the testimony I gave, science, there are many different types and kinds of science that come together. In the case of ozone, we have clinical studies where people have been exposed to ozone, we have epidemiological studies——

Senator ALEXANDER. I have about 1 minute left. Let me ask my last minute of questions having to do with the question of transparency. Are the recommendations of the scientific advisory committee concerning the ozone decision public?

Mr. GRAY. Yes, they are.

Senator ALEXANDER. Did the Administrator, in your judgment, State publicly why he disagreed with or why he came to a different conclusion than the scientific advisory committee?

Mr. GRAY. There is actually a requirement that the Administrator explain the reasons for a different choice than the committee, and he did that.

Senator ALEXANDER. So we know what the science advisory committee recommended and why? I assume they stated their reasons?

Mr. GRAY. That is correct.

Senator ALEXANDER. And we know why the policymaker made his decision and why, and he has a requirement that you say he followed in doing that. That sounds to me like what Senators do every day. We take advice, we don't always publicize what our staff tells us, I don't think any of us does that very often. But then we say publicly what we are for and why we made the decision and then we argue about it, because we might have come to a different conclusion.

Thank you, Mr. Chairman.

Senator WHITEHOUSE. Senator Boxer.

Senator BOXER. I want to show you a series of charts that indicate what we have been seeing in the press lately and why we wanted to hold this hearing. So we will have to move through these quickly. White House meddling hobbles the EPA. EPA ignored law by using rules on mercury. The court says, EPA drops ball on dangerous chemicals to children. EPA bans staff from discussing issue of perchlorate. Bush fights science again and we all lose. Ozone rules weakened at Bush's behest. EPA's chief ignores his advisors again. Bush appointees, not scientists, will have the first say on air quality. As toxic clouds roll by, EPA weakens regulation for chemical storage.

This hearing is extremely important and I couldn't disagree with Senator Alexander more. Now, I respect him very much. But the fact is, if you just read the Supreme Court case that dates back to an argument that was decided in 2002, 2001, February 2001, written by Justice Scalia, it is supposed to act, Senator, the way we act, yes, we listen to science, we listen to the politics, here it is, written by Justice Scalia, and it talks about the Clean Air Act. The text interpreted in statutory and historical context and with appreciation for its importance to the Clean Air Act as a whole, unambig-

uously bars cost considerations from the National Air Ambient setting process. And thus ends the matter for us as well as the EPA.

EPA cannot consider cost in setting Clean Air Act health standards. Period, end of quote. They are not to allow politics into this. That is up to you and me. And we could argue and listen to the special interests. They are not supposed to. What is happening now, and it is a disgrace, and it is dangerous for our people, is that politics is front and center of the EPA, and what they have been doing, starting with the risk assessment process, the GAO, who knows what they are talking about, they have no axe to grind, GAO clearly states that the scientists are not being listened to and the special interests are invited in and everything is kept secret. And this is the problem.

I want to pick up where Senator Whitehouse left off. The GAO has clearly told us what has happened. I have to say, Mr. Gray, and I mean, I think you are a very nice man, and this is not a personal attack, but what do you mean when you say it is transparent over there? What is your definition of transparent?

Mr. GRAY. My definition of transparent is that we lay out for the consideration of everyone the scientific and other bases of our decisions.

Senator BOXER. Do you support keeping all the records secret from these meetings where GAO says, OMB considers agency's comments on IRIS assessments to be internal, executive branch documents that may not be made public. Given the importance of IRIS assessments, it is essential that input from all parties be made part of the public record. Do you agree with GAO and disagree with OMB? Where do you stand?

Mr. GRAY. It has always been—]

Senator BOXER. Do you agree with them?

Mr. GRAY. I disagree with GAO. It has always been our process that discussions within our agency and other agencies are kept deliberative.

Senator BOXER. OK, you disagree with GAO and you therefore agree with OMB, who says that these documents have to be kept secret from Senator Alexander's constituents, from Senator Inhofe's constituents, from mine, from Sheldon's, from Senator Klobuchar? I really need to know, again, you agree with keeping it secret. And yet on the other hand, you say you are for transparency. How can you possibly say both things? That doesn't make sense to me.

Mr. GRAY. Because at the end of the process, we are very transparent about what we have done in that assessment, about what science decisions have been made, what science policy decisions have been made. And those have been reviewed by independent, external scientists.

Senator BOXER. Now, let me just say this. You have lost all credibility with me. I still like you. But you have lost all credibility. Let me read you, how you can sit there and say on the one hand, I am for transparency and then say you agree with OMB to keep these meetings secret is an outrage. Honestly, be honest, say you don't agree with transparency. But don't sit here and say you believe in transparency. Own up to it. Listen to what the GAO says, and I ask unanimous consent, Mr. Chairman, to put this in the record.

Senator WHITEHOUSE. Without objection.

[The referenced material was not received at time of print.]

Senator BOXER. A lack of transparency at the OMB interagency review process reduces the credibility of EPA's IRIS assessments. Because the agency's comments and the changes EPA makes in response are treated as internal executive branch documents not subject to release outside the executive branch, the OMB interagency reviews occur in what amounts to a black box. A black box. And we all know what a black box is. That is top secret, sir. Thank you.

Senator WHITEHOUSE. Senator Inhofe.

Senator INHOFE. Thank you.

Mr. Chairman, I have two documents, each with three pages, I want to ask unanimous consent that they be made a part of the record.

Senator WHITEHOUSE. Without objection.

[The referenced material was not received at time of print.]

Senator INHOFE. The first is from the Center for Consumer Freedom. It is an analysis of the Union of Concerned Scientists, I will only read a couple of sentences here. "UCS embraces and environmental agenda, the office stands at odds with their rigorous scientific analysis it claims to employ. A radical green wolf in sheep's clothing, UCS tries to distinguish itself from the Greenpeace of the world by convincing the media that its recommendations reflect a consensus." That is one document.

The other one is, we had put together a list of 12 specific items from the Clinton administration on politicized science. This is all documented and it is all footnoted and I ask that both of these be made a part of the record.

Senator WHITEHOUSE. They will be, without objection.

Senator INHOFE. All right. Dr. Gray, you used the words, I think, single, precise answer. Why is it so important to focus on uncertainty? Is there usually a single answer? It is often demanded of you, I want a single, precise answer. What is the difficulty in that?

Mr. GRAY. That is really an important question, Senator, and it is a major source of confusion for a lot of people. The reality is that scientific assessments, particularly those that are done at EPA, rarely do point to a single best or right answer. There are usually a range of plausible answers, all of which are scientifically defensible and could be chosen.

So this is where the science policy considerations come into play. That is why transparency and accurate characterization of that uncertainty is so important.

Senator INHOFE. Transparency of the uncertainty?

Mr. GRAY. And transparency of the way in which the data are being used, and specific choices that the agency has made.

Senator INHOFE. Have you experienced any resistance within the EPA as it focused on these important issues? In other words, uncertainty in analysis, transparency, and if so, what are the reasons?

Mr. GRAY. I would say that yes, in some instances there has been reluctance on the part of some of the agency to acknowledge its debt of uncertainty that is present in many of our assessments and the key role that many of our science policy considerations really do play. I think there are a couple of reasons for this. The agency has had an approach in the past of providing that single answer,

a point estimate, often an upper bound estimate. There are concerns at the agency about, how do I defend things if I actually acknowledge that the science is uncertain.

And yet it is really important to recognize, and we have been hearing from the outside scientific community that for the credibility of our assessments, we have to do this. We are working to advance the way in which we do our assessments, to be more transparent, to characterize uncertainty. It is something that is very important for the credibility of this organization.

Senator INHOFE. How has the ORD's science improved the management of air quality in the United States?

Mr. GRAY. I think there have been a number of ways. As we have already discussed, our science helps to support the decisions that are made about ambient air quality standards, and we have been important contributors to the scientific base that has led to the recent tightening of the particulate matter standard, the tightening of the ozone standard and the proposed tightening of the lead standard, for example.

But we are also out there trying to actually put that science to work. We have efforts underway to better measure ozone, for example, across the Country, to feed that into things like the air quality index that you can find on the back of USA Today that tells you whether the ozone levels should be a concern, depending on what you plan to do that day, where you live and what your health status is.

So I think the agency has provided improved air quality all the way from the scientific bench all the way up into the kinds of things that you see in USA Today.

Senator INHOFE. That is good. In my opening statement, Dr. Gray, I mentioned sound science. This has always been something that I have been a stickler for. I recall during the previous Administration, the Clean Air Science Advisory Board, at one time I think the board was 21 scientists at that time. Then 19 of them disagreed with the conclusion that the Administration came up with. So I have always really been concerned about that. Could you, in this remaining 30 seconds, explain the EPA science policy, the infrastructure of the science policy?

Mr. GRAY. Science policy really arises when we are taking tens, hundreds, even thousands of individual acts of science that have been done, we gather that best available science together and we have to use it to inform a decision. When we do that, science policy choices that are developed within the agency help to guide choices that are made, data that is used, assumptions that are invoked. This is done in a process through the agency, through our science policy council. It is externally peer-reviewed. It is a way to have a consistent science policy approach in the agency.

Senator INHOFE. And transparency.

Mr. GRAY. Transparency is very important.

Senator INHOFE. Thank you, Dr. Gray.

Senator WHITEHOUSE. Senator Klobuchar.

Senator KLOBUCHAR. Thank you very much, Senator Whitehouse, Mr. Gray. I come from Minnesota, a State where we believe in science. We brought the world everything from the pacemaker to the post-it note, we are the home of the Mayo Clinic and other

places. In my year and a half here, I have been concerned with things that come to my attention. One was when Dr. Julie Gerberding, from the Centers for Disease Control, testified before this Committee and it turned out later that her testimony had been edited while the fires were raging in California, parts were taken out about how climate change can lead to more fires on the west coast. Everything she said, the White House responded by saying, well, it was edited because it wasn't consistent with some things that the Union of Concerned Scientists said. And in fact, we were able to show everything she said had been in their report.

Then I hear about the decision involving Mary Gade. We are shocked at the forced resignation of Mary Gade, the head of EPA's Midwest region, which includes Minnesota. She had been fighting Dow Chemical, as Senator Whitehouse pointed out, to force them to clean up the dioxide contamination in Michigan. She invoked her emergency authority to order Dow to clean up three hot spots last summer when dioxide levels 50 times the Michigan standard were found.

So my first question is about that. I understand the decisions didn't come from your office, it was the Office of Research and Development. But what seems to me a clear case here, where policy was driven by politics, what protections do we need at the EPA to make sure that dedicated officials aren't forced out trying to do their jobs?

Mr. GRAY. In this case, as you said, this is something that I have no direct knowledge of, this situation in Region 5. In fact, because it is an internal agency personnel matter, it is something that I cannot comment on.

Senator KLOBUCHAR. But I am asking just in general, then, if you don't want to comment on this specific case, which I think is a very troubling case for the Country, but in general, what kind of protections are in place, I know we are going to hear from Dr. Francesca Grifo from the Union of Concerned Scientists about some potential ideas, whistleblower protections for scientists, elevating EPA to the Cabinet level, establishing an Inspector General. What do you think would be the most important to re-establish the credibility of the agency?

Mr. GRAY. I actually think the credibility of this agency is enhanced through our use of the best available science and the way that we do our work. I will say that it is very important to us, for example, in the Office of Research and Development, which I can speak to directly, we have no restrictions on things that our scientists can do in interacting with the press or the public or in ways in which they can publish their work. We believe that getting the best science out into the scientific community is the way to advance our knowledge and advance our mission.

Senator KLOBUCHAR. But then we were just talking about the fact that it is not transparent, that GAO has begged you and pushed you to try to make this information transparent. I don't understand how we are going to know that we have the best science when we don't know what is coming in your door.

Mr. GRAY. The scientific information that we put out is transparently described. We have a risk characterization handbook that

was first issued in 2000 that has 11 principles of transparency that we are working our best to adhere to.

Senator KLOBUCHAR. But then why can't see publicly the information that is coming to you?

Mr. GRAY. You can see——

Senator KLOBUCHAR. The comments that were——

Mr. GRAY [continuing].—the information that we have used, the choices that we have made, and you can see what the independent scientists have said about our use of science——

Senator KLOBUCHAR. I just don't think that is true from what we have heard in other hearings about the information coming. But specifically you just said that you are making decisions based on the best available science. Then could you explain EPA's decision to ignore the unanimous recommendation of its own Clean Air Scientific Advisory Committee? Why would you do that if you are listening to science and setting a weaker standard for ozone than recommended?

Mr. GRAY. The Administrator certainly did not ignore the advice of the Clean Air Science Advisory Committee. In fact, he values their input, the input from our other advisory committees, from other agencies, from the public, very highly. That is the basis of his ultimate decision. In fact, in the case of ozone, he agreed with them that we needed to tighten that standard. He made a different choice, based on his view of the science, of what the appropriate level would be.

Senator KLOBUCHAR. But isn't it true that we have 1,700 peer-reviewed studies and the unanimous recommendation of your 23 science advisors to the EPA? That sounds like something he would want to listen to.

Mr. GRAY. Again, all of those studies are exactly why there is no single right answer that comes out of that scientific process, why the data that are available have to be weighed, they have to be analyzed and they have to be considered in their entirety. We get advice to help us through that, but ultimately that decision is the Administrator's decision.

Senator KLOBUCHAR. Again, 1,700 peer-reviewed studies and unanimous recommendations of 23 science advisors, it seems to me that that would be certainty. To also add to that, I would think, if you have a choice and you have all these scientists, wouldn't you want to go with a standard that is a more cautious standard that would protect human health?

Mr. GRAY. The Administrator has particular guidelines under the Clean Air Act for the decision that he makes, that it has to be requisite to protect public health, with an adequate margin of safety being neither higher nor lower than necessary. In his judgment, that is the level that he set.

Senator KLOBUCHAR. Thank you.

Senator WHITEHOUSE. I am going to ask a few more questions of the witness, probably for about 4 minutes, then I will offer anybody else the chance to follow on, if they choose, in the second round. I just wanted to followup on what you have said, Mr. Gray. You indicated that the ozone decision was made by the Administrator, based on how he weighed the science and not because of any economic or other considerations, political considerations, which you

admit would be illegal. It sounds like the Clean Air Science Advisory Committee was unanimous, recommending a range of .06 to .07, the Children's Health Protection Advisory Committee recommendation was unanimous, recommending a range of .06. What other science did you look to to find a different recommendation of .075? You said that he has his own view of the science, but his own view of the science as informed by what? And why won't he come here? Why has he been unwilling to explain to us his own decision-making if it is legitimate?

Mr. GRAY. I will start with the first part of your question first. This is actually a very good example of the way in which uncertainty and science plays an important role in decisions. There is a particular study——

Senator WHITEHOUSE. You are telling me, you have two unanimous, you are telling me and you expect me to believe that two unanimous decisions by panels that EPA chose creates scientific uncertainty in the mind of EPA?

Mr. GRAY. They certainly do. Many of them put a lot of weight on this particular Adams study, and the finding in one of their chamber studies that people exercising moderately for 6 hours and exposed to ozone had responses. The author of that paper himself commented to the agency that he thought that was an incorrect interpretation of his own work. There is clearly not scientific agreement about how to interpret science. That is my point. The Administrator interpreted the science——

Senator WHITEHOUSE. Is there scientific agreement by the people that you chose to be the experts, unanimously supported this decision, there is no indication of what science to the contrary the Administrator relied on, none, he made a different decision and he won't come before us and explain it. And frankly, I can't see a legitimate explanation for that chain of events. This is not some alien group that came out from strange places to make this stuff up. This is the best scientists in the Country chosen by you, and you ignore their recommendation.

Mr. GRAY. We certainly never ignored the advice of our advisory committees, but I will tell you that the preamble to the ozone rule——

Senator WHITEHOUSE. Well, they recommend .06 and .07 and you do .075, I don't know how you could have ignored it much more than that.

Mr. GRAY. I think that if you read the preamble to the ozone rule, you will see exactly what reasoning went into our decision.

Senator WHITEHOUSE. We can't see what reasoning went into that decision, because we can't get the Administrator to come here and explain it. And I strongly suspect it is because there were considerations other than science that dictated, because nobody can show me where the science is that would indicate that number. And frankly, uncertainty is a lousy explanation for what you have said, because it would just as easily justify a number that is five points lower than the low range, or .055, as it would justify a number that is five points higher than the high range. In fact, because your job is to protect people, you would think that would be the way you would err.

My time is expired.

Senator ALEXANDER. Mr. Gray, this is a very interesting discussion. Exactly what did the science advisory committee recommend on ozone? My colleagues seem to say that they were certain. So exactly what was their precise, certain recommendation? What was the level they recommended?

Mr. GRAY. To my recollection, the board that was just up reflected their recommendation that it would be somewhere in a range between 0.06 and 0.07.

Senator ALEXANDER. Oh, but I thought they were certain about it. Do you mean they disagreed between, did they not recommend .61?

Mr. GRAY. They recommended a range.

Senator ALEXANDER. Did they recommend .062? Did they recommend .063 and .064 and they couldn't agree on .065 or .066 or .067? So they disagreed between .06 and .07.

Senator WHITEHOUSE. Thank you.

Senator ALEXANDER. And what did the Administrator choose?

Mr. GRAY. The Administrator set the annual standard at .075.

Senator ALEXANDER. So actually, the scientists who are being cited here disagreed among themselves more than the Administrator disagreed with them? Am I correct about that? The .005, they had a whole one range of disagreement and he had a half. So we are saying over here that these scientists have a certain agreement and they can't even agree between .06 and .07, he goes to .075. So in my opinion, they disagreed more among themselves than he disagreed with them. Now, who has the judgment under the law to make the decision about ozone, based on an adequate margin of safety requisite to protect public health?

Mr. GRAY. That responsibility is the Administrator of EPA.

Senator ALEXANDER. Is that exclusively his decision?

Mr. GRAY. That is correct.

Senator ALEXANDER. Is the scientific advisory committee, which couldn't agree among itself about what to do, are they purely advisory in their capacity?

Mr. GRAY. They are advisory. We take their advice very, very seriously.

Senator ALEXANDER. But they are advisory in their capacity. Are their recommendations public?

Mr. GRAY. Yes, they are.

Senator ALEXANDER. So any of us can read their recommendations, is that correct?

Mr. GRAY. That is correct.

Senator ALEXANDER. And did you not say earlier that the Administrator, who has the exclusive authority to make this decision and whose decision was closer to the top range of this committee than the top range was to the low range of the committee, did he State in his opinions why he made his decision at .075?

Mr. GRAY. Yes, he is required by law to do that.

Senator ALEXANDER. He is required by law to do that?

Mr. GRAY. Yes.

Senator ALEXANDER. So the only area, it seems to me, of objection here is that there was an interagency review of this decision. Was there such a review?

Mr. GRAY. Yes, under an executive order dating back to 1993, there is interagency review.

Senator ALEXANDER. And that information, what went on there isn't public? Is that correct?

Mr. GRAY. That is correct.

Senator ALEXANDER. We had a Republican conference the other day, all the Republican Senators talking about climate change. The Democrats do the same. Actually we do that about every lunch. They are not public. Now, they are not our decisions. And when we go out and talk, these are internal discussions. And I assume that an internal discussion in the executive branch would be like an internal discussion among our offices, among our Senators. And I don't think we are going to haul a camera into the Democratic Policy Committee meeting, or in the Republican Policy Committee meeting.

So you are saying that the scientists' recommendations are public; the Administrator's recommendation is public, we can read it; and he has the exclusive authority to make the decision. And the way I read it, he disagreed more with the top range of the scientists' group than the bottom range of the scientists' group did. Thank you, Mr. Chairman.

Senator WHITEHOUSE. Senator Boxer.

Senator BOXER. Comparing EPA to us doesn't even make any sense whatsoever.

Senator ALEXANDER. I compared the interagency——

Senator BOXER. If I might say, they, according to Justice Scalia, cannot consider all these other things that we can consider. And again, we put it in the record, you are not allowed to, you have to go protect the health of the people, No. 1.

Now, you sir, your continuous claim that there is transparency at the EPA in setting protective health standards for dangerous pollutants is ludicrous. Why do I say that? The GAO approved it, they said the OMB's secret policy that you embrace here today, which is shocking from someone at the Environmental Protection Agency, is the equivalent of putting the information into a black box. That is not me saying it, that is not the Chairman saying it, it is the GAO saying it after a very, I think, very important review.

Two, your stated view that costs and other factors should be considered flies in the face again of the Supreme Court decision. So this is Alice in Wonderland. The facts are the facts are the facts. There is no transparency on ozone. My understanding, and my staff can correct me if I am wrong, they didn't follow the science. They went over the level that any scientist recommended. Outrageous on its face.

Now, do you know why Administrator Johnson could not be here today?

Mr. GRAY. I don't know. I know that he has been out of work and I think he is back.

Senator BOXER. He is back, but he couldn't come up here today?

Mr. GRAY. Correct.

Senator BOXER. Do you know why he will not give us any date to explain his ozone decision, the decision that we have all asked you about today? Do you know why he couldn't give us any date?

Mr. GRAY. I don't know that. I could get that information for you.

Senator BOXER. Good. Thank you. There are serious charges that the White House interfered with setting the standard. We want the head of the EPA up here to explain it. Do you know why we have yet to receive any e-mails that were promised to me and this Committee? We were supposed to get these e-mails that went back and forth between the White House and the EPA regarding the California waiver? We were promised that we would get those e-mails in February. Do you know why we have yet to receive those e-mails?

Mr. GRAY. I don't know.

Senator BOXER. Will you please find out why? Will you please go back and ask the question and would you please send me a letter as to why we cannot get these?

Mr. GRAY. I can do that.

[The referenced document was not received at time of print.]

Senator BOXER. Because you want to talk about transparency, I will tell you, many States in the Union are very angry at what this Administration did. And for the first time, never granting a waiver to California, which impacts 19 other States, so we can begin cleaning up our air and doing what the Supreme Court said we have to do under the Clean Air Act, which is fight global warming. And I have to tell you, what is going on at this Administration is so dangerous, it is not a game. We have had a stall for seven and a half years about doing anything on global warming. We have had a change that is now trying to be institutionalized where you shut the scientists back in a room. And there is no transparency here. We don't know what is going on in those secret meetings, I say to my friend from Tennessee, because they are in a black box.

So it is very, very troubling and I want to thank Senator Whitehouse for his leadership.

Senator WHITEHOUSE. Senator Klobuchar.

Senator KLOBUCHAR. Thank you very much, Senator Whitehouse.

Sir, I just wanted to followup a little bit on a hearing we had just yesterday on perchlorate. And in your testimony, you State that in order to meet our statutory requirements, we often cannot wait for independent scientific findings to converge on a solution. This would cause long delays in environmental decisionmaking.

How would you say this statement fits in with the hearing we held yesterday to examine why the EPA has still not issued a standard for perchlorate decades after we became aware that it was a toxic chemical with developmental impacts on pregnant women and children?

Mr. GRAY. Thank you. First, I need to make a response to Senator Boxer. I want to make clear that under the Clean Air Act, there are no consideration of cost that go into the setting of a National Ambient Air Quality standard, and the Administrator is very clear about that, when that decision is made.

To your point, perchlorate is something that we take very seriously. We are moving and I know that you had testimony yesterday from the Assistant Administrator for the Office of Water that we are moving to have a decision on perchlorate by the end of this year. I will tell you that we in the Office of Research and Development are working very hard to make sure that the Office of Water is able to meet their requirement under the Safe Drinking Water

Act that says we must use the best available science. And we are looking at the best available science to clean——

Senator KLOBUCHAR. How long has it been since we knew that this was a risk?

Mr. GRAY. We are using things like physiologically based pharmacokinetic models to allow us to look at the potential susceptibility of different life stages, including infants and children. That is something that is very important to the Office of Water ultimately making a sound scientific decision.

Senator KLOBUCHAR. The statements that you have made in your testimony about how we cannot wait for independent scientific findings to converge on a solution, because it would cause long delays in environmental decisionmaking. How does this fit also with the reluctance of the EPA to support concrete action on greenhouse gas emissions, so that they had to have courts push them into it? To me, that statement isn't completely with odds in terms of how the EPA has been handling greenhouse gas emissions.

Mr. GRAY. The point of that statement is that scientific information rarely in fact, I will say never converges on a single point, a single answer. What we do as an agency is do our assessments with the best science we have available to us at the time to help inform the various decisions we have to make. We try to reflect the uncertainty in that to make sure that people know what we know and what we don't know, where more research will help us to understand——

Senator KLOBUCHAR. Do you think some of the best science available comes from the Annapolis Center? I notice you were on their board.

Mr. GRAY. I was on their board many years ago, yes, I was.

Senator KLOBUCHAR. From 1995 to 2000. They just gave an award to Senator Inhofe. I think they have argued that, they have argued against the idea that global warming is a result of burning fossil fuels. Is that something that goes into your thinking?

Mr. GRAY. I certainly haven't been part of that organization, as you said, for the last 8 years. I don't know what informs their decisions.

Senator KLOBUCHAR. My concern here is not to bring up something that you may not consider relevant, but when you have a situation where we are basically, things are in a black box and we can't get to the bottom of what is going on with the EPA's decisionmaking and they are making decisions that are contrary to scientific recommendations on ozone, the courts are having to push them into act, you have to look at where is the head coming from, where is the mind set coming from. And so you have to look at the outside forces, because we cannot figure out, when your own scientists are telling you to move on this and Congress is trying to push as hard as we can with the resources we have to move on this, why you haven't. Thank you.

Senator WHITEHOUSE. I thank the witness for his testimony.

Senator BOXER. Mr. Chairman, I would like to put two things in the record, if I might.

First of all, I have to do this, as a privilege of the Chairman of the Committee. When Mr. Gray says that, when it comes to clean air, only science, sir, I would have to call this, I am not saying you

are a liar, I am not saying that, but I am saying that statement is a big lie. Why do I say that? Because the last two things that you did, ozone, which Senator Alexander has gone over, and soot, the fine particulate matter, and I would put in the record the fact that your scientific ozone review panel said, it is the Committee's consensus, scientific opinion, that your decision to set the primary ozone standard above the range fails to satisfy the explicit stipulations of the Clean Air that you ensure an adequate margin of safety for all individuals, including sensitive populations, that is from your scientists, and that is on ozone and fine particulate matter.

Here is what your scientists said. "There is clear and convincing scientific evidence that significant adverse human health effects occur at the retained standard which does not provide an adequate margin of safety requisite to protect the public health." And that is when you didn't go to 13 or 14 micrograms, you kept it at 15.

Now, these are two specific examples. And for you to sit here and say that you follow the law. Listen, you have lost every lawsuit, I count 11 major lawsuits where the most conservative courts have found that you are not protecting the public health. So I am putting these documents into the record. And the other thing I am putting into the record is the dictionary definition of transparency, which says, literally understood or characterized by visibility or accessibility of information, especially concerning business practices. So I think that your testimony here today, you have tried to defend the indefensible. And you have failed as far as this Senator is concerned.

Senator WHITEHOUSE. Without objection, the documents will be made a matter of record.

[The referenced material was not received at time of print.]

Senator WHITEHOUSE. Senator Alexander.

Senator ALEXANDER. Thank you, Mr. Chairman.

Then I would like to add something to the record in pursuit of transparency. I would like to ask consent to put into the record the recommendations of the scientific committee, the Clean Air Science Advisory Committee that recommended the ozone standard of .060 to .070. Then I would like to put into the record the response of the Administrator of the EPA, who has explained his readings, which under the law, he has the sole judgment to make, based on criteria in allowing an adequate margin of safety that are requisite to protect public health.

And I would like to suggest to the Senator from California that if she wants to change that, she should change the law. Because the law says that Section 109 of the Clean Air Act gives him the exclusive decisionmaking, and he agreed with the top range of his scientific advisors, more than the bottom range of the scientific advisors agreed with the top range.

Senator WHITEHOUSE. Those documents will also be made a matter of record.

[The referenced material was not received at time of print.]

Senator KLOBUCHAR. And Senator Whitehouse, I just want to put into the record as well a list of organizations that supported the range of .06 to .07, and in fact supported the .06 number, that would be the American Academy of Pediatrics, the American Association of Cardiovascular and Pulmonary Rehabilitation, the Amer-

ican College of Crest Physicians, the American College of Preventative Medicine, the American College of Occupational and Environmental Medicine, the American Heart Association, the American Lung Association, the American Medical Association, the American Nurses Association, the American Public Health Association, the American Thoracic Society, the Asthma and Allergy Foundation of America, the National Association for Medical Direction of Respiratory Care, the National Association of City and County Health Officials, the Physicians for Social Responsibility and Trust for America's Health.

Senator WHITEHOUSE. That also will be made a matter of record, without objection.

[The referenced material follows:]

List of Medical Societies and Public Health Organizations Supporting a Primary 8-hr Ozone NAAQS of 0.060 ppm

American Academy of Pediatrics

American Association of Cardiovascular and Pulmonary Rehabilitation

American College of Chest Physicians

American College of Preventive Medicine

American College of Occupational and Environmental Medicine

American Heart Association

American Lung Association

American Medical Association

American Nurses Association

American Public Health Association

American Thoracic Society

Asthma and Allergy Foundation of America

National Association for Medical Direction of Respiratory Care

National Association of City and County Health Officials

Physicians for Social Responsibility

Trust for America's Health

Senator WHITEHOUSE. We appreciate the testimony of Mr. Gray, and he is excused.

Would the next panel please come forward?

I want to thank this distinguished panel for being here today. The manner in which we proceed will be right across the panel, beginning with Dr. Grifo. We will allow 5 minutes each for your oral testimony, so it may be necessary for you to summarize what you have submitted in writing in order to fall within that timeframe. If you hear a noise like that, it means that your time is up and I would appreciate it if you would wrap it up.

Dr. Grifo, please.

STATEMENT OF FRANCESCA GRIFO, PH.D., SENIOR SCIENTIST, DIRECTOR, SCIENTIFIC INTEGRITY PROGRAM, UNION OF CONCERNED SCIENTISTS

Ms. GRIFO. Good morning. My name, as you said, is Francesca Grifo, and I am a senior scientist and the Director of the Scientific Integrity Program at the Union of Concerned Scientists, a leading science-based non-profit working for a healthy environment and a safer world.

Thank you, Senator Whitehouse, Senator Boxer and Senator Alexander, and members of the Subcommittee, for the opportunity to speak this morning about the problem of political interference in the work of Federal scientists. I thank the Committee for your oversight and I strongly urge you to keep the pressure on. The next 8 months promises to be filled with additional abuses of science that, while last-minute in their implementation, are sure to be long-lasting in their consequences.

While I am sure we can all agree that the Environmental Protection Agency has a skilled and dedicated work force, our research, based on survey responses from 1,586 scientists, combined with essays from 850 of these scientists, forces us to conclude that this is an agency in crisis. Hundreds of EPA scientists reported interference on issues ranging from mercury pollution to climate change.

You might note that no rank and file EPA scientist is speaking today, despite significant efforts by the Committee. Unfortunately, 612 EPA scientists responded that they fear retaliation for openly expressing concerns about their agency's mission-driven work, work that is compromised by the influence of political appointees at EPA or other agencies, as well as non-governmental interests.

This influence takes the following forms: scientists told to exclude or alter technical information or to provide incomplete, inaccurate or misleading information; selective or incomplete use of data; edits that change the meaning of scientific findings; disappearance or unusual delay in the release of scientific information; statements by EPA officials that misrepresent scientists' findings; and suppression of scientists' ability to speak freely to other scientists, the news media and the public.

Eight hundred and eighty-nine scientists personally reported experiencing, or reported personally experiencing one of these events in the last 5 years. Of these, 234 reported experiencing 6 or more such incidents. Because of such interference, EPA has failed, for example, to sufficiently tighten standards for key air pollutants,

such as ozone, soot and mercury, resulting in millions of Americans breathing unhealthy air, and has also compromised the quality and quantity of publicly available toxicological information, leaving families in the dark about what chemical dangers are in their neighborhoods.

By suppressing, distorting and manipulating science, the White House has consistently attempted to subvert the 12 pieces of legislation that authorize the Environmental Protection Agency to protect human health and the environment, and in so doing, has made an end run around the legislative branch. Furthermore, by creating systemic changes in the way the EPA creates and utilizes scientific information, the Administration has reduced the capacity of the executive branch to meet complex environmental and public health challenges.

For example, just 2 weeks ago, we learned that agencies who would be liable for costly cleanups are now given expanded over EPA's scientific assessments of chemical toxicity. Scientific advisory committees, which used to have critical roles at the beginning of their quality assessments, now have a reduced role much later in the rulemaking process.

Fortunately, this is not a problem without a solution. A suite of reforms are detailed in our report, Interference At The EPA. But here are a few, selected few. Last year, both the House and Senate overwhelming approved bipartisan legislation to strengthen whistleblower protections for Federal employees. It is crucial that the final version of the whistleblower bill now being negotiated by the two chambers contain specific protections for scientists who expose efforts to suppress or alter Federal research, similar to those protections in the House-passed version of the bill.

To ensure the work of Federal scientists will not be subject to political manipulation, the EPA should increase openness in the decisionmaking process to expose manipulation. Specifically, the expanded reach of the Office of Management and Budget must be pushed back. If research results in their application to the creation of public protections are made public before they drop into the black hole, as GAO has put it, of OMB, attempts to distort science to support political goals will be exposed.

EPA should adopt media, communication and scientific publication policies across the whole agency that ensure taxpayer-funded scientific research is accessible to Congress and the public and the media and so on. The GAO has more work to do. There are many changes that have become embedded in the agency that if not exposed will continue to harm scientific integrity.

Finally, there is one action that can and must happen immediately. Administrator Johnson should send a clear message to all political appointees that he will not tolerate attempts to alter or suppress Federal research. Just as William Ruckelshaus did shortly after appearing before this Committee 25 years ago in 1983, Administrator Johnson should pledge to operate EPA in a fishbowl. The original memo, still in the history section of EPA's website, should be moved to its home page. This memo sets a standard for an agency so open that it earned the trust of the American people.

Thank you.

[The prepared statement of Ms. Grifo follows:]

Written Testimony of Francesca T. Grifo, Ph.D.
Senior Scientist with the Union of Concerned Scientists
Director of the Scientific Integrity Program

Before the U.S. Senate Committee on Environment and Public Works
Subcommittee on Public Sector Solutions to Global Warming, Oversight, and Children's Health Protection

"Oversight Hearing on *Science and Environmental Regulatory Decisions*"
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This testimony is presented by Dr. Francesca Grifo, Senior Scientist with the Union of Concerned Scientists (UCS), a leading science-based nonprofit working for a healthy environment and a better world. The full testimony is submitted for the record and Dr. Grifo will summarize her statement for the Committee on the problem of political interference in the work of federal government scientists.

Good morning, my name is Dr. Francesca Grifo. I am a Senior Scientist and the Director of the Scientific Integrity Program at the Union of Concerned Scientists, a leading science-based nonprofit working for a healthy environment and a safer world. I would like to thank Chairman Boxer, Ranking Member Alexander, Senator Whitehouse and the Members of the Committee for the opportunity to speak to you this morning about the problem of political interference in the work of federal government scientists.

This written testimony contains a brief introduction (p. 1), an overview of the issue of scientific integrity (p. 2), a summary of the report *Interference at the EPA: Politics and Science at the U.S. Environmental Protection Agency* released April 23, 2008 (p. 6), a summary of reforms needed to restore scientific integrity to the federal policy making process (p. 11) and some concluding thoughts (p. 16). Also included are a timeline of abuses of science compiled by UCS (p. 18), selected essay responses from UCS's survey of EPA scientists (p. 21), a statement on *Scientific Freedom and the Public Good* endorsed by many prominent scientists (p. 26), and brief summaries of four past surveys of federal government scientists conducted by UCS (p. 27).

I. Introduction

The United States has enjoyed prosperity and health in large part because of its strong and sustained commitment to independent science. As the nation faces new challenges at home and growing competitiveness abroad, the need for a robust federal scientific enterprise remains critical. Unfortunately an epidemic of political interference in federal science threatens this legacy, promising serious and wide-ranging consequences.

The U.S. Environmental Protection Agency (EPA) has been especially harmed by political interference in its work to protect human health and the environment. Bush administration political appointees have rewritten EPA scientific documents concerning climate change and pressured EPA scientists to support predetermined conclusions regarding mercury pollution. The White House has also interfered in the EPA's recent decisions regarding particulate matter and

ozone air pollution and has pushed for rules that politicize the scientific findings contained in the IRIS toxics database.

To assess the breadth and depth of political interference at the EPA, and to give voice to the thousands of civil servant scientists working at the agency, the Union of Concerned Scientists (UCS) distributed a 44-question survey to nearly 5,500 scientists at the EPA in the summer of 2007 and received responses from 1,586 scientists. The results of that survey, as well as additional investigations, are contained in our recently released report *Interference at the EPA: Politics and Science at the U.S. Environmental Protection Agency*.[1] We summarize here the problems with scientific integrity across the federal government, the major findings of this latest report and outline the solutions needed to restore scientific integrity to federal decision making.

Political interference has penetrated deeply into the culture and practices of federal agencies. This interference in science threatens our nation's ability to respond to complex challenges to public health, the environment, and national security. It risks demoralizing the federal scientific workforce and raises the possibility of lasting harm to the federal scientific enterprise. It betrays public trust in our government and undermines the democratic principles upon which this nation was founded. The thousands of scientists in the employ of the federal government represent a tremendous resource and their knowledge and advice should not be manipulated or ignored. Without strong action to restore integrity to federal science our nation will be ill-prepared to deal with the challenges we face.

II. Scientific Integrity

Successful application of science has played a large part in the policies that have made the United States of America the world's most powerful nation and its citizens increasingly prosperous and healthy.

Although scientific input to the government is rarely the only factor in public policy decisions, scientific input should always be weighted from an objective and impartial perspective. Presidents and administrations of both parties have long adhered to this principle in forming and implementing policies. However, the current Bush administration has consistently undermined this legacy by manipulating, censoring and suppressing the work of federal government scientists—with serious consequences for our health, safety, and environment.

Misrepresenting and suppressing scientific knowledge for political purposes can have serious consequences. For example, if the Nixon administration suppressed air quality studies and vetoed the Clean Air Act of 1970, Americans would have suffered more than 200,000 premature deaths and millions of cases of respiratory and cardiovascular disease over the next 20 years.[2]

This misuse of science has led Russell Train, the EPA administrator under Presidents Nixon and Ford, to observe: "How radically we have moved away from regulation based on independent findings and professional analysis of scientific, health and economic data by the responsible

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[1] To read the text of the report and see supporting materials go to http://www.ucsusa.org/EPAscience/.
[2] See http://www.epa.gov/oar/sect812. See also data from the American Meteorological Society, online at http://ametsoc.org/sloan/cleanair/index.html.

agency to regulation controlled by the White House and driven primarily by political considerations."[3]

Political interference in the work of federal scientists has become widespread in the past several years. To catalog these abuses, UCS launched the *A-to-Z Guide to Political Interference in Science* (see p. 18)[4] a webpage that now documents 85 case studies of such interference, involving 24 government agencies. In our February 2008 report, *Federal Science and the Public Good*,[5] we outlined the patterns of interference with government science. The report also highlights the deeper systemic changes that have been made to the structure and policies of the executive branch that threaten to enshrine politicized science even after George W. Bush leaves office. These findings are summarized below.

Patterns of Abuse

Specific examples of the misuse of science have occurred across a broad range of issues such as childhood lead poisoning, toxic mercury emissions, climate change, reproductive health, and nuclear weapons. Experts at the FDA charged with ensuring the safety of our food and drug supply, report being pressured to alter their scientific conclusions. Political appointees in the Department of the Interior have been exposed for overruling the scientific consensus and refusing to protect endangered species. Scientists nominated to serve on scientific advisory boards report being asked about their political leanings. And scientists studying what may very well be the most profound global change of this century – global warming – are effectively barred from communicating their findings to the news media and the public.

Interference can take many different forms, including:

- Falsifying data and fabricating results. Federal officials with little or no scientific background have misrepresented scientific data and presented scientific results not based on actual research.

- Selectively editing reports and creating false uncertainty. Political appointees have selectively deleted evidence from scientific documents, and exaggerated uncertainty in scientific findings.

- Tampering with scientific procedures. Federal agencies have replaced standard scientific procedures with flawed methodologies, biased toward finding predetermined results.

- Intimidating and coercing scientists. High-level administration officials have directly pressured researchers at federal agencies to alter scientific findings, threatening reprisal if they refuse.

- Censoring and suppressing scientists. Federal officials have prevented scientists from communicating with their colleagues, the media, and the public.

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[3] Train, R. 2003. "E.P.-Eh?" Grist Magazine, September 23.
[4] See http://www.ucsusa.org/AtoZ/.
[5] To read the text of the report go to http://www.ucsusa.org/scientific_integrity/restoring/federal-science.html.

- Hiding, suppressing, and delaying release of scientific findings. Federal officials have buried scientific findings and prevented their public release.

- Disregarding legally mandated science. Federal agencies have repeatedly ignored scientific research that by law must form the basis for certain policy decisions.

- Allowing conflicts of interest. Officials with clear conflicts of interest have held key positions throughout the federal government, from which they have made decisions harming the integrity of federal science.

- Corrupting scientific advisory panels. Political interests have manipulated the process for selecting members of independent scientific advisory panels.

Changing the Rules
Beyond the system-wide epidemic of interference, the Bush administration has instituted deeper changes in the structure and policies of the executive branch. Without a strong commitment to scientific integrity from the next president and Congress, these changes may ensure that politicization of science will continue after President Bush leaves office.

- Centralizing decision making and the unitary executive. The Bush administration has invoked the theory of the "unitary executive" to justify tight White House control over federal agencies. For example, President Bush has greatly expanded the use of signing statements. He has used them to assert his right to ignore or disobey any laws or requests he considers unconstitutional, including congressional requests for scientific information and whistle-blower rights for federal employees. Executive order 13422 dramatically expands the role of the Office of Management and Budget (OMB) in reviewing all agency regulations, including the scientific basis for regulations.

- Homogenizing agency decision making. The White House has sought to replace the policies of individual agencies regarding peer review of scientific findings, risk assessment, and cost-benefit analysis with inappropriate government-wide standards, ignoring the reality that each federal agency requires different tools to best fulfill its mission.

- Reducing transparency. The Bush administration has limited government transparency and accountability by preventing public disclosure of information on the internal workings of the federal government. New policies regarding Freedom of Information Act requests and classification of government documents have created a "presumption of secrecy." In this approach, agencies automatically keep information from public view unless someone specifically requests it, or the law requires them to disclose it.

- Adding unnecessary bureaucracy. New demands, including interagency review and excessive legal challenges from industry, have prevented federal agencies from acting promptly to protect public health and safety.

- Retaliating against whistle-blowers. The Bush administration's penchant for secrecy and centralizing executive power has increased the vulnerability of federal employees who blow the whistle on government waste, fraud, or abuse.

- Foxes guarding the henhouse. The revolving door for officials who shuttle between high-level government positions and regulated industries has harmed the integrity of federal science. The legacy of political appointees with conflicts of interest lives on in the agencies after their departure—through both the flawed policies they helped enact and the erosion of public trust in agency integrity.

- Removing science from decision making. Administration officials have often simply shut out scientists and scientific information from the policy discussion.

- Weakening enforcement and monitoring. Many federal agencies have seen their ability to enforce the nation's laws decline under the Bush administration. In many cases, agencies are simply not collecting the data they need to ensure robust enforcement.

Scientist Surveys

To move beyond anecdotes and to gather information about the extent and nature of the interference, UCS has conducted a series of surveys of federal scientists. Previous surveys have given voice to scientists at the Fish and Wildlife Service, the National Ocean and Atmospheric Administration Fisheries, the Food and Drug Administration and climate scientists working in seven federal agencies.[6] The survey of EPA scientists is the fifth in the series.

Collectively 3,400 federal government scientists responded to these five surveys. Several common themes ran through their responses:

- 1301 scientists across nine federal agencies reported that they fear retaliation for openly expressing their concerns about the mission driven work of their agencies.
- 688 scientists from four agencies reported that they were not able to publish work in peer reviewed journals if it did not adhere to agency policies.
- 150 federal climate scientists from seven agencies personally experienced at least one incident of political interference in the past five years.
- And from our most recent report, 889 EPA scientists personally experienced at least one incident of inappropriate interference in their work over the past five years.

Scientists Respond

The scientific community has responded to this growing problem. The more than 15,000 individual scientists, including 52 Nobel Laureates and nearly 200 members of the National Academies, who have called for a restoration of scientific integrity in federal policy making have been joined by several major scientific associations, including the American Association for the Advancement of Science, the American Public Health Association, the American Geophysical Union, and the Ecological Society of America, which have addressed the problem at society wide meetings and have begun to investigate how to defend science.

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[6] More information about the surveys can be found at http://www.ucsusa.org/surveys/.

III. Interference at the EPA

The U.S. Environmental Protection Agency (EPA) has the simple yet profound charge "to protect human health and the environment." EPA scientists apply their expertise to protect the public from air and water pollution, clean up hazardous waste, and study emerging threats such as global warming. Because each year brings new and potentially toxic chemicals into our homes and workplaces, because air pollution still threatens our public health, and because environmental challenges are becoming more complex and global, a strong and capable EPA is more important than ever.

Yet challenges from industry lobbyists and some political leaders to the agency's decisions have too often led to the suppression and distortion of the scientific findings underlying those decisions—to the detriment of both science and the health of our nation. While every regulatory agency must balance scientific findings with other considerations, policy makers need access to the highest-quality scientific information to make fully informed decisions.

Concern over this problem led the Union of Concerned Scientists (UCS) to investigate political interference in science at the EPA. In the summer of 2007, UCS, working with the Center for Survey Statistics and Methodology at Iowa State University, distributed a 44-question survey to nearly 5,500 EPA scientists, asking for information about political interference in their scientific work, the use of science in EPA decision making, barriers to communication, employee morale, and the agency's effectiveness. UCS identified these scientists through EPA websites, consultations with current and former employees, and targeted Internet searches.

We received completed surveys from 1,586 scientists, for a response rate of 29 percent. These respondents represented every scientific program office at EPA headquarters, all 10 regional offices, and more than a dozen research laboratories across the country. Most respondents were agency veterans, with more than a decade of experience at the EPA. Beyond specific survey questions, more than 850 scientists also provided written comments in response to an open-ended essay question. To add to this information, UCS interviewed dozens of current and former EPA scientists.

The results of these investigations show an agency under siege from political pressures. On numerous issues—ranging from mercury pollution to groundwater contamination to climate change—political appointees of the George W. Bush administration have edited scientific documents, manipulated scientific assessments, and generally sought to undermine the science behind dozens of EPA regulations.

These findings highlight the need for strong reforms to protect EPA scientists, make agency decision making more transparent, and reduce politicization of the regulatory process.

Political Interference in Scientific Work
Large numbers of EPA scientists reported widespread and inappropriate interference by EPA political appointees, the White House, and other federal agencies in their scientific work:

- 889 scientists (60 percent of respondents[7]) personally experienced at least one incident of political interference during the past five years.

- Among EPA veterans (scientists with more than 10 years experience at the agency), 409 (43 percent) said interference occurred more often in the past five years than in the previous five-year period.

EPA scientists also reported personally experiencing specific forms of political interference, from the explicit to the subtle:

- 94 scientists (7 percent) had frequently or occasionally been "directed to inappropriately exclude or alter technical information from an EPA scientific document."

- 191 scientists (16 percent) had personally experienced frequent or occasional "situations in which scientists have actively objected to, resigned from, or removed themselves from a project because of pressure to change scientific findings."

- 232 scientists (18 percent) had personally experienced frequent or occasional "changes or edits during review that change the meaning of scientific findings."

- 285 scientists (22 percent) had personally experienced frequent or occasional "selective or incomplete use of data to justify a specific regulatory outcome."

- 153 scientists (13 percent) had personally experienced frequent or occasional "pressure to ignore impacts of a regulation on sensitive populations."

- 299 scientists (24 percent) had personally experienced frequent or occasional "disappearance or unusual delay in the release of websites, press releases, reports, or other science-based materials."

- 394 scientists (31 percent) had personally experienced frequent or occasional "statements by EPA officials that misrepresent scientists' findings."

Respondents indicated that political interference arose from both internal and external sources:

- 516 scientists (43 percent) knew of "many or some" cases where EPA political appointees had inappropriately involved themselves in scientific decisions.

- 560 scientists (49 percent) knew of "many or some" cases where political appointees at other federal agencies had inappropriately involved themselves in decisions.

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[7] Unless otherwise stated, percentages reflect the share of respondents who answered a specific question.

- 507 scientists (42 percent) knew of "many or some" cases where "commercial interests have inappropriately induced the reversal or withdrawal of EPA scientific conclusions or decisions through political intervention."

- 329 scientists (28 percent) knew of such interference by "nongovernmental or advocacy groups."

In essay responses, nearly 100 scientists identified the White House Office of Management and Budget (OMB), which oversees the federal budget and coordinates all federal regulations, as the primary source of external interference.

Respondents reported widespread respect for their direct supervisors, but had fewer commendations for EPA's senior leaders:

- 1,282 scientists (81 percent) respected the integrity and professionalism of their direct manager or supervisor, while 686 (43 percent) said the same about EPA's senior leaders.

- A majority of respondents (906 scientists, or 59 percent) agreed that their direct supervisor stands behind scientific staff who express politically controversial opinions.

Rates of political interference varied widely among offices and divisions within the agency:

- The percentage of scientists reporting interference was highest in the program offices with regulatory duties, and at EPA headquarters. A total of 337 scientists in the program offices (68 percent), and 379 scientists at headquarters (69 percent), reported at least one incident of interference in the past five years.

- The percentage of scientists reporting interference was lower—although still significant—in the Office of Research and Development (ORD), the EPA's main research arm. The ORD's National Health and Environmental Effects Research Laboratory was notably freer of interference (39 percent) than any other EPA division, while its National Center for Environmental Assessment had the highest percentage of scientists reporting interference of all EPA divisions (84 percent).

- The percentages of scientists reporting interference in the 10 regional offices varied widely, from 44 percent (region 6) to 73 percent (region 9).

To place these results in context, we cite specific incidents of interference. For example, political appointees at the White House and in top positions at the EPA manipulated scientific findings and analyses regarding mercury pollution and climate change. These incidents involved pressure to change scientific methods and findings, direct editing of scientific documents by nonscientists, and delayed release of scientific reports.

A third case—involving interagency review of the EPA's assessment of toxic chemicals—illustrates the growing ability of the OMB and other federal agencies to review and second-guess the work of the EPA's scientific experts.

Barriers to the Free Communication of Science

The free communication of scientific results is a critical part of the scientific process. Despite statements by EPA leaders asserting that the agency supports scientific openness, many scientists report that it restricts free communication of the results of taxpayer-funded research:

- 783 scientists (51 percent) disagreed or strongly disagreed that EPA policies allow scientists to "speak freely to the news media about their findings." Another 556 scientists (36 percent) had no opinion or were unsure. Only 197 scientists (13 percent) agreed that the EPA allows scientists to communicate freely with the media.

- 291 scientists (24 percent) disagreed or strongly disagreed that they are "allowed to publish work in peer-reviewed scientific journals regardless of whether it adheres to agency policies or positions."

Beyond these restrictive policies, hundreds of scientists said they fear retaliation for speaking candidly about the EPA's work. More scientists feared retaliation for speaking candidly inside the agency than outside it:

- 492 scientists (31 percent) disagreed or strongly disagreed that they could openly express concerns about the EPA's work *inside* the agency without fear of retaliation.

- 382 scientists (24 percent) disagreed or strongly disagreed that they could openly express concerns about the EPA's work *outside* the agency without fear of retaliation.

Interviews with current and former EPA scientists revealed new examples of problems in communicating scientific research. In two cases, EPA scientists were barred from presenting research on climate change at scientific conferences. Other scientists reported difficulties speaking with the media and obtaining EPA clearance to publish their findings in scientific journals.

Political interference in scientific work combined with barriers to the free communication of scientific findings affect the amount and quality of information the U.S. public receives.

Undermining the Role of Science in EPA Decision Making

Scientific information is the lifeblood of much of the EPA's work and the credibility of its decisions depends on the quality of its scientific work. A plurality of EPA scientists reported that the agency's regulatory policies are consistent with its scientific findings. However, a similar number felt that the EPA could do a better job of using the best judgment of its scientific staff:

- 745 scientists (48 percent) felt that the EPA's determinations and actions are frequently or always consistent with the scientific findings in agency documents and reports.

- 719 scientists (47 percent) felt that the EPA's determinations occasionally, seldom, or never make use of the best judgment of its scientific staff.

Hundreds of EPA scientists also felt that the agency only occasionally incorporates expert advice from advisory committees into policy decisions:

- 553 (36 percent) scientists felt that the agency occasionally, seldom, or never heeds advice from independent scientific advisory committees.

Recent changes in the EPA's process for setting the National Ambient Air Quality Standards provide one prominent example of how political considerations have trumped scientific expertise and sidelined EPA's scientific advisory committees.

Challenges to Agency Effectiveness

Beyond political interference in EPA science, several survey questions asked respondents about other factors that could impair their ability to do their jobs, and the ability of the agency as a whole to fulfill its mission. Large numbers of EPA scientists indicated that a lack of sufficient or appropriate resources was a serious issue in their office or division:

- 969 scientists (62 percent) disagreed or strongly disagreed that the "EPA division where I work has sufficient resources to adequately perform its mission of protecting human health and the environment."

- 555 scientists (36 percent) agreed or strongly agreed that the "recent changes and closures in the EPA library system have impaired my ability to do my job." This opinion was especially prevalent among scientists in regions 5, 6, and 7, which had their libraries closed (86 of these scientists, or 48 percent, agreed).

- 574 scientists (41 percent) agreed or strongly agreed that "the trend toward contracting out scientific work is harming the effectiveness of my division."

Survey questions also asked scientists about their job satisfaction, and the morale in their division:

- Respondents were twice as likely to report a decrease in job satisfaction over the past five years as to report an increase (670 versus 328 scientists).

- Opinions about workforce morale ranged widely. A total of 564 scientists (37 percent) said morale was fair, and 387 (25 percent) said morale was poor or extremely poor. A total of 570 scientists (37 percent) said morale was good or excellent.

Questions about the overall effectiveness of the EPA elicited a range of responses:

- Respondents were more likely to agree than disagree that the EPA was acting effectively to clean up environmental problems. A total of 812 scientists (52 percent) agreed that the

EPA acts effectively to "clean up and/or mitigate existing pollution or environmental problems," while 522 (33 percent) disagreed.

- 694 scientists (44 percent) agreed that the EPA acts effectively to "foster practices that prevent environmental degradation or adverse health effects before they occur," while 629 scientists (40 percent) disagreed.

- Respondents were twice as likely to report a decrease in the effectiveness of their office or division (696 scientists, or 45 percent) as an increase (321 scientists, or 21 percent) over the past five years.

- Respondents were evenly split on whether the EPA is moving in the right direction. A total of 685 scientists (44 percent) disagreed that EPA is moving in the right direction, while 624 scientists (40 percent) agreed.

IV. Solutions and Reforms

The results of our survey and interviews with EPA scientists show widespread problems at the agency. Hundreds of scientists report direct and indirect interference with their scientific work by political appointees at the EPA and the White House. Despite claims to the contrary from EPA leaders, scientists also report institutional barriers to freely communicating their findings through both the media and scientific publications. EPA scientists are not confident that environmental decision makers respect their expertise. And the agency's effectiveness needs to improve on several fronts.

Wide-ranging political interference in EPA science requires a suite of reforms in five major arenas: protecting EPA scientists, improving the agency's transparency, reforming its regulatory framework, strengthening its system of scientific advice, and depoliticizing funding, monitoring, and enforcement. These efforts to revitalize the EPA and allowing it to fulfill its mission of protecting human health and the environment will require strong leadership from Congress, the next president, and the next EPA administrator, joined by EPA scientists and the broader scientific community.

Protecting EPA Scientists

To fulfill their profound responsibility to the public, EPA scientists need assurance that standing behind their scientific work will not open them to either official or unofficial retaliation. Congress is now considering several bills that would strengthen the federal whistle-blower system:

- Both houses of Congress have passed legislation that would enhance protections for whistle-blowers under the Whistleblower Protection Act of 1989, and members are now working to reconcile the two versions. The House version, HR 985, includes specific protections from retaliation for scientists, who expose efforts to distort or suppress federal research. The Senate bill, S. 274, unfortunately, lacks these protections for scientists. It is crucial that these protections are part of the final law now being

negotiated by the Senate Homeland Security and Governmental Affairs and the House Oversight and Government Reform Committees.

- Members of the House and Senate have introduced bills to reauthorize the Office of Special Council and the Merit Systems Protection Board—federal entities that investigate claims of reprisal against federal whistleblowers and adjudicate whistleblower claims, respectively. Although the legislation includes many important reforms, the Senate has taken no action, and the House bill is still in committee.

- The House has recently passed legislation to grant greater autonomy to inspectors general (IGs), and immunity from coercion by the agencies they police. The Senate has reported such legislation out of committee. Both versions contain an important requirement that IG websites enable employees to anonymously report waste, fraud, and abuse. Government scientists could use this mechanism to confidentially challenge scientific misconduct. Both versions of such legislation also give IGs subpoena power.

Congress should pass the strongest-possible whistle-blower protections, and the president should sign them into law. The next EPA administrator should also work with the coalition of EPA unions to integrate the agency's Principles of Scientific Integrity (EPA 1999) into the official employee grievance procedure.

Making the EPA More Transparent

Some aspects of EPA decision making are open to public scrutiny, but many "predecisional" meetings and discussions are not. The integrity of EPA science is threatened in no small part by decisions made behind closed doors. Opening up these processes to congressional and public scrutiny is an important way to reveal and end abuses of science. The EPA should also better explain how it arrives at decisions that affect health and the environment.

The agency should institute a transparency policy for all meetings attended by non-EPA personnel. Such a policy need not be burdensome to EPA employees: outside participants could enter the required information directly into a database before any meeting, or within a specified time period after a meeting.

- This policy should require the EPA to post all meetings with outside entities on its website, including those with for-profit and not-for-profit organizations, and representatives of other agencies.

- The database should include the names and affiliations of attendees as well as the date, time, location, and subject of each meeting, with an exception granted for cases of national security.

Official EPA reports and documents in draft form are exempt from release under the Freedom of Information Act. Abuse of this exemption—wherein documents remain in draft form indefinitely—does occur.

- To prevent abuse of the "predecisional" exemption, the next EPA administrator should adopt procedures that allow the periodic release of documents that have remained in draft form for a given length of time.

The EPA should also publish a summary statement discussing the scientific basis for any significant policy, guidance, or regulation informed by science. This statement should be available in a timely fashion, and should include:

- The scientific rationale for a decision, and all scientific documents and data used to make it (including reasonable release of information from industry)
- A minority report voicing any significant dissenting scientific evidence or opinions
- An explanation of how the agency resolved such differences of opinion
- Identification by name of each official and employee who participated in the decision.

The Food and Drug Administration Amendments Act of 2007 already incorporates such transparency requirements, and the EPA could adapt them.

Reforming Media Policy

Both science and democracy thrive in an open environment. The EPA should clarify its policies on the interaction between scientists and the media, to ensure that the public has access to taxpayer-funded information that affects their health and safety, and to ensure that scientists and other employees can exercise their rights to free speech:

- Any EPA media policy must respect at least two fundamental rights: (1) scientists have the right to speak freely about any topic (including EPA policy) if they clarify that they are speaking as private citizens, not as agency representatives; and (2) scientists should have the right to review and correct any official document (such as a press release or report) that cites or references their scientific work, to ensure that accuracy has been maintained after the clearance and editing process.
- Congress or the EPA may need to impose narrow restrictions on these basic rights in certain instances, such as in cases under litigation. Officials should clearly define these situations.
- However, because the EPA is also a scientific agency, it should also exceed these basic rights by creating a public affairs system that actively disseminates agency research and codifies the positive rights of EPA scientists.
- The next EPA administrator should review the written policies of all offices and regions on the interaction between agency scientists and the media. Policies that do not explicitly protect scientists' fundamental right to freely communicate their scientific findings should be rewritten, and offices and regions without explicit policies should create them.

- The EPA should hold training sessions to clearly explain employees' rights in communicating their research to the media and the public, and the resources available to them to do so.

Reforming Publication Policy

Peer review is a pillar of the scientific method; political review is not. The EPA's process for clearing information for outside publication sometimes becomes a de facto policy review, and delays publication of controversial papers despite disclaimers that the views are personal.

- The next EPA administrator should review the agency's clearance policies, and work with the agency's offices and divisions to streamline excessive review.

- A disclaimer on a published paper that it is not official agency policy should exempt it from a full policy review.

- The clearance process should set reasonable yet strict time limits on how long the agency can delay publication of a paper. If officials do not reach a decision within that time frame, the paper should automatically proceed to publication with a written disclaimer. If officials deny clearance, they should provide a written explanation to the authors.

- The process for reviewing and clearing papers for outside publication must be transparent, and thus posted on the website of each EPA office and division.

Reforming the Regulatory Process

While the White House oversees federal agencies, it must strike a balance between administration priorities and agency independence. The EPA was created to implement and enforce the nation's environmental laws, and it has developed the expertise, experience, processes, and policies to fulfill those critical duties. The regulatory process should respect the agency's reservoir of scientific and technical knowledge. Congress should also consider ways to strengthen our nation's environmental regulatory system, to fortify the EPA's scientific mission and meet the pressing challenges of the twenty-first century.

Ensuring Agency Independence

The EPA is the nation's first line of defense against threats to public health and the environment. As such, the EPA should be empowered to take the lead on environmental concerns and to push back against interference in its science and decisions by the OMB and other federal agencies. To accomplish this:

- The next president should elevate the EPA to a cabinet-level agency, or establish a Department of the Environment.

- The next president should reverse executive order 13422, removing the power of presidential appointees unaccountable to Congress to commence rulemaking, and returning that power to the EPA and its administrator.

The OMB and its Office of Information and Regulatory Affairs play important roles in coordinating and overseeing the regulatory process. However, those roles should not include second-guessing or editing the science underlying EPA decisions:

- The next president should establish a regulatory process that respects the scientific and technical expertise of the EPA, and that excludes the OMB from interfering in EPA's scientific and technical determinations.

- The next president should repeal the OMB's one-size-fits-all directives on peer review and risk assessment. The EPA should have the flexibility to choose the form of peer review best suited to its needs.

- In particular, EPA experts should prepare risk assessments and the scientific component of regulatory impact assessments without interference from the OMB.

Enacting Legislative Reforms

The dozen or so environmental laws noted in Chapter 2 have led to dramatic improvements in public health and environmental quality. Yet the challenges the nation faces today are very different from those of 30 years ago. Congress should assess the adequacy of our current environmental regulatory structure, and consider reforms to close loopholes and strengthen the EPA's ability to address pressing threats to human health and the environment. (See CPR 2007 for possible recommendations.)

To support the quality of the EPA's scientific work, these reforms should focus on ensuring that the agency has the regulatory tools it needs to collect critical environmental data. Such tools could include stronger scientific testing requirements for pesticides and chemicals used in commerce, expanded TRI reporting requirements, and the authority to broaden environmental monitoring networks where necessary.

Congress should also consider new legislation that gives the EPA a framework to address emerging challenges such as climate change, nanotechnology, and endocrine-disrupting chemicals. Environmental justice should be a guiding principle in these efforts, to ensure that the costs of pollution and the benefits of environmental protection are shared equitably among all parts of society.

Ensuring Robust Scientific Input to EPA Decision Making

The EPA should review and strengthen the ways it uses the scientific expertise of its staff and advisory committees, especially in cases where scientific input is critical or the law requires it. The agency should also tighten its conflict-of-interest restrictions.

Disclosing and Mitigating Conflicts of Interest

The next EPA administrator should work with employees, industry, and the scientific community to develop comprehensive conflict-of-interest policies for both staff and members of advisory committees:

- Government employees and members of advisory committees who are involved in regulation should disclose all conflicts of interest and special interests that might affect their ability to do their job in an unbiased manner.

- Individuals with a significant conflict of interest may still contribute to a project as invited experts, but the EPA should restrict them from decision-making authority or otherwise influencing policy outcomes.

Conflict-of-interest policies should also prohibit the revolving-door practice of appointing individuals from industry as senior EPA officials who regulate those industries:

- The next administration should provide clear guidelines for minimizing the appointment of senior officials with conflicts of interest. At a minimum, federal employees should be required to recuse themselves from decisions involving former employers (RDWG 2005).

Reforming Advisory Committees

The EPA should pursue reforms to make better use of its independent advisory committees. Specifically, the next EPA administrator should work with the Clean Air Scientific Advisory Committee to improve the process for setting the National Ambient Air Quality Standards, to ensure that decision makers have access to the "best available science."

Depoliticizing Funding, Monitoring, and Enforcement
These actions are essential to restore the scientific integrity of EPA decision making. But, in addition, problems with funding, monitoring and enforcement—which relate to EPA's scientific integrity—also need to be addressed by Congress and the next President to ensure that the EPA is the robust environmental agency that our country needs. In particular, Congress should provide the EPA with resources commensurate with its growing responsibilities and should work to ensure that selective internal budget cuts are not used to punish inconvenient programs or offices. The next president should commit to strong and consistent enforcement of the nation's environmental laws.

V. Concluding Thoughts

The EPA's scientific enterprise is our nation's first line of defense against threats to public health and the environment. These threats are growing more complex and global, with the potential to harm the nation's health and prosperity. Despite notable successes, air and water pollution remain serious public health problems. Each year brings new and untested chemicals into our homes, schools, and workplaces. Climate change alone is projected to have profound impacts on public health, agriculture, the economy, and even national security.

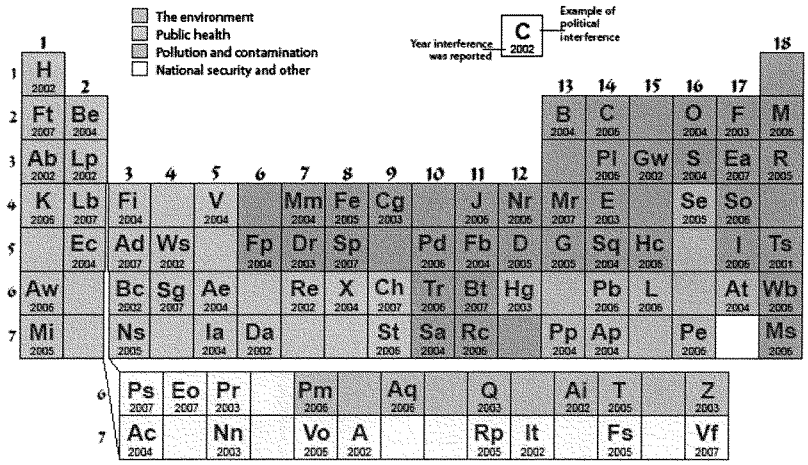
These problems are not insurmountable. The environmental and public health successes of the past several decades show that the country can rise to the challenge of environmental threats—but only if the EPA has the proper tools. Given the complexity of today's environmental challenges, a credible scientific knowledge base is essential to an effective response. To foster and sustain a healthy scientific enterprise, Congress and the next president should take concrete steps to protect EPA's scientists, make the agency more transparent, reform the regulatory process, strengthen the scientific advisory system, and depoliticize funding, monitoring, and enforcement.

Science is not the only element of effective policy making. However, because science enjoys widespread respect, appointed officials will always be tempted to manipulate or suppress scientific findings to support predetermined policies. Such manipulation is not only dishonest; it undermines the EPA's credibility and affects the health and safety of Americans.

The Bush administration's direct abuse of science—combined with systemic changes to the regulatory system that threaten the integrity of EPA science—highlight the need for strong action by the next president and Congress to restore scientific integrity to the agency's decision making. Only then can the EPA fully mobilize to serve the public good and ensure the nation's health.

A. The A to Z Guide to Political Interference in Science

In recent years, scientists who work for and advise the federal government have seen their work manipulated, suppressed, distorted, while agencies have systematically limited public and policy maker access to critical scientific information. To document this abuse, the Union of Concerned Scientists has created the A to Z Guide to Political Interference in Science. To read the full A to Z Guide visit http://www.ucsusa.org/AtoZ/.



From air pollution to Ground Zero, the *A to Z Guide* showcases dozens of examples of the misuse of science on issues like childhood lead poisoning, toxic mercury contamination, global warming, and endangered species. These 85 examples originate in 24 federal agencies and departments.

Timeline of abuses of science

April 2008	Integrity of EPA's toxics database threatened by interagency review
December 2007	All-terrain vehicle danger report
October 2007	NASA pilot survey
	Censoring climate change health hazards
August 2007	Mountain removal mining
July 2007	Surgeon general muzzled
	FEMA trailers
May 2007	Southwestern bald eagle
	Spotted owl
April 2007	Voter fraud
March 2007	Polar bear travel restrictions
February 2007	Lead testing of children's lunchboxes
January 2007	Executive Order 13422

December 2006	Lead national ambient air quality standards
October 2006	Prairie dogs
	Roundtail chub
	Tabernaemontana rotensis
August 2006	EPA closes its scientific libraries
	EPA ignores scientific studies on pesticides
July 2006	Education Department suppresses study on school vouchers
	NASA mission statement
June 2006	Changes in climate change websites
May 2006	STD Panel at CDC conference manipulated,
	Science disregarded for prescription drug Ketek
April 2006	National ambient air quality standards process changes
	Muzzled scientists at carbon conference
	Global warming news releases
	Minders on climate media interviews
February 2006	Navy downplays sonar impact on marine life
	Science suppressed on hurricane/global warming connection
	Bureau of Land Management suspends forest study funding
	EPA distorts evidence for tightening particulate matter standard
January 2006	NASA censors climate scientist James Hansen
November 2005	Economic analysis distorted for endangered red frog habitat
October 2005	EPA limits information about their release of toxic chemicals
August 2005	Department of Justice suppresses racial profiling study
July 2005	EPA report on fuel efficiency withheld
	Top FDA official overrules staff to approve nerve stimulator
June 2005	Bureau of Land Management altered a cattle grazing impact study
	Distortion and censorship of global warming documents
May 2005	Genetics eliminated from Endangered Species Act decisions
April 2005	World Health Organization approval of abortion pill block attempt
March 2005	New selenium pollution control standards misrepresent science
February 2005	First UCS surveys of federal agencies scientists released
December 2004	Endangered Species Act scientific documents altered for greater sage grouse
	Federally funded abstinence-only curriculum contains false science
November 2004	FDA ignores scientists' warnings on arthritis drug Vioxx
October 2004	EPA promotes flawed study on hydraulic fracturing, an oil drilling technique
September 2004	Endangered Species Act science ignored for the marbled murrelet
August 2004	Science obscured on health impacts of weedkiller Atrazine
	Forest Service exaggerates wildfire threat to spotted owl to promote logging
June 2004	Health Organization panel experts are vetted by Health and Human Services
May 2004	EPA uses bad science to create plywood plant pollution rule
	FDA appointees distort science to deny access to emergency contraception
	Research at the U.S. Fish and Wildlife Service is distorted
April 2004	EPA distorts guidelines for monitoring air pollution over national parks
	CDC researchers kept from international AIDS conference
	Fish and Wildlife Service distorted economic analysis of bull trout habitat
	NIH advisory board rejects scientists subjected to political litmus tests
March 2004	Science-based recommendations removed from an official report on salmon
	Scientists dismissed from President's Council on Bioethics
	Carbon sequestration pamphlet
February 2004	Arms Control Advisory Panel dismissed and never reappointed.
January 2004	Multiple agencies disregard science on mountaintop removal mining

December 2003	Office of Management and Budget adopts flawed peer review rule
	Administration officials manipulate Endangered Species Act science
August 2003	White House orders misleading of public on Manhattan air quality after 9/11
July 2003	National Nuclear Security Administration Panel dismissed
	EPA withheld an analysis of alternatives to President Bush's Clear Skies Act
June 2003	Administration officials undermined science behind climate change
March 2003	Forest Service overruled science-based old-growth forest management plan
February 2003	White House suppressed information on impact of mercury on public health
December 2002	Obscured scientific evaluation of abstinence-only education programs
	CDC ordered to change website about the effectiveness of condoms
	NIH Drug Abuse Advisory Panel subject to political litmus tests
	Abortion and breast cancer linked on National Cancer Institute website
	Microbiologist prohibited from publishing on airborne bacteria
November 2002	Workplace Safety Panel scientists rejected because of their beliefs
October 2002	Childhood lead poisoning panelists replaced by scientists with industry funding
	Underqualified doctor nominated to chair FDA reproductive health committee
September 2002	Administration disregarded scientific analysis of aluminum tubes in Iraq
	Engineer rejected from Army Science Board because of political contributions
May 2002	Manipulation of global warming science
August 2001	Fish and Wildlife Service misrepresented information on rare trumpeter swans

B. Selected Quotes from EPA Scientists Arranged by Topic

The following are selected quotes from EPA scientists who responded to a survey by the Union of Concerned Scientists. For more information about the survey, including the text of all essay responses, please visit http://www.ucsusa.org/EPAscience. The quotes are organized by topic.

When asked how to improve scientific integrity at the EPA, scientists said:

Political interference

There are still good scientists producing good science at USEPA. The main problem I see is an administration that considers science only if it supports its agenda. As in other areas, science is used only if it furthers preexisting policy; otherwise it is ignored, marginalized or suppressed (e.g. climate change).
-A scientist from the EPA regional offices

EPA needs dynamic, scientific leadership interested in the well being of the environment and public health. EPA should not be the political agency it has become, the right hand of industry and short economic gain.
-A scientist from the Office of Solid Waste and Emergency Response

Do not trust the Environmental Protection Agency to protect your environment. Ask questions. Be aware of political and economic motives. Become politically active. Elect officials with motives to protect the environment and hold them accountable.
-A scientist from the EPA regional offices

Political considerations should not trump environmental stewardship, and the EPA should not be forced to be silent on the environmental consequences of policy shifts.
-A scientist from the EPA regional offices

Do not allow other entities such as [the White House Office of Management and Budget] to interfere with, or suppress the publication of, EPA's scientific work products. Maintain an open peer review process.... Strengthen whistleblower protections for civil servants.
-A scientist from the EPA regional offices

EPA needs to be an independent agency and the amount of political interference needs to be curtailed.
-A scientist from the EPA regional offices

Keep political appointees from interfering in scientific decisions or publications. Do not allow political appointees to pressure authors to withdraw from publication or pressure their supervisors to carry out actions that inhibit publication.
-A scientist from the EPA regional offices

Funding and Staffing

MORE FUNDING! We do NOT have the resources to meet our mission. My division has seen its resources - in purchasing power- cut over 50% since 10 years ago.
-A scientist from the Office of Research and Development

EPA was created and began recruiting scientists in the 1970s; many have retired or will shortly do so. The inability to fill technical vacancies along with the loss of EPA libraries are bleeding down the EPA's technical knowledge base and our ability to provide or share the skills and knowledge that are critical to overall mission success.
-A scientist from the EPA regional offices

Increase the morale of the employees by providing incentives for growth. New hires, at least among scientists in my area are few and far between (no hires in almost 10 years) and the shrinking and aging employee population is more looking forward to retirement than providing ideas that work and will make a difference, because nobody seems to really listen.
-A scientist from the Office of Prevention, Pesticides, and Toxic Substances

External Interference

[The White House Office of Management and Budget] and the White House have, in some cases, compromised the integrity of EPA rules and policies; their influence, largely hidden from the public and driven by industry lobbying, has decreased the stringency of proposed regulations for non-scientific, political reasons. Because the real reasons can't be stated, the regulations contain a scientific rationale with little or no merit.
-A scientist from the EPA regional offices

Currently, [the White House Office of Management and Budget] is allowed to force or make changes as they want, and [EPA actions] are held hostage until this happens.
OMB's power needs to be checked as time after time they weaken rulemakings and policy decisions to favor industry.
-A scientist from the Office of Air and Radiation

External scientific advisory processes associated with risk assessment should not incorporate industrial perspectives. In other words, "risk management" should be recognized as a human values problem, and should be more explicitly separated from risk assessment.
-A scientist from the EPA regional offices

Openness

Remove the political screening step in science at the Agency. For example, we are not allowed to talk to the press when they call but must refer them to a person in the front office. Often this results in the press not getting the true facts but only those that don't make the Agency look bad.
- A scientist from the Office of Prevention, Pesticides and Toxic Substances

The premise should be that all documents (except enforcement related stuff) start out as public documents unless EPA has jumped through a lot of legal hoops to be able retain them.
-A scientist from the EPA regional offices

The science and risks and benefits need to be honestly and fairly considered. The decisions that are made should be justified and be transparent as to why a decision was made and the risks and benefits be clearly and honestly presented.
-A scientist from the Office of Prevention, Pesticides, and Toxic Substances

I perceive that there is a gag rule that prevents government employees from being allowed to tell the public what they have learned on the job, as well as their job-informed and educated opinions. This work, and knowledge gained during that work, is paid for by the taxpayers.
-A scientist from the Office of Air and Radiation

Scientific Review

Do not allow political appointees into the process of scientific review. Their job is to make management decisions, not influence the data and information before it is collected and presented.
-A scientist from the EPA regional offices

Improve the peer review process by not making it so cumbersome and by allowing those with real experience to participate.
-A scientist from the Office of Solid Waste and Emergency Response

One of the best current safeguards is review of Agency documents and policies by independent advisory boards including the Science Advisory Board, the Clean Air Scientific Advisory Committee, and the Board of Scientific Counselors. Much EPA work in human health risk assessment is now subjected to Inter-Agency Review by other Federal entities which appear to be more closely aligned with private interests than with the public health community.... Maybe more Congressional oversight would help the Executive Branch straighten its priorities.
-A scientist from the Office of Research and Development

Organizational Improvements

I have never seen morale at a lower point than we currently have in EPA. Good scientists are leaving because they can no longer put up with all the micro-management that is heaped on them in lieu of effective administrative leadership.
-A scientist from the Office of Research and Development

Reduce the power of [the White House Office of Management and Budget] over EPA scientific products. All communications between EPA and OMB during the development of Agency technical products and actions should be preserved for the public record.... In particular, implementation of OMB's risk assessment guidelines would be disastrous.
-A scientist from the Office of Air and Radiation

Make sure that there is no way that you can change the science to accommodate a political "need." Currently I think EPA's credibility is in the tank due almost entirely to trying to make the science fit a political need rather than openly admitting that both paradigms exist and then deal with the realities of both politics and science to make the decision.
-A scientist from the EPA regional offices

This is a young and small agency that has, since its inception, been under enormous pressures. The ability to protect the environment is often also bound by the laws that govern the agency. So, the best way to improve the scientific work at EPA is to ensure that appropriate governing laws are enacted so that with reasonable interpretation the goals of protecting the environment may be met.
-A scientist from the Office of Prevention, Pesticides, and Toxic Substances

EPA is by mandate a regulatory agency charged with protecting human health and the environment. To restore the integrity of scientific work at EPA, political appointees must be removed from all levels within the Agency. Those appointees influence ranges from subtle to direct manipulation of statutory/regulatory actions. Further, the influence of other agencies, particularly [the White House Office of Management and Budget] significantly affects the actions of specific individual program offices, which amounts to direct oversight of almost everything EPA does. These influences are not limited to manipulation of the results of basic scientific work, but from everything from how vigorously the Agency pursues oversight, weakening guidance and enforcement of statutes/regulations that are detrimental to human health and the environment.
-A scientist from the EPA regional offices

Respect for Science

My opinion of EPA has changed since being here. Specifically, I had believed EPA was more scientific in its approach. Now I realize that EPA has politically driven agendas that sometimes, not always, affects decisions of scientific nature.
-A scientist from the EPA regional offices

Science and technical information needs to be given more weight in decision-making rather than just seen as background information.
-A scientist from the EPA regional offices

Managers need to learn to trust the expertise of the technical staff.
- A scientist from the Office of Water

Take the politics out of science. Senior EPA leaders and White House officials over the past 6 years have used "junk" science along with biased opinions to make bad environmental decisions. EPA needs to be fully funded to perform its mission.
-A scientist from EPA headquarters

[The integrity of EPA science could best be improved] by allowing scientists with internationally acknowledged expertise to work and publish in their fields, instead of withholding support and restricting activity.
-A scientist from the Office of Air and Radiation

[The integrity of EPA science could best be improved] by staying true to the pollution laws that congress gives us (which means much more frequent revision to reflect the latest science), by leaving less discretion to the executive branch, and by giving the scientific advisory boards more weight to make decisions.
-A scientist from the EPA regional offices

Allow the science to drive policy rather than the other way around.
-A scientist from the Office of Research and Development

Other

Strong, independent oversight and protection of "whistleblowers" (real protection - not what is there now) could stem the most damaging practices.
-A scientist from the Office of Research and Development

As a user rather than producer of technical and scientific information, I find it very frustrating that I have to search out myself research findings and recommendations [of various advisory bodies] that directly affect the management of my programs. By the time the reports filter down to the staff program levels, they have either mutated beyond recognition during intervening manager reviews, or have simply been lost in the fog of the bureaucracy.
-A scientist from the EPA regional offices

1) Improve transparency in government by requiring comments from [the White House Office of Management and Budget] and other agencies on science documents to be made public
2) ensure science decisions on conclusions contained in EPA science documents are made by EPA career scientists
3) require political appointees to post summary of discussion (including any documents provided) and attendees when they meet with external stakeholders
4) encourage accountability in EPA political appointees through Congressional inquiry regarding basis for decisions and role of science versus political considerations in decision making
-A scientist from the Office of Research and Development

"[Restore] the Agency's public role as a faithful advocate for and protector of the environment, as opposed to publicly downplaying the need for action in so many instances. Such a stance would communicate from the top that we are all about scientific excellence because, at heart, we sincerely care about environmental protection."
-A scientist from the Office of Research & Development

C. Scientific Freedom and the Public Good

On February 14, 2008, a group of prominent scientists called on the U.S. government to establish conditions that would enable federal scientists to produce the scientific knowledge that is needed by a government dedicated to the public good.[8] *In an accompanying report,* Federal Science and the Public Good,[9] *UCS details specific steps that Congress and the administration can take to restore scientific integrity to federal policy making.*

Scientific knowledge and its successful applications have played a large role in making the United States of America a powerful nation and its citizens increasingly prosperous and healthy. The challenges that face the United States in the twenty-first century can only be met if this tradition is honored and sustained.

To that end, the U.S. government must adhere to high standards of scientific integrity in forming and implementing its policies. Breaches of this principle have damaged the public good and the international leadership of the United States. To meet its obligation to serve the public interest, the government must have reliable scientific work and advice at its disposal, and provide the public with reliable scientific information. This requires the government to provide federal scientists with the resources and the professional environment necessary to carry out their missions effectively and honestly. The government should also draw on the knowledge of federal scientists and of the larger scientific community to formulate public policy in an objective and transparent manner.

Scientists employed by government institutions commit themselves to serve the public good free from undisclosed conflicts of interest and to carry out science that is reliable and useful, while respecting statutory limitations such as national security laws. Therefore, government scientists should, without fear of reprisal or retaliation, have the freedom:

- to conduct their work without political or private-sector interference;
- to candidly communicate their findings to Congress, the public, and their scientific peers;
- to publish their work and to participate fully in the scientific community;
- to disclose misrepresentation, censorship, and other abuses of science; and
- to have their technical work evaluated by scientific peers.

We call on Congress and the executive branch to codify these freedoms, to establish stronger means for gathering scientific advice, and to take concrete steps to enhance transparency, so as to create conditions conducive to a thriving scientific enterprise that will serve our democracy with integrity and bring the full fruits of science to all Americans and to the world.

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[8] For more information and to see the names of the endorsers go to http://www.ucsusa.org/scientific_integrity/restoring/scientificfreedom.html.

[9] To read the text of the report go to http://www.ucsusa.org/scientific_integrity/restoring/federal-science.html.

D. Previous UCS Surveys of Federal Agency Scientists

Previous UCS surveys have given voice to over 1,800 scientists across the federal government. Full results for these surveys can be found at http://www.ucsusa.org/surveys/. The survey findings include the following:

U.S. Fish and Wildlife Service (FWS)
In February 2005, the Union of Concerned Scientists (UCS) and Public Employees for Environmental Responsibility (PEER) released the results from a 42-question survey distributed to 1,410 FWS biologists, ecologists, botanists and other science professionals working in Ecological Services field offices across the country. The survey was designed to obtain their perceptions of scientific integrity within the FWS, as well as political interference, resources and morale. 414 scientists returned completed surveys (29 percent), despite agency directives not to reply—even on personal time.

Notable results include:

- Nearly half of all respondents whose work is related to endangered species scientific findings (44%) reported that they "have been directed, for non-scientific reasons, to refrain from making jeopardy or other findings that are protective of species."
- One in five agency scientists revealed they have been instructed to compromise their scientific integrity—reporting that they have been "directed to inappropriately exclude or alter technical information from a FWS scientific document," such as a biological opinion.
- More than half of all respondents (56%) knew of cases where "commercial interests have inappropriately induced the reversal or withdrawal of scientific conclusions or decisions through political intervention."

National Oceanic and Atmospheric Administration (NOAA) Fisheries
In June 2005, UCS and PEER released the results from a 34-question survey distributed to 464 NOAA Fisheries biologists, ecologists, botanists and other science professionals working in headquarters and regional and field offices across the country. The survey was designed to obtain their perceptions of scientific integrity within the agency, as well as political interference, resources and morale. 124 scientists returned completed surveys (27 percent).

Notable results include:

- More than one third of respondents positioned to make such recommendations (37%) have "been directed, for non-scientific reasons, to refrain from making findings that are protective" of marine life.
- Nearly one in four (24%) of those conducting such work reported being "directed to inappropriately exclude or alter technical information from a NOAA Fisheries scientific document."
- More than half of all respondents (53%) knew of cases where "commercial interests have inappropriately induced the reversal or withdrawal of scientific conclusions or decisions through political intervention."

Food and Drug Administration (FDA)
In June 2006, UCS and PEER released the results of a 38-question survey distributed to 5,918 scientists at the FDA to obtain their perceptions about scientific integrity. 997 scientists filled out and returned the survey (17 percent).[10]

Notable results include:

- Almost one in five (18 percent) responded, "I have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or my conclusions in an FDA scientific document."
- Three in five (60 percent) knew of cases "where commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal or modification of FDA determinations or actions."
- Approximately half of the respondents (51 percent) felt the "FDA is acting effectively to protect public health."

Federal Climate Scientists
In January 2007, UCS released the results of a 40-question survey distributed to 1,630 climate scientists at seven federal agencies (NASA, NOAA, EPA, USGS, USDA, DOE and DOD) and 119 climate scientists at the independent National Center for Atmospheric Research (NCAR). 279 federal scientists and 29 NCAR scientists filled out and returned the survey. The survey results were released as a joint report with the Government Accountability Project (GAP) entitled *Atmosphere of Pressure*.[11]

Notable results include:

- 150 scientists (58 percent) said they had personally experienced at least one incident of political interference in the past five years.
- Nearly half of all respondents (46 percent) perceived or personally experienced pressure to eliminate the words "climate change", "global warming" or other similar terms from a variety of communications.
- More than half of respondents (52 percent) said that their agencies always or frequently require public affairs officials to monitor scientists' communications with the media.

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[10] For more information about the FDA survey go to http://www.ucsusa.org/scientific_integrity/interference/fda-scientists-survey-summary.html.
[11] To read the text of the report go to http://www.ucsusa.org/scientific_integrity/interference/atmosphere-of-pressure.html.

Responses by Francesca Grifo to Additional Questions
From Senator Boxer

Question #1: Potential Solutions to Problems at EPA
Your testimony described a litany of serious problems with the EPA's abuse of science under the Bush Administration. If you had to pick three or four things to change with EPA's use of science, what would they be?

The many forms of political interference in EPA science revealed through our survey, our interviews, and other sources of information require a suite of solutions in five major arenas: protecting EPA scientists, increasing agency transparency, reforming its regulatory process, strengthening its scientific advisory system, and depoliticizing funding, monitoring, and enforcement.

- Protecting EPA Scientists: The agency's scientists have a profound responsibility to the U.S. public. To fulfill that responsibility, they need reassurance that standing behind their scientific work will not open them to official or unofficial retaliation. Last year, the House and Senate passed versions of whistleblower protection legislation that now is being informally negotiated primarily by the staffs of Senators Daniel Akaka (D-HI), Joseph Lieberman (I-CT), and Susan Collins (R-ME) and Representatives Henry Waxman (D-CA) and Tom Davis (R-VA). It is crucial that Congress enacts a final whistleblower bill that contains specific protections from retaliation for scientists who report efforts to alter or suppress federal research or technical information. A strong whistleblower law will send a clear signal to the next EPA Administrator that EPA science should not be tampered with.

- Making the EPA More Transparent: Decisions made behind closed doors threaten the integrity of EPA science and the agency's ability to protect public health and the environment. Opening up these decisions to congressional and public scrutiny is an important step in revealing and ending the misuse of science. The EPA should institute a transparency policy requiring disclosure of the participants and a summary of the subjects discussed for all meetings with representatives of other federal agencies and outside entities. The agency should also create procedures that ensure the periodic release of scientific documents and prevent them from remaining in draft form indefinitely. The EPA should publish a summary statement discussing the scientific basis for each significant regulatory decision, and document dissenting opinions. The agency should also reform its policies to allow scientists to communicate freely with the media, and to quickly clear their findings for publication in scientific journals, to ensure the free flow of scientific information.

- Reforming the Regulatory Process: The EPA was created to implement and enforce the nation's environmental laws, and it has developed the expertise, experience, processes, and policies needed to fulfill that charge. While the White House is responsible for overseeing federal agencies, it must strike a better balance between administration priorities and agency independence. The White House should respect the agency's reservoir of scientific and technical knowledge and restrain the OMB from reviewing the EPA's scientific and technical documents. At a minimum, the next Administration should repeal Executive Order 13422, which gives the OMB more power over the regulatory process and gives regulatory policy officers (RPOs) the final authority to sign off on proposed new agency rules.

  To ensure the central role of the environment in high-level decision making, the next president should elevate the EPA to a cabinet-level agency. Congress should also consider how to reform and strengthen our nation's regulatory structure, to meet the pressing environmental challenges of the twenty-first century.

- Ensuring Robust Scientific Input to the EPA's Decision Making: The EPA should review and strengthen how it uses the scientific expertise of its staff and external advisory committees to create policies—especially when scientific input is critical or required by law. Specifically, the next EPA administrator should work with the Clean Air Science Advisory Committee to improve the process for setting the National Ambient Air Quality Standards, to ensure that the administrator relies on the "best available science." The agency should also tighten its conflict-of- interest restrictions.

- Depoliticizing Funding, Monitoring, and Enforcement: Problems with funding, monitoring and enforcement also need to be addressed by Congress and the next president to ensure that the EPA is the robust environmental agency that our country needs. Congress should provide the EPA with resources commensurate with its growing responsibilities and should work to ensure that selective internal budget cuts are not used to punish inconvenient programs or offices. The next president should commit to strong and consistent enforcement of the nation's environmental laws.

Question #2: New IRIS Policy
What is your opinion of EPA's new policy for developing IRIS assessments?

The IRIS database is a crucial resource for federal, state, local and international efforts to protect the public from the adverse health effects of toxic chemicals. It is important to note that IRIS is a scientific product – not a policy document. As such, IRIS should solely reflect the best peer-reviewed science and a firewall should be constructed to insulate that science from political manipulation.

Unfortunately, the recent changes to the process for completing IRIS assessments throw open the gates and expressly allow political appointees and other agencies to meddle in EPA's scientific findings. A recent report by the Government Accountability Office found that the new process is likely to reduce the "usefulness and credibility" of IRIS assessments, and stated that "Congress should consider requiring EPA to suspend its new process and develop one that is responsive to GAO's recommendations."

We agree with the findings of the GAO, and highlight three primary areas of concern with the new IRIS process:

1. **Delay**. The new process provides other federal agencies multiple points at which they may interfere in the routine creation of IRIS assessments by suggesting and carrying out alternative studies. It seems likely that these changes could add months or even years to an already painfully slow process.

2. **Lack of Transparency**. The new IRIS process explicitly labels most inter-agency communication to be "deliberative" and therefore not part of the public record. Given the importance of IRIS assessments the American public deserves to know about decisions made behind closed doors that may impact their health.

3. **Lack of Credibility**. The new IRIS process gives a greater role to other federal agencies, like the Department of Defense, who may be responsible for clean-up of the pollutant in question and therefore have significant conflicts of interest. While it is certainly appropriate for other agencies to suggest scientific studies for consideration, the ultimate authority on the scientific content of IRIS should rest with EPA's experts.

We echo GAO's call for Congress to step in to ensure the scientific integrity of EPA's IRIS database. An improved IRIS process would include safeguards to prevent inappropriate involvement by entities with conflicts of interest and, at the very least, full transparency, so the American public can understand how interagency review impacts the integrity of EPA's science.

Responses by Francesca Grifo to Additional Questions
From Senator Inhofe

1. Dr. Grifo, The Union for Concerned Scientists recently released the results of a survey that focused on political interference and scientific integrity at EPA. The results stated that over 1600 scientists at EPA participated. Can you tell me how you verified that the survey recipients at EPA were scientists? How did you distinguish EPA staff from EPA scientists?

We verified that *survey respondents* were scientists or engineers by researching their backgrounds before sending the survey whenever possible. When this was not possible we used their responses to three survey questions. For the purposes of this investigation we adopted a definition of "scientist" that would encompass both Ph.D. level researchers as well as individuals with Bachelor's degrees who are involved in the EPA's day-to-day scientific work.

Question #2 asked what percentage of respondents' job duties are related to scientific topics. We excluded from the sample all EPA employees who responded that zero percent of their job duties involved scientific topics. Question #43 asked about the respondents' highest level of education. 485 respondents (32.7%) had earned a Ph.D. while another 640 respondents (43.1%) held a Master's level degree.

Question #1 asked about the respondents' major field of training. The vast majority of these responses were various fields of the sciences with the largest numbers coming from

Environmental Sciences, Engineering and Life Sciences. Out of 1,586 respondents only 66 employees (4.2%) responded "Non-Science" and 15 employees (0.9%) were primarily trained in "Policy," however, all these respondents indicated that a non-zero percentage of their job duties involved scientific topics.

Our initial background research together with the responses to these three questions indicate that all the EPA employees included in our sample were involved in EPA's scientific work and that the vast majority were scientists with advanced degrees.

The mailing list of *survey recipients* was constructed from a variety of sources including the EPA website, staff lists, lists of conference attendees and the authors of scientific papers. As we state in our report, it is likely that some non-scientists did receive the survey, but we are confident that our survey methodology selected only those respondents involved in EPA's scientific work.

Senator WHITEHOUSE. Thank you very much.

I would like to just take a moment before we go to Dr. Gilman. I have been asked to add to the record, the growing record of this hearing, an article from the Washington Post that discusses the Center for Consumer Freedom, which was just used as a source by Ranking Member Inhofe, which indicates that the Center for Consumer Freedom was founded about 10 years ago with tobacco company money, Philip Morris, USA, Inc., pledge about $600,000, most of the feed money for this group in 1995. Its founder has declined to give specifics about who funds the Center for Consumer Freedom now.

The Citizens for Responsibility and Ethics in Washington has challenged the Center for Consumer Freedom on grounds that its founder has used the Center to funnel money to himself and his company, a violation of Federal tax law that bars companies or individuals from running a non-profit for their private benefit. And the Citizens for Responsibility and Ethics in Washington has also challenged the group's 501(c)(3) status on grounds that it was established solely to promote the causes of restaurants and food producers, not consumers. Its activities, the organization said, are "not remotely charitable." So without objection, that will be made a matter of record as well.

[The referenced material follows:]



Union of Concerned Scientists
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Analysis by the Center for Consumer Freedom

Overview

Committed to an "open-minded search for truth," and armed with "unrivaled scientific expertise," the Union of Concerned Scientists (UCS) "doesn't say anything [it] can't back up with solid evidence." At least, that's what its fund-raising letters say. The reality is quite different.

UCS embraces an environmental agenda that often stands at odds with the "rigorous scientific analysis" it claims to employ. A radical green wolf in sheep's clothing, UCS tries to distinguish itself from the Greenpeaces of the world by convincing the media that its recommendations reflect a consensus among the scientific community. And that's what makes it so dangerous. Whether it's energy policy or agricultural issues, UCS's "experts" are routinely given a free pass from newspaper reporters and television producers when they claim that mainstream science endorses their radical agenda.

Here's how it works: UCS conducts an opinion poll of scientists or organizes a petition that scientists sign. Then it manipulates or misconstrues the results in order to pronounce that *science has spoken*. In 1986 UCS asked 549 of the American Physical Society's 37,000 members if Ronald Reagan's Strategic Defense Initiative (SDI) was "a step in the wrong direction for America's national security policy." Despite the biased wording of the push-poll question, only 54 percent disapproved of SDI. Even so, UCS declared that the poll proved "profound and pervasive skepticism toward SDI in the scientific community."

More recently, UCS pulled a partisan, election-year stunt in 2004 aimed at the Bush Administration. The group rounded up 60 scientists to sign a statement complaining that "the administration is distorting and censoring scientific findings that contradict its policies; manipulating the underlying science to align results with predetermined political decisions."

On issue after issue, UCS insists, the White House fails to embrace global scientific "consensus" -- and that automatically means it has "politicized" science. But UCS itself is frequently guilty of that exact sin. For instance, it works overtime to scare Americans about a whole host of imagined environmental problems associated with genetically modified food. But every authoritative regulatory agency, including the Environmental Protection Agency and the World Health Organization, declares that biotech food crops are perfectly safe.

UCS routinely abuses and politicizes science. Its crusade against farm animals receiving antibiotics presents guesswork as scientifically rigorous analysis, and is calculated to scare the public about risks it admits are groundless. UCS helped initiate the vicious attacks on Danish scientist (and "Skeptical Environmentalist") Bjorn Lomborg, only to be repudiated by the Danish Ministry of Science, Technology, and Industry. And in 2003, the group dressed up its "strong opposition to the US invasion of Iraq" as an exercise in science.

Like many environmental activist groups, UCS uses the twin motivators of cheer and fear. A giggly Gwenyth Paltrow and a catty Cameron Diaz headlined a series of short appeals about energy conservation that UCS produced. The two mega-stars crow that they turn the water off while brushing

their teeth, switch off the light when they leave their bedrooms, and keep the thermostat at 65 degrees. "Its time for us to band together and really make every effort to conserve our natural resources," chirps Diaz. That's the sunny side.

But UCS is more adept at producing horror stories than chick flicks. They are fear-mongers of the first order -- turning the sober science of health and environmental safety into high drama for public consumption. For example, UCS recently warned that by 2100 the U.S. might suffer 50-80 *million* more cases of malaria *every year* if the Senate fails to ratify the Kyoto treaty. Such racy statistics are based on clumsy modeling of worst-case scenarios, and assume -- against all evidence of human behavior -- that no countermeasures whatsoever would be employed. "Not considering factors such as local control measures or health services," in their own words. Of course, you won't find those caveats in the press release.

Genetically Modified Science

Among UCS's many concerns, "the food you eat" is at the top of the list. More than a million dollars went to its food program in 2001. Genetically enhanced foods -- dubbed "Frankenfoods" by opponents -- have caused worldwide hysteria even though no reputable scientific institution can find anything to be afraid of. But that doesn't stop UCS's "experts" from playing cheerleader to these unfounded fears.

They warn that biotech foods could result in the "squandering of valuable pest susceptibility genes," "enhancement of the environment for toxic fungi," and the "creation of new or worse viruses." They scream about "Poisoned wildlife" and "new allergens in the food supply." Biotech foods, they claim, might "increase the levels of toxic substances within plants," "reduce the effectiveness of antibiotics to fight disease," "contaminate foods with high levels of toxic metals," "intensify weedy properties" and cause the "rapid evolution of resistance to herbicides in weeds," leading to "superweeds."

Rigorous scientific analysis led UCS to this list of horrors, right? Wrong. That was merely a "'brainstorming' of potential harms." So how likely are any of these to occur? "Risk assessments can be complicated," UCS says, and pretty much leaves it at that. In other words, they have absolutely no idea.

In contrast, more reputable authorities have a very good grasp of the potential risks of genetically enhanced foods. The U.S. Environmental protection Agency says that genetically enhanced corn "does not pose risks to human health or to the environment." The World Health Organization says that biotech foods "are not likely to present risks for human health" and observes that "no effects on human health have been shown as a result of the consumption of such foods by the general population." Even the European Union, which has gone out of its way to stifle food technology for political reasons, notes: "The use of more precise technology [in genetically enhanced crops] and the greater regulatory scrutiny probably make them even safer than conventional plants and foods."

The Food and Environment Program at UCS is headed up by Margaret Mellon and her deputy Jane Rissler, both of whom hold Ph.Ds and have held positions at prestigious universities. So what do a couple of highly trained research scientists, armed with nothing but guesswork, ideology and a million dollar budget, do? They fight biotech food every step of the way.

Although UCS claims that it "does not support or oppose genetic engineering per se," Mellon and Rissler in fact have never met a GM food they didn't mistrust. That's because they hold biotech foods to an impossibly high standard.

In 1999, UCS joined the National Wildlife Federation, the Sierra Club, the Natural Resources Defense

Council, the Arizona-Sonora Desert Museum, and the Defenders of Wildlife, in petitioning the EPA for strict regulation of corn modified to produce large amounts of the *bacillus thuringiensis* (*Bt*) toxin. Bt is a naturally occurring insect poison that protects plants from pests like the European corn borer. UCS's letter was part of a major scare campaign to convince the public that *Bt* corn posed a risk to the Monarch Butterfly.

Both the USDA and the EPA later concluded that *Bt* corn caused no harm to the Monarch. This reinforced the findings of federal regulators who had performed a comprehensive safety review of *Bt* corn before it was allowed into the marketplace. UCS remains unconvinced, even though the safest place for a Monarch larva to be is in a *Bt* cornfield. Rissler argued there was "insufficient data" to make such a conclusion.

Precautionary Nonsense

Of course, "sufficient" data can never exist for zealots like Rissler. She continued: "Do we assume the technology is safe... or do we prove it? The scientist in me wants to prove it's safe." It's impossible to prove a negative, to absolutely demonstrate that there are no dangers whatsoever for any given product. The scientist in her knows that too, but she and her colleagues at UCS continue to be guided by the "Precautionary Principle." This misguided maxim argues that, based on the fear that something harmful may *possibly* arise, we should opt for technological paralysis.

The Wall Street Journal editorialized in 2000 that The Precautionary Principle "is an environmentalist neologism, invoked to trump scientific evidence and move directly to banning things they don't like." It's a big hit among anti-technology activists because it justifies their paranoia and serves to bludgeon technological progress.

Martin Teitel, who runs another misnamed activist group called the Council for Responsible Genetics, admitted as much in 2001. "Politically," Teitel said, "it's difficult for me to go around saying that I want to shut this science down, so it's safer for me to say something like, 'It needs to be done safely before releasing it.'" Requiring scientists to satisfy the Principle by proving a negative, Teitel added, means that "they don't get to do it period."

It should come as no surprise that UCS joined Teitel's organization and other die-hard opponents of biotech foods in an activist coalition called the Genetic Engineering Action Network. While acknowledging that "we know of no generic harms associated with genetically engineered organisms," UCS consistently opposes their introduction to the market on the basis of purely hypothetical risk.

Confronted with the real-world *benefits* of biotech foods, UCS simply changes the subject to its anti-corporate, socialist leanings. Rissler's appearance on the PBS show Nova – on a program called "Harvest of Fear" -- is a case in point. When the interviewer suggested that "genetically modified crops are arguably much less harmful to the environment" Rissler responded: "It depends on where you want to compromise. There's another issue here with corporate control of the food supply."

UCS's knee-jerk reaction to biotech foods is matched only by its animus towards agribusiness. A 1994 press release condemning FDA approval of biotech foods complained that some of the data used by the oversight agency was provided by private enterprises.

In her zeal to decry increased food production from the corporate adoption of biotechnology, Mellon has argued that it's "not clear that more milk or pork is good." And UCS supports a radical vision of "sustainable agriculture." That means no pesticides or herbicides; no fertilizer (other than *E.coli*-rich manure); and eating only "locally grown" produce. If it's not clear under this plan where New York City

would get its rice or how Chicago would scrounge up any bananas, there's a reason for it. They wouldn't.

Pigs, Chickens and Cows, Oh My!

Hogging It, a UCS report published in 2001, argues that the use of antibiotics in farm animals could result in human diseases that are resistant to conventional treatments. The report received a great deal of press attention, and UCS is not afraid to brag about it. "We developed the numbers that everyone uses when talking about... overuse of antibiotics," trumpets a fund-raising letter. But how did they go about developing those numbers? "Rigorous scientific analysis"? Hardly. While the livestock industry actually calculates the amounts of antibiotics administered to farm animals using hard sales figures, UCS guesses at average drug dosages and then multiplies by the total number of animals. That's "brainstorming." Not science.

The real experts, like David Bell, coordinator of the Centers for Disease Control and Prevention's anti-microbial resistance programs, aren't impressed by *Hogging It*. Interestingly, UCS admits the weakness of its evidence. The executive summary of *Hogging It* complains about a "gaping chasm" in the data. Nevertheless, the authors are proud to produce the "first transparent estimate" of livestock antibiotic use in America.

Estimate? That's right. "The numbers everyone uses" are just estimates. Moreover, UCS measures antibiotic usage in total tonnage. But is that relevant in any way? UCS concedes that it's not. The activist group wants the FDA to track antibiotic usage by "type," since most antibiotics used in animals are unlike those used in humans.

Consumer Reports quotes Margaret Mellon saying, "We know nothing. We are flying blind." No wonder the American Veterinary Medical Association and the Coalition for Animal Health also reject *Hogging It*'s findings. But none of that stops UCS from scaring the wits out of the public. Mellon warns of an "era where untreatable infectious diseases are regrettably commonplace." That might be worth getting "Concerned" about, if only it were based on good science.

Unfortunately, political science masquerading as real science can have real-world consequences. In July 2003, identical bills introduced in the U.S. House and Senate threatened to ban the routine use of eight entire classes of antibiotics in livestock. Keep Antibiotics Working (KAW), a slick PR coalition of activist groups, was especially pleased with the news because its favorite statistic became the legislation's main factual "finding." Namely: "An estimated 70 percent of the antibiotics and other antimicrobial drugs used in the United States are fed to farm animals."

Guess who "estimated 70 percent" for KAW? The Union of Concerned Scientists, a long-time coalition member. UCS admits that this estimate was created from mere guesswork, saying on its own website that "data to answer [the following] questions are not available":

> What is the total amount of antibiotics used each year in the United States?
> How much of this is used to treat human disease?
> How much is used in animal agriculture?
> How much is used to treat sick animals and how much to promote their growth?
> How much of each major class of antibiotics is used as supplements to animal feed or water?
> Is agricultural use increasing? By how much?
> Which agricultural uses are most likely to contribute to problems in treating human disease?

For a group facing so many unanswered questions, answers seem to come remarkably easily. While

freely admitting that no good science exists to determine the effect (if any) of livestock antibiotics on human health, UCS managed to convince members of Congress otherwise. At the same time, UCS activists protested outside fast-food restaurants, holding giant "pillburgers" (prop hamburgers stuffed with oversized drug capsules) and chanting "Hey hey -- ho ho -- Drugs in meat have got to go."

Motivation

The Union of Concerned Scientists was born out of a protest against the war in Vietnam. In 1969, a group of 48 faculty members at MIT -- the original "union" -- sponsored a one-day work stoppage of scientific research. A conference that coincided with the strike included appearances from such notables as Noam Chomsky (who is now recognized as a leader of the 21st Century "hate-America left"); Eric Mann, who led the 1960s terrorist Weather Underground; and Jonathan Kabat, who argued: "We want capitalism to come to an end."

Later that year, when the founding document of the Union of Concerned Scientists was formalized, the United States' relationship with the Soviet Union was featured even more prominently than environmental issues. Three of the five propositions in the founding document concern political questions of the Cold War -- a topic about which even the brightest physicists and biologists can claim no particular expertise.

UCS continues to involve itself in issues where scientific credentials carry little weight. For example, the group opposes urban sprawl, disputes a war in Iraq, and supports abortion. While these positions may be perfectly legitimate in themselves, they are hardly the product of "rigorous scientific analysis."

An early petition from UCS argues: "A new ethic is required -- a new attitude towards discharging our responsibility for caring for ourselves and for the earth... This ethic must motivate a great movement." So activists with lab coats are now presuming to instruct us on matters of ethics and politics.

Among its ethical appeals that have nothing to do with science, UCS's approach to farming stands out. The activist group advocates "a sustainable approach, based on understanding agriculture as an ecosystem." They call it an "agroecosystem," and label it "holistic." They call it "science"; the rest of us call it Zen.

At UCS, politics drives science -- not the other way around. "We undervalue our scientists and agriculturalists if we accept today's productive, but highly polluting agriculture," UCS claims. Of course, UCS advocates organic-only agriculture, the widespread adoption of which (at today's anemic levels of production) would result in mass starvation. So in this instance, some form of technology will surely have to save the day, even for organic farmers. But when it comes to something UCS opposes -- like missile defense -- they argue that the technology will never work.

Respectable scientists operate by considering a question, developing a methodology to answer that question, and only then arriving at a conclusion. They disdain political interference, and go to the media only when their conclusions warrant immediate public attention. The Union of Concerned Scientists stands this process on its head. It develops a press strategy first, and then conducts politically tainted and methodologically flawed analysis. After all, it's getting harder to convince the media that *your* environmental scare is more lurid than the next guy's. You need good PR. That's why UCS partners with slick Washington PR firms -- to get attention, whether or not there's good science behind the sound bites.

Blackeye

By any real scientific yardstick, the Union of Concerned Scientists has a lousy track record. Their predictions are often laughably, and sometimes tragically, wrong. A few examples:

In 1997 UCS organized a petition that warned of "global warming" and advocated U.S. ratification of the Kyoto treaty. It was signed by 1,600 scientists, and so UCS declared that "the scientific community has reached a consensus." But when a counter-petition that questioned this so-called "consensus" was signed by more than 17,000 other scientists, UCS declared it a "deliberate attempt to deceive the scientific community with misinformation."

UCS invested significant resources in "a multiyear effort to protect *Bacillus thuringiensis*, a valuable natural pesticide, by bringing high visibility to a preliminary report on the toxic effect of transgenic [biotech] corn pollen on the Monarch Butterfly." Unfortunately for them, both the USDA and the EPA have concluded that *Bt* corn is only a threat to the crop-devastating insects it's supposed to kill.

Based, we suppose, on some "science" or other, UCS's Margaret Mellon predicted in 1999 that American farmers would reduce their planting of genetically enhanced seeds in the year 2000, saying it "probably represents a turning point." What happened? Just the reverse. Planting of biotech crops has increased in 2000, 2001 and 2002 -- and shows no sign of slowing down.

In 1980 UCS predicted that the earth would soon run out of fossil fuels. "It is now abundantly clear," the group wrote, "that the world has entered a period of chronic energy shortages." Oops! Known reserves of oil, coal and natural gas have never been higher, and show every sign of increasing.

To improve fuel efficiency, UCS argues for lighter tires on SUVs. But lighter tires are blamed -- even by Ralph's Nader's Public Citizen -- for tread separation. 148 deaths and more than 500 injuries were attributed to tread separation in Firestone tires alone.

UCS apparently hasn't learned from its many, many mistakes. But if at first you don't succeed, scare, scare again.

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washingtonpost.com

Obesity Hype?

Post
Monday, May 2, 2005; A16

Hilton
Travel should take you places®
Hilton's Bed & Breakfast Package

Escape now.

IF A GROUP calling itself the "Center for Consumer Freedom" were to take out $600,000 worth of newspaper advertising claiming that the link between smoking and mortality is nothing but "hype," it would be a national scandal or, perhaps, just a national joke. Even the tobacco companies no longer dispute the health dangers of smoking.

Nevertheless, a group actually calling itself the Center for Consumer Freedom did buy $600,000 worth of advertising in The Post and elsewhere last week calling the links between obesity and mortality "hype" fostered by the government's Centers for Disease Control and Prevention. In principle, these advertisements are no less of a scandal: The high cost of diabetes and other obesity-related illnesses is not in dispute, any more than is the cost of tobacco-related illnesses. Obesity rates in the United States have more than doubled in the past 30 years and have tripled among children.

More to the point, the Center for Consumer Freedom is not an ordinary consumer advocacy group pushing neutral "facts." It is, by its spokesman's admission, funded by the restaurant and food industries. A Post story last week revealed that the group was started by Philip Morris USA Inc., the tobacco company that also owns Kraft -- maker of cookies, crackers, and macaroni and cheese.

Thanks to mistakes made by bureaucrats at CDC, the food and restaurant companies behind the "consumer freedom" label could make some headway. In seeking to push obesity into the forefront of public health concerns, CDC has indeed published, if not "hyped," incorrect information about the links between obesity and death. In a report that appeared last year in the Journal of the American Medical Association, a group of CDC authors -- including Julie L. Gerberding, the CDC director and formerly an infectious-disease specialist -- claimed that annual obesity-related deaths in this country topped 400,000, making obesity a greater cause of death than tobacco. But in a report last month, also co-authored by researchers at the CDC and making use of CDC data, the number was found to be closer to 100,000.

The same study questioned whether being slightly overweight -- as opposed to obese -- was unhealthy at all. CDC spokesmen explain that the disparities are explained by the fact that the study of obesity and its relationship to mortality is "evolving." Fair enough, but the original report, which was criticized even before its publication, also contained serious methodological and calculation errors, which CDC was slow to acknowledge and now tries to play down.

None of this should change the health advice that the government gives to schools and other institutions that serve and teach children about food: Maintain a balanced diet, eat less junk food, exercise regularly and don't smoke. CDC administrators would do better to leave science to the

full-time scientists and to focus on repeating this simple message to the public. That would make the organization, and its statistics, less open to simple-minded attack.

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Senator WHITEHOUSE. Dr. Gilman.

STATEMENT OF PAUL GILMAN, PH.D., CHIEF SUSTAINABILITY OFFICER, COVANTA ENERGY

Mr. GILMAN. Thank you, Mr. Chair, thank you, members of the Committee, for the opportunity to be here.

I am going to start by adding to our list of headlines in order to make a point, this one from a journal called Pest Control: "EPA has become too politicized in its actions, too eager to pursue narrow political goals and too willing to ignore congressional intent." One from Resources for the Future: "EPA also should reinstitute and strengthen the internal scientific review process to ensure transparency, accountability for scientific uncertainty and improve its analytical base for its political decisions."

One from USA Today, "At least a dozen former EPA officials who played roles in setting pesticide policy now work as industry consultants. The EPA has become the farm team for the pesticide lobby," it quotes an observer as saying. One from the Chattanooga Free Press, "In a scathing opinion the court stated the EPA publicly committed a conclusion before research had begun adjusted scientific procedure and scientific norms to validate the agency's public conclusion." One from the Orlando Sentinel, "Science is as politicized in America as it was in the Soviet Union and Nazi Germany, and EPA is a prime example."

One from Portland Press Herald, "For years the Federal Government has known power plants produce mercury. It knows how technology could be used to reduce that pollution, but the EPA's efforts to regulate toxic metal has been slowed by industry lobbyists and all of their allies in Congress."

I want to make the point that these headlines all came prior to the current Administration and pertain to the previous Administration. I make that point simply because science is the battleground today, science supporting the policy decisions at the EPA. It is where the things are being fought out that really are about the economics, the predispositions of our different constituent groups that speak to you in the Congress and people at the EPA.

I don't say it to say who is more guilty in the process of using science either correctly or incorrectly, only to make the point that science is the battleground today, and that is why this hearing is so important. In my statement I say the keys to making sure the process of using the science and the process of making policy with the science rests on the very things you have already touched on: a quality control process for that science; transparency for the science as the Chair has stated; and a very aggressive peer-review process.

I would only note that on a number of those fronts, the agency has come quite a long way. In the area of peer review, which has long been a sore point, Dr. Genny Matanowski said in a 2002 hearing before the Science Committee that really, the agency sort of reached a peak in terms of the practice of peer review. At that same time, of the 859 scientific products of the agency, it sent 750 to review and 91 percent of those were by outside reviewers. I had, while at EPA, the opportunity to testify on peer review. I testified alongside folks from the Corps of Engineers. At the time, they were

trying to see if they could submit a single study in a given year to outside external review.

So that is to say that the fundamentals of good science and good science policy have been growing at the agency through time. They continue to need to be emphasized. I welcome the Committee's effort to do that here today and I am happy to take any questions you have.

Senator WHITEHOUSE. Thank you, Dr. Gilman.

Dr. MICHAELS.

STATEMENT OF DAVID MICHAELS, PH.D., MPH, RESEARCH PROFESSOR AND ASSOCIATE CHAIRMAN, DEPARTMENT OF ENVIRONMENTAL AND OCCUPATIONAL HEALTH, THE GEORGE WASHINGTON UNIVERSITY

Mr. MICHAELS. Good morning. My name is David Michaels. I am Associate Chairman of the Department of Environment and Occupational Health at the George Washington University School of Public Health.

Previously, I served as Assistant Secretary of Energy for Environment, Safety and Health, responsible for protecting the health of workers, communities and environments around the Nation's nuclear weapons complex. I am also the author of "Doubt is their Product: How Industry's Assault on Science Threatens Your Health," which has just been published this week by Oxford University Press, in which I detail how industry and the Bush administration manufacture scientific uncertainty in order to prevent regulation. In fact, I discuss the Center for Consumer Freedom and the Annapolis Center, and the tobacco industry's foundation of all that that we are discussing today.

I would like to take a moment out of my prepared testimony to note that my testimony about the Bush administration does not apply to Dr. Paul Gilman, who as Assistant EPA Administrator for Research and Development defended the integrity of EPA's science and scientists from some of the efforts I will be describing today. I am honored to be on the panel with him.

There are three major components of the Administration's anti-science agenda. The first is the widespread practice of ignoring the advice of scientific experts. Environmental issues are very complex and the Government needs the wisdom and advice of the Nation's best scientists. For decades, the advisory system has provided this wisdom. The Bush administration has rejected this approach by the stacking advisory panels, by dropping renowned scientists and replacing them with scientists whose job it is to defend polluters or just by simply ignoring the advice of these august panels.

One of our most important sources for scientific advice is CASAC, which, as we have discussed, consists of preeminent scientists appointed by the Administrator of EPA. In a series of decisions without historical precedent, the Administrator has ignored CASAC's advice on lead and pollution. Not considered and rejected, but the evidence is ignored. Senators, I want to be very clear that I am not talking about what might be called academic disputes among scientists. In epidemiology, we remind our students that statistics are people with the tears washed off. Exposure to air pol-

lutants kills thousands of Americans every year. EPA regulations are literally life or death decisions.

The second anti-science component of the Bush administration's regulatory philosophy is its predilection to manufacture uncertainty: manipulating, distorting or hiding scientific evidence because this evidence is the most important driver of public policy decisions around environmental health. Books have been written about the lengths to which the Administration has gone to deny the scientific evidence or confuse the public about global warming. As late as June 2006, President Bush was still denying the significant role of human activity in global climate change. The scientific evidence is now so powerful and the popular acceptance of this evidence is so widespread, that it is no longer credible to manufacture uncertainty about the causes of global warming.

So now the White House has moved on to manufacture uncertainty about the public health impacts of severe climate change. This is a strategic retreat with the same objective: delay steps to reduce our use of fossil fuels. Call it Climate Change Manufactured Uncertainty 2.0.

Christie Todd Whitman, the first head of the EPA under President Bush, once said "The absence of certainty is not an excuse to do nothing." But for this Administration, right now, it is.

A basic tenet of public health is that decisions must be made on the basis of the best available evidence. We can't afford to wait until scientific certainty is reached, because in many cases, it cannot and will not be reached.

The third component is what I call institutionalizing uncertainty. Since coming to power in 2001, this Administration has attempted to radically alter the way scientific information is produced, communicated, analyzed, synthesized and acted upon by Federal agencies. I have no doubt that the objective of these measures is to limit the ability of future administrations to protect the public health and environment.

Last week you heard testimony on the EPA's IRIS program. I won't go into all the details, but I think your characterization of OMB as a black box is too generous. I think black hole may be a better phrase for it. IRIS assessments go in there and they do not go out.

The Administration now is proposing a policy that gives agencies like the Department of Defense, who clearly oppose more protective standards, the opportunity to challenge EPA science in secrecy. We would never permit a process that would allow the EPA, in secret, to delay military activities needed to protect our Nation. How can we permit a system in which the Pentagon, in secret, has the ability to block EPA efforts to protect human health and the environment?

This is only the most recent example of several unfortunate efforts by the White House to institutionalize uncertainty that I go that through in the book and on our website, http://www.defendingscience.org/.

Thanks to our regulatory agencies, we have made great progress in reducing toxic exposures and protecting our health. But we must not stop. Much remains to be done. In the not too distant future, I am hopeful that our political leadership responsible or protecting

the public health and environment will be committed to the independent scientific evaluation of the risks posed by air pollutants and toxic chemicals. When this happens, we will surely view the activities of the current Administration with the same dismay and outrage with which we now look back on the deceits of the tobacco industry. But by then, the price already paid in preventable illness and premature deaths, in destroyed habitats and extinct species, will have been enormous.

Thank you for inviting me to testify today.

Responses by David Michaels to Additional Questions
From Senator Boxer

Senator Boxer's Question 1: Use of Strategies to Highlight Uncertainty:

You have testified that the Bush Administration is "manufacturing uncertainty" and that the tobacco companies helped to develop this strategy a while ago. Could you please describe some of the parallels that you see between the Administration's actions and strategy developed by tobacco companies?

Answer:

The Bush Administration has been engaged in what I call "institutionalizing uncertainty" — constructing administrative mechanisms through which polluters and manufacturers of dangerous products can question the science underlying not just regulation but virtually any "information" disseminated by federal agencies as well. The mechanism for this is the Data Quality Act, an appropriations rider conceived of and promoted by the tobacco industry, which was particularly concerned about the federal government's attempts to label second-hand tobacco smoke as carcinogenic.[1,2]

The Bush Administration has used the poorly defined provisions of the Data Quality Act, under the alleged authority under the Paperwork Reduction Act, as the basis for a series of attempts to restructure the process by which regulatory agencies (and even non-regulatory agencies) function. These attempts have included efforts to require agencies to put large numbers of products through something called "peer review" (but bearing little resemblance to the peer review known to the scientific community), and to require all agencies to apply prescriptive procedures to their risk assessment methods, even procedures that are expressly contradicted by

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[1] Baba A, Cook DM, McGarity TO, Bero LA. Legislating "sound science": the role of the tobacco industry. *Am J Public Health.* 2005;95 Suppl 1:S20-7.
[2] Neff RA, Goldman LR. Regulatory parallels to Daubert: stakeholder influence, "sound science," and the delayed adoption of health-protective standards. *Am J Public Health.* 2005;95 Suppl 1:S81-91.

agencies' authorizing statutes. The scientific community has been very critical of these efforts. I discuss this in the attached chapter entitled "The Institutionalization of Uncertainty" of my book *Doubt is Their Product* (Oxford University Press 2008).

Senator Boxer's Question 2: Institutionalizing Uncertainty and Risks to Public Health

You testified that you believe the Bush Administration is institutionalizing uncertainty with this new policy on IRIS assessments. Could you go into that a little bit more and explain what you mean, and also provide any other examples of the dangers to public health from this problem?

Answer:

Changes being imposed by the White House on the IRIS assessment process are an excellent example of the way in which the Bush Administration's actions mirror those of the tobacco industry.

As I wrote in my testimony:

> In addition to heaping further delays onto an already extensive process, this new interagency review process gives OMB and other federal agencies that might be affected by IRIS assessment more power than EPA scientists when it comes to adding new assessments to the IRIS database. EPA must send draft assessments to OMB; OMB provides comments and questions to EPA from OMB and other federal agencies; and then EPA revises the assessments to address those comments and provides OMB with a document describing how it has addressed each issue that was raised. Only after OMB verbally informs EPA that all issues are resolved (to OMB's satisfaction) can EPA send the assessments for external peer review.
>
> To agencies like the Department of Defense (DoD), protecting human health and the environment is not a primary concern. DoD is concerned with national security first and foremost, and as a general rule opposes efforts to force them to clean up toxic waste. At interagency meetings, the Pentagon advocates for its needs, and the needs of its contractors, many of whom are responsible for the accumulation of huge quantities of toxic waste near military bases. DoD scientists currently are welcome to participate in the public process in which scientists comment on proposed IRIS assessments. The new structure will give those agencies who clearly oppose more protective standards the opportunity to challenge EPA's science in secrecy, so the public and the scientific community can't even monitor what's going on.
>
> We would never permit a structure which would allow the EPA, in secret, to delay military activities; why should we permit a system in which DoD, in secret, has the ability to block EPA efforts to protect human health and the environment?

The process violates a basic tenet of risk assessment, which is the use of objective scientific information in designing management activities. It is problematic to allow those agencies who

are responsible for pollution, and who will bear the costs of the cleanup, to shape the assessments that dictate the aspects and the extent of the clean-up activities. Moreover, it is extremely dangerous to allow these agencies, some of whom are unlikely to have expertise comparable to that of EPA scientists, to shape the IRIS assessments *in secret*, so that the public health and scientific communities have no idea if the risk assessments have been influenced by conflicted interests. The danger is that the IRIS assessments will lose credibility. They will no longer be seen as "the best science," and the decisions made by federal and non-federal agencies and organizations that rely on these assessments will be in question.

Response by David Michaels to an Additional Question
From Senator Whitehouse

Dr. Michaels, you testified and you have written about organizations like the Annapolis Institute and the Center for Consumer Freedom which purport to be scholarly public policy institutions but are in fact industry-funded fronts that seek to influence or distort science-based agency decisionmaking for the benefit of special interests.

a) Do you have any thoughts about how to ensure that (i) the industry connections of these groups are fully exposed, and (ii) these groups are limited in their ability to wield influence over the regulatory process?

b) Is this area that is ripe for a legislative solution? If so, do you have any thoughts about what can be done legislatively to address this issue?

c) Would the FTC or any other independent federal regulatory agencies have enforcement authority to deal with these sham institutions?

Answer:

Senator Whitehouse's questions raise difficult philosophical issues. There is little question that corporate spin experts have a pernicious influence on the regulatory process. However, given our commitment to free speech (even if that speech misleading or even demonstrably false), I do not think that the problem of misleading advocacy is amenable to a legislative solution.

Most of what these groups do is to put together advocacy documents. They present selected scientific information, often cherry-picked to put the best spin on their advocacy, and publish their materials to make them resemble scientific documents. They are then promoted through press releases, op-eds, and other means.

As public speech, I do not think they can (or should) be limited. There are, however, several steps that can be taken, both through legislation or administration policy, that would level the playing field, and limit the influence of these groups.

The first approach is to require disclosure of information about sponsorship in those cases where the material in question is being produced to influence regulatory policy. When these materials

are submitted for consideration by regulatory agencies, the agencies have the right to know who paid for the documents, and the relationship between parties subjected to the regulation and the producers of the materials in question. This is especially true of the financial relationship, since it is well recognized in the scientific literature that there exists something known as "the funding effect," a term used to describe the close correlation between the results desired by a study's sponsors and the results reported. For this reason, the editors of most leading scientific journals insist on disclosure of financial conflict; knowledge of financial conflict is vital to interpreting the results of any scientific paper.

Although editors of journals like the New England Journal of Medicine and the Journal of the American Medical Association require extensive information from persons submitting papers for consideration for publication, our regulatory agencies do not have similar requirements. I attempt to address this issue in Chapter 18 of *Doubt is Their Product* entitled "Sarbanes-Oxley for Science: A Dozen Ways to Improve our Regulatory System." The entire chapter is attached; here is a relevant excerpt:

> Money changes everything. Financial conflict of interest inevitably shapes judgment—the funding effect—and this correlation must be factored into the consideration of the analyses and opinions of scientists employed by industry. During the late 1990s there was a series of alarming instances in which corporations blocked the publication of research that was detrimental to the companies but important for protecting the public's health. Outraged, the editors of thirteen of the world's leading biomedical journals, including the New England Journal of Medicine and the Journal of the American Medical Association, declared in 2001 that they will publish only studies done under contracts in which the investigators are "free of commercial interest." The editors would no longer accept papers about studies performed under contracts that allowed the sponsor to control the results. In a joint statement, the editors asserted that contractual arrangements that allow sponsor control of publication "not only erode the fabric of intellectual inquiry that has fostered so much high-quality clinical research, but also make medical journals party to potential misrepresentation, since the published manuscript may not reveal the extent to which the authors were powerless to control the conduct of a study that bears their names."
>
> Federal regulatory agencies, charged with protecting the public's health, must make life-and-death decisions based largely on scientific evidence submitted by the regulated parties themselves. Yet the policies of the federal regulatory agencies to ensure the honesty of the reporting of this research have not kept pace with developments in the academic and biomedical communities. In many ways, the FDA is somewhat more insulated from corporate data manipulation than the other agencies. When a manufacturing company applies for approval to market a new drug, it must supply the FDA with all of the raw data from its clinical trials and safety studies. Granted, the manufacturer's scientists may also publish the study results in a medical journal, where they may apply whatever spin they want. However, the FDA's scientists will generally ignore those papers and perform their own analyses of the raw data. Even with this system, the world of pharmaceutical research continues to be filled with scandals. No wonder the other federal agencies, which have fewer resources and no legislative

> authority to demand raw data, have such problems coping with the corporations. They are condemned to rely on the work of the hired guns in the product defense industry—studies bought and paid for by the regulated parties. As a regulator in the Department of Energy, I thought I knew the provenance of the studies submitted to my agency, but I could never be sure.
>
> The EPA, OSHA, MSHA (Mine Safety and Health Administration), and most other regulatory agencies have no formal mechanisms to identify potential conflicts of interest, and their regulations do not provide any incentives for sponsors to ensure that research is free of sponsor control. When studies are submitted to EPA or OSHA, for example, these agencies do not have the authority to inquire who has paid for the studies or whether they were performed under the types of contracts the medical journals have banned. I do not believe that regulators should use conflict disclosures to exclude research (we have an obligation to consider all of the evidence and to accord greater importance to those studies that are of higher quality and relevance), although we should certainly be informed about those conflicts. Recognizing that sponsors with clear conflicts of interest have no incentive to reveal them or to relinquish control over sponsored research,
>
> University of Texas law professor Wendy Wagner and I developed a series of recommendations that would begin to improve the situation. Writing in the journal Science, we proposed that federal agencies should adopt, at a minimum, requirements for "research integrity" comparable to those used by biomedical journals. Corporations, trade associations, unions, public interest groups, and others who submit studies for consideration should be required to disclose the financial and other conflicts of interest of the investigating scientists, and they should also divulge whether the scientists had the contractual right to publish their findings without influence and without obtaining consent of the sponsor.

There is a second way to level the playing field. Corporate advocacy groups have huge resources at their disposal and can outgun federal scientists. I have had numerous conversations with scientists working for regulatory agencies who describe arriving at a meeting on one of the several areas on which they are working, to encounter a large group of corporate attorneys and product defense scientists. Polluters know they can raise enough questions and challenges on any topic to keep regulatory scientists busy for years, enough to dramatically slow down any proposed regulations. I also address this in Chapter 18:

> Occasionally an environmental organization or union will challenge the work of the product defense scientists or try to influence a government agency to take a stronger position, but these groups have relatively few resources at their disposal. University scientists are generally uninformed about the regulatory process and rarely participate; their work is published in academic journals and used in the regulatory arena only when advocates translate it and inject it into the regulatory discussions.
>
> We also have the Small Business Regulatory Enforcement Fairness Act (SBREFA), which established a Small Business Administration Office of Advocacy to promote the

needs of small businesses to the EPA and OSHA. SBREFA, a remnant of Newt Gingrich's Contract with America, establishes a formal mechanism in which these two public health agencies must present regulations still in the planning stage to panels of small business representatives and advocates and invite their input. This is yet another opportunity for polluters to demand that concern about public health and the environment be balanced against economic impact on small businesses. The EPA and OSHA already consider the economic impact of their regulations, and if they did not, the White House and Congress would remind them of their need to do so. Every proposed regulation goes through extensive interagency review. However, the Small Business Advocate gives antiregulatory forces another bite of the apple by pushing EPA and OSHA to weaken standards.

To help level the playing field, the system needs an equal and opposite advocate—this one for public health and the environment, a well-funded office with the power to review all of the science, including privately funded science, used by the regulators and to advocate for standards that would truly protect the public.

Senator WHITEHOUSE. Thank you, Dr. Michaels. We are glad you could be with us.

Dr. THURSTON.

STATEMENT OF GEORGE D. THURSTON, SC.D., PROFESSOR OF ENVIRONMENTAL MEDICINE, NEW YORK UNIVERSITY SCHOOL OF MEDICINE, NELSON INSTITUTE OF ENVIRONMENTAL MEDICINE

Mr. THURSTON. I am George Thurston, a tenured professor of environmental medicine at the NYU School of Medicine. At NYU I conduct the health effects research that we are discussing here today.

Despite progress since the Clean Air Act was enacted by you, the Congress, Americans are still suffering from the adverse health effects of air pollution. The adverse health consequences of breathing air pollution are severe and well-documented in the published medical and scientific literature.

Over the past few decades, medical researchers examining air pollution and public health, including myself, have shown that ambient air pollution is associated with a host of serious human health effects, including asthma attacks, heart attacks, hospital admissions, adverse birth outcomes and premature death.

The Clean Air Act provides a clear process for the U.S. EPA to establish air quality standards. The EPA must set the primary or health base standard NAAQS at a level requisite to protect public health with an adequate margin of safety. Unfortunately, the EPA has failed to follow the latest scientific knowledge and to thereby establish a NAAQS, a National Air Quality Standard, for ozone or particulate matter, that meets this congressional requirement.

In particular, the EPA Administrator has failed to heed the expressed recommendation of his scientific advisors, CASAC, and the solid recommendation of the mainstream medical and public health community as required by the Clean Air Act. Now, Senator Alexander in his comments seems to dismiss this process as just between a committee that is set up by the EPA Administrator and his staff, so they had a little disagreement. But actually, this is all stipulated that the Administrator must listen to CASAC by the Congress.

So when the Administrator ignores CASAC, he is not just ignoring some committee, he is ignoring the Congress. He is ignoring the law of the land, the Clean Air Act. It is all stipulated right there what he has to do and he hasn't done it. My testimony today focuses primarily on the argument the Administrator made for questioning and rejecting the latest scientific knowledge, and those words are in the law, in the most recent case of ozone.

In rejecting CASAC's advice to adopt an ozone standard within the range of 60 to 70 ppb, the Administrator argued that uncertainty over the research prevented him from following the guidance of CASAC. Indeed, from promulgating a standard in the Federal Register the Administrator referred to uncertainty or uncertainties more than 150 times, 172 by my count.

In the face of a strong scientific consensus, it is just untenable to cite uncertainty as a rationale for failing to promulgate a tighter standard. There are two basic problems with the Administration's

uncertainty argument for choosing a standard less stringent than recommended by CASAC. First, in the face of uncertainty, the Clean Air Act stipulates that the Administrator must choose a more stringent standard to ensure a margin of safety.

Also, EPA's uncertainty claims failed to address uncertainties that favor a more protective standard. For instance, controlled human exposure studies typically use healthy young adults as test subjects. This creates uncertainty about what the results would be on more vulnerable populations, such as infants, children or people with severe respiratory disease, such as asthma, simply because we cannot and should not use them as test subjects in experiments. But the fact is, we know that if we were to do such experiments, they would have effects at much lower levels than the subjects we use.

Second, the Administration has apparently confused scientific uncertainty regarding the sizes of the pollution health effects or confidence intervals, the confidence intervals around the health estimates. In other words, when a scientist talks about uncertainty of effect, they are saying, well, it could be this big or it could be this big, it is in this range. But the Administrator is confusing uncertainty with doubt. There is no doubt that there are adverse health effects occurring below 75 ppb, or .075 ppm. There just isn't.

There is uncertainty about the size of those effects. The Administrator plays up this uncertainty, uncertainty, uncertainty. But I think that is a mis-use or a misunderstanding of the word uncertainty.

As a result of the Administrator's intransigence, CASAC has in recent years undertaken an unprecedented number of letters to the EPA objecting to the Administrator's actions that did not reflect their advice. So what are the impacts? We have the present annual air PM 2.5 standard, and the newly adopted 8-hour average ozone standard that failed to fully protect the public from the increased risk of asthma attack, heart attack, stroke, lung cancer and premature death. Since they failed to protect the public from pollution at levels demonstrated to cause harm, they certainly failed to provide a margin of safety as unequivocally required by the Clean Air Act.

Overall, it is vital that the Administrator give proper deference to CASAC's advice in the air quality standard setting process and thereby apply sound science, which Senator Inhofe and I apparently agree on, that we need to apply sound science, and that is defined by the law as CASAC. Only in this manner can Congress' intent of the Clean Air Act be fulfilled and the health of the public be protected.

Thank you.

[The prepared statement of Mr. Thurston follows:]

STATEMENT OF DR. GEORGE D. THURSTON, Sc. D.

TO THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

OF THE

UNITED STATES SENATE

SUBCOMMITTEE ON PUBLIC SECTOR SOLUTIONS TO GLOBAL WARMING,
OVERSIGHT, AND CHILDREN'S HEALTH PROTECTION

RE: SCIENCE AND ENVIRONMENTAL REGULATORY DECISIONS

MAY 7, 2008

George D. Thurston, Sc.D.

I am George D. Thurston, a tenured Professor of Environmental Medicine at the New York University (NYU) School of Medicine. I am a member of the American Thoracic Society, and, in connection with that membership, I also serve on the Healthy Air Committee of the ATS' sister organization, the American Lung Association. I testify today on behalf of the American Lung Association. I would like to submit the attached statement for the record which amplifies on my testimony.

My scientific research involves the investigation of the human health effects of air pollution. Unfortunately, despite progress over the last few decades, Americans are still suffering from the adverse health effects of air pollution. The health consequences of breathing air pollution are severe and well documented in the published medical and scientific literature. Over the past few decades, medical researchers examining air pollution and public health, including myself, have shown that ambient air pollution is associated with a host of serious adverse human health effects, including asthma attacks, heart attacks, hospital admissions, adverse birth outcomes, and premature death. [1] [2]

The Clean Air Act Amendments of 1970 first introduced enforceable National Ambient Air Quality Standards (NAAQS) to effectively regulate ozone and other pollutants. The Act provides a clear basis for the U.S. Environmental Protection Agency to establish the NAAQS: the EPA must set the primary, or health-based, NAAQS at a level "requisite to protect the public health" with "an adequate margin of safety."

Unfortunately, the EPA failed to follow the science and establish a NAAQS for ozone that meets that requirement. The EPA Administrator failed to heed the express recommendations of his scientific advisors—the Clean Air Science Advisory Committee—and the solid recommendations of the mainstream medical and public health community.[3] In doing so, he raised arguments that misinterpreted the fundamental soundness of the scientific evidence and CASAC recommendations.

My testimony today will focus on the arguments that the Administrator made for questioning and rejecting the science in this case.

First, I'd like to review the evidence that supports a much more protective standard. Scientific evidence accumulated over the last ten years provides clear evidence that ozone creates adverse health effects at lower levels. Since I testified before this committee in 1996, more than 1,700 peer-reviewed studies examining the health effects of ozone were published. The 23 expert scientists on the CASAC extensively reviewed this new body of evidence in six in-person meetings, in detailed oral comments and seven sets of written comments totaling 500 pages. Their conclusions

were clear: to meet the basic requirements to protect public health, the NAAQS needed to be between .0.060 and 0.070 parts per million.

Following their review, a host of the nation's leading medical societies and public health organizations led by the American Lung Association and the American Thoracic Society called on the EPA to adopt standards in keeping with the CASAC's recommendations. That group included the American Academy of Pediatrics, the American Medical Association, the American Academy of Chest Physicians and the American Public Health Association. In addition, over 100 leading independent air quality scientists and physicians endorsed these recommendations.

Without doubt, the consensus of the scientific community believed the evidence sufficient to require the EPA to adopt a standard within the range of .0.060 to 0.070 ppm. Instead the Administrator selected a much weaker standard, that of 0.075 ppm, arguing that the uncertainty over the research prevented him from following the guidance of the CASAC.

In the face of this strong consensus, it is untenable to cite "uncertainty" as a rationale for failing to promulgate tighter standards. Indeed, the EPA mentions uncertainty no fewer than 100 times in the preamble, despite the massive accumulation of published evidence. There are two basic problems with the Administrations "uncertainty" argument for choosing a standard less stringent than recommended by CASAC.

First, in the face of uncertainty, the Clean Air Act says that the Administrator must choose a more stringent standard, to ensure a margin of safety.[4] If uncertainty is really the reason for deviating from CASAC's advice, then the Administrator should have set an even more stringent standard to provide a margin of safety against that uncertainty.

EPA's uncertainty claims arbitrarily ignore uncertainties that favor more protective standards. For instance, controlled human exposure studies typically use healthy young adults as test subjects. This creates uncertainty about what the results would be on infants, or children, or children with severe respiratory disease, for example, simply because we cannot use them as test subjects.

Secondly, the Administration has apparently confused scientific uncertainty in the size of the pollution effect estimates (i.e., the confidence intervals around those estimates), with scientific doubt about the health effects. While there is uncertainty about the exact size of the health benefits of lowering the ozone standard below .075 ppm, there is *no doubt* that health benefits would be achieved by setting a more stringent ozone standard. Furthermore, due to uncertainty, these benefits may prove greater than those the EPA estimated.

The Administrator similarly deviated from CASAC's advice in setting the recent standards for particulate matter, most notably in not lowering the long-term PM standard below 15 micrograms per meter cubed, and thereby failing to sufficiently protect public health from this pollution.

As a result of the Administrator's intransigence, CASAC has, in recent years, written an unprecedented number of letters objecting to decisions he made that differed significantly from their advice. The following is a quote from their most recent letter comments on the ozone NAAQS decision:[5]

> "*...the members of the CASAC Ozone Review Panel do not endorse the new primary ozone standard as being sufficiently protective of public health.* The CASAC -- as the Agency's statutorily-established science advisory committee for advising you on the national ambient air quality standards -- *unanimously recommended* decreasing the primary standard to within the range of 0.060-0.070 ppm. It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations."

As this letter notes, the EPA Administrator has failed to follow the ample scientific evidence and the expert advice of CASAC, particularly in setting the ozone standards and, as well, the most recent $PM_{2.5}$ standard. In doing so, not only has the EPA Administrator dismissed the recommendations of CASAC, he has failed to provide a sufficient scientific justification for these decisions. So what are the impacts? We have the present annual average $PM_{2.5}$ standard and the newly adopted 8-hr. average ozone standard, which fail to protect the public from the increased risk of asthma attacks, heart attacks, stroke, lung cancer, and premature death, protections they deserve and to which they are entitled. . Since they fail to protect from ozone at levels demonstrated to cause harm, they certainly fail to provide a margin of safety for the protection of public health, as unequivocally required by the Clean Air Act.

Overall, it is vital that the Administrator give proper deference to CASAC's advice in the air quality standard-setting process, and, thereby, apply sound science to the setting of EPA's air pollution regulations. Only in this manner can the intent of the Clean Air Act be fulfilled, and the health of the public be properly protected.

Thank you for the opportunity to testify on this important issue.

[1] The list of citations for the health effects of ozone and particulate matter is extensive. The references below are primarily for ozone. Horstman DH, Folinsbee LJ, Ives PJ, Abdul-Salaam S, McDonnell WF. Ozone concentration and pulmonary response relationships for 6.6-hour exposures with five hours of moderate exercise to 0.08, 0.10, and 0.12 ppm. *Am Rev Respir Dis* 1990; 42:1158-1163. McDonnell WF, Stewart PW, Smith MV, Pan WK, Pan J. Ozone-induced respiratory symptoms: exposure-response models and association with lung function. *Eur Respir J* 1999;14:845–853. Triche EW, Gent JF, Holford TR, Belanger K, Bracken MB, Beckett WS, Naeher L, McSharry JE, Leaderer BP. Low-level ozone exposure and respiratory symptoms in infants. *Environ Health Perspect* 2006;114:911–916. Mudway IS and Kelly FJ. An investigation of inhaled ozone dose and the magnitude of airway inflammation in healthy adults. *Am J Respir Crit Care Med* 2004;169:1089-1095.Gent JF, Triche EW, Holford TR, Belanger K., Bracken MB, Beckett WS, Leaderer BP. Association of low-level ozone and fine particles with respiratory symptoms in children with asthma. *JAMA* 2003;290:1859-1867; Desqueyroux H, Pujet J-C, Prosper M, Squinazi F, Momas I. Short-term effects of low-level air pollution on respiratory health of adults suffering from moderate to severe asthma. *Environmental Research* 2002;89:29-37; and Burnett RT, Brook JR, Yung WT, Dales RE, Krewski D. Association between ozone and hospitalization for respiratory diseases in 16 Canadian cities. *Environmental Research* 1997;72:24-31. Tager IB, Balmes J, Lurmann F, Ngo L, Alcorn S, Kunzli N. Chronic exposure to ambient ozone and lung function in young adults. *Epidemiology* 2005;16:751–759. Bell ML, Dominici F, Samet JM. A meta-analysis of time-series studies of ozone and mortality with comparison to the National Morbidity, Mortality, and Air Pollution Study. *Epidemiology* 2005;16:436-445; Ito K, DeLeon S F, Lippmann M. Associations between ozone and daily mortality: Analysis and meta-analysis. *Epidemiology* 2005;16:446-457; Levy J I, Chemerynski SM, Sarnat JA. Ozone exposure and mortality: An empiric Bayes metaregression analysis. *Epidemiology* 2005;16:458-468. Horstman DH, Folinsbee LJ, Ives PJ, Abdul-Salaam S, McDonnell WF. Ozone concentration and pulmonary response relationships for 6.6-hour exposures with five hours of moderate exercise to 0.08, 0.10, and 0.12 ppm. *Am Rev Respir Dis* 1990; 42:1158-1163.

[2] A sample of the major studies documenting the health effects of particulate matter include the following: Pope CA III, Burnett RT, Thurston GD, Thun MJ, Calle EE, Krewski D, Godleski JJ. Cardiovascular Mortality and Year-round Exposure to Particulate Air Pollution: epidemiological evidence of general pathophysiological pathways of disease. *Circulation*. 2004;109:71-77. Pope CA, Burnett RT, Thun MJ, Calle EE, Krewski D, Ito K, Thurston GD. Lung Cancer, Cardiopulmonary Mortality, and Long-Term Exposure to Fine Particulate Air Pollution.*JAMA* 2002;1132-1141. Dominci F, Peng RD, Bell ML, Pham L, McDermott A, Zeger SL, Samet JM. Fine Particulate Air Pollution and Hospital Admission for Cardiovascular and Respiratory Diseases. *JAMA* 2006;295:1127-1134. Pope CA III, Dockery DW. Health Effects of Fine Particulate Air Pollution: Lines that Connect. *J Air Waste Mange Assoc* 2006; 56:709-742. Gauderman WJ, Avol E, Gilliland F, Vora H, Thomas D, Berhane K, McConnell R, Kuenzli N, Lurmann F, Rappaport E, Margolis H, Bates D, Peters J. The Effect of Air Pollution on Lung Development from 10 to 18 Years of Age. *NEJM* 2004;351:1057-1067.

[3] 40 U.S.C. § 7409(b)(1)

[4] For example, see *American Lung Assn. v. EPA*, 134 F.3d 388, 389; D.C. Cir. 1998.

[5] Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, re Clean Air Scientific Advisory Committee Recommendations Concerning the Final Rule for the National Ambient Air Quality Standards for Ozone, EPA-CASAC-08-009, April 7, 2008.

Responses by George D. Thurston to Additional Questions
From Senator Boxer

Question #1: UnprecedentedActions

Dr. Thurston, your testimony characterizes the Clean Air Science Advisory Committee's (CASAC) reaction to the Bush Administration's actions as "unprecedented". Could you please describe that a little more? How is CASAC's reaction unprecedented?

RESPONSE: The CASAC recently stated, in a letter to the Administrator dated April 7, 2008, that:

> *"the members of the CASAC Ozone Review Panel do not endorse the new primary ozone standard as being sufficiently protective of public health.* The CASAC — as the Agency's statutorily-established science advisory committee for advising you on the national ambient air quality standards — *unanimously recommended* decreasing the primary standard to within the range of 0.060–0.070 ppm. It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations."

To my knowledge, CASAC has never had call to write such an unsolicited letter, signed unanimously, stating its opposition to a NAAQS after it was issued, as occurred during this Administrator's standard setting process for ozone.

Question #2: Medical Associations Agree on Need for Stronger Ozone Standard

Dr. Thurston, you mentioned that the American Lung Association, American Medical Association, American Academy of Pediatrics, American Public Health Association, and many other medical associations led a "consensus in the scientific community "that EPA should follow CASAC's recommendations. Yet the EPA Administrator ignored this consensus. Please explain to me why you believe the science is so strong supporting the need for this stronger standard, and what the health effects are that CASAC and the experts are so worried about?

RESPONSE: A comprehensive response to this broad question is beyond the scope of this question and answer process, but let me try to respond in brief. Ozone (O_3) is harmful to the body because, when breathed, it can react chemically with (i.e., "oxidize") internal body tissues, such as those in the lung. Some have described this as a "sunburn" on the lungs. This, in turn, acts as a powerful acute respiratory irritant at the levels frequently found across the nation during the summer months, as well as causing long-term cumulative damage to the lung.

Ozone exposure has been associated with increased risk of:

- inflammation and damage to the lining of the lung;
- shortness of breath, chest pain, wheezing and coughing;
- reduced lung capacity from long-term, repeated exposure to high levels of ozone.
- asthma attacks, greater need for medical treatment;
- hospitalization, especially among those with preexisting lung diseases, such as asthma or chronic obstructive pulmonary disease (COPD), and;
- premature death.

Those most at risk to these adverse affects include:

- people with lung disease, especially chronic lung diseases such as asthma and COPD;
- children, because their airways are smaller, their respiratory defenses are not fully developed, and their higher breathing rates increase their exposure per pound of body weight;
- people who work or exercise outdoors;
- older adults, and;
- otherwise healthy individuals who respond to lower levels of exposure than the average person (i.e., ozone "responders").

I believe that, since many of these effects have been well documented at levels below an 8-hour average of 0.075 ppm ozone in the published literature, that they provide a strong justification for a standard lower than that selected by the Administrator.

Question #3: Impact of Uncertainty

Dr. Thurston, many scientific decisions will always have uncertainty. Can you please describe what EPA's proper role is when faced with uncertainty over the amount of protection provided by a proposed national ambient air quality standard to protect public health?

RESPONSE: As I noted in my testimony, the EPA is required to resolve uncertainty in favor of greater protection in the face of uncertainty. However, by its own description in the Federal Register when promulgating the most recent ozone standard (Thursday, March 27, 2008; 40 CFR Parts 50 and 58, National Ambient Air Quality Standards for Ozone; Final Rule, pg. 16481), the Administrator states that a standard was selected that would allow more ozone exposures of children, with more associated asthma attacks. However, the Administrator decided that "Given the degree of uncertainty associated with exposure assessment", these impacts were not a sufficient "public health concern". This would, on its face, be an example where the Administrator has instead resolved uncertainty in favor of less health protection, rather than on the side of caution.

Response by George D. Thurston to an Additional Question
From Senator Inhofe

Question #1: Dr. Thurston, we have heard criticism of the EPA Administrator's use of the scientific recommendations of CASAC in setting the recent PM and ozone standards. Can you further comment on the role of CASAC as an Advisory Committee and not a Standard Setting Committee? Doesn't the Clean Air Act give the Administrator the exclusive authority and responsibility for using judgment in setting the standard?

RESPONSE: It's my understanding that, in setting such standards, the Administrator must exercise judgment consistent with the relevant provisions of the Clean Air Act, its Amendments, and their respective legislative and judicial histories. Collectively, these have set out a deliberate process for standard setting, as well as specific criteria governing the Administrator's decision. In particular to this issue, the statute requires CASAC to periodically review air quality criteria and recommend to the Administrator any revisions of existing criteria and standards, as may be appropriate. The law contemplates that the Administrator will give due deference to CASAC's recommendations, and specifically requires that the primary standards be requisite to protect the public health, allowing an adequate margin of safety.

Senator WHITEHOUSE. Thank you, Dr. Thurston.
Dr. MCCLELLAN.

STATEMENT OF ROGER O. MCCLELLAN, ADVISOR, TOXICOLOGY AND HUMAN HEALTH RISK ANALYSIS, ALBUQUERQUE, NEW MEXICO

Mr. MCCLELLAN. Good morning, Chairman, members of the Committee. Thank you for the invitation to present my views on the use of science in environmental regulatory decisionmaking.

I am going to focus on two issues that have received considerable attention this morning, the PM standard and the ozone standard. I do ask that my comments be entered into the record as though read in their entirety.

The testimony I offer today draws on my experience serving on more than 60 major scientific advisory committees for 8 agencies going back to President Johnson and including every President from then up to the present time. This includes service on many EPA scientific advisory committees from the origin of the agency to the present time, including chairing CASAC.

I want to preface my remarks today by emphasizing a fact that is frequently ignored. Scientists understand science. However, scientists also have personal opinions, including how low is low enough in setting standards.

Let's talk first about the PM standard. I served on that panel. And as required by law, the Administrator put forth a proposal. And in that proposal, he you suggested a 24-hour averaging time standards in the range of 25 to 65 micrograms per cubic meter, and an annual standard in the range of 12 to 15 micrograms per cubic meter.

The CASAC particulate matter panel recommended a 24 hour standard in the range of 30 to 35 and an annual standard be set at 13 to 14 micrograms per cubic meter. I disagreed with the majority and offered on dissenting view. I took strong exception to the view that the science would support a 14 microgram per cubic meter standard and not support a 15 microgram per cubic meter standard.

Ultimately, Administrator Johnson issued a final rule. He made a drastic reduction in the 24 hour averaging time standard from 65 to 35 micrograms per cubic meter and he retained the annual standard at 15 micrograms per cubic meter. In my opinion, he made a reasonable policy choice from among an array of acceptable science-based options. I was disappointed that some chose to characterize his decision as being a political decision. I think he did follow the science.

Let me turn to the issue of the ozone standard. And again, there was considerable debate and contentiousness. Throughout the review, there was debate over the numerical level of the revised standard. In my opinion, much of that debate was premature and it focused on the desire of various parties to lower the standard even before the review of the science was complete. This resulted in a blurring of the boundary between the role of science and judgment in setting the standard. We have already heard reference to the specific numbers and the ultimate setting of the standard at

0.075 ppm. I think that was a reasonable policy decision from among an array of acceptable science-based options.

In my opinion, the CASAC ozone panel moved from the science arena into the policy arena in advocating an upper bright line value of 0.070 ppm for the primary standard. That value represented the personal judgment of the ozone panel members, not just their interpretation of the science. As we have already heard, the Administrator has the exclusive responsibility and authority for setting the standards.

The law purposefully calls for a Clean Air Scientific Advisory Committee, and I underscore advisory. It does not call for a clean air standard setting committee. I commend to everyone a reading of the opinion of Supreme Court Justice Breyer, when he concurred with the majority in saying that economics should not be considered in setting the standard. But he also gave some very good advice in terms of a common-sense approach to deciding what risks are acceptable in the world in which we live and for deciding how low is low enough in setting the standards.

I think that the ozone panel was offering their collective opinion as to the level of the standard and they went beyond simply offering a scientific opinion. I think that it is humbling for scientists to acknowledge the distinction between science and personal policy preferences. But in fact, we as scientists must do that and accept the fact that at some point the science stops and then a policy decision must be made informed by that science.

Thank you for the opportunity to testify before your committee. I look forward to your questions.

[The prepared statement of Mr. McClellan follows:]

STATEMENT OF

Roger O. McClellan
Advisor, Toxicology and Human Health Risk Analysis
Albuquerque, New Mexico

Before the

Subcommittee on Public Sector Solutions to Global Warming, Oversight and Children's Health Protection
Committee on Environment and Public Works
United States Senate

Oversight Hearing on Science and Environmental Regulatory Decisions

May 7, 2008

Good Morning, Chairman and Members of the Committee. Thank you for the invitation to present my views on the use of science in making environmental regulatory decisions. My testimony will focus on two recent examples involving the setting of National Ambient Air Quality Standards (NAAQS), commenting first on the Particulate Matter Standard and then on the Ozone Standard.

My biography is attached to this statement (Attachment 1). Since 1999, I have served as an Advisor to public and private organizations on issues related to air quality in the ambient environment and workplace drawing on more than 45 years of experience in comparative medicine, toxicology, aerosol science, and risk analysis. Prior to 1999, I provided scientific leadership for two organizations – the Chemical Industry Institute of Toxicology (1988-1999) in Research Triangle Park, NC and the Lovelace Inhalation Toxicology Research Institute (1966-1988) in Albuquerque, NM. Both organizations, under my leadership, earned an international reputation for developing scientific information under-girding occupational and environmental health standards.

The testimony I offer today also draws on my experience serving on numerous scientific advisory committees. This has included service on many EPA Scientific Advisory Committees from the origin of the Agency to the present time. In 1977-1978, I chaired an *ad hoc* committee which reviewed the scientific criteria for setting the original NAAQS for lead. That *ad hoc* committee preceded the authorization in the Clean Air Act of the Clean Air Scientific Advisory Committee (CASAC) and in many ways, served as a template for CASAC's early operation. I have served on CASAC, including service as chair from 1988 to 1992, and on CASAC Panels that have considered all the criteria pollutants at various times. I served on both the CASAC Particulate Matter Panel and the CASAC Ozone Panel that reviewed the basis for revision of the NAAQS for particulate matter and ozone in the late 1990s. I also served on the most recent CASAC Particulate Matter Panel related to the 2006 revision of the Particulate Matter Standard. I did not serve on the CASAC Ozone Panel that reviewed the basis for the 2008 revision of the Ozone Standard. However, I have closely followed the current NAAQS Ozone review process from its inception in September 2000 the present. The testimony I offer today reflects my own views on the role of science and judgment in setting NAAQS standards. In Attachment 2, I briefly review the NAAQS process as background for my comments.

Let me first focus on the recent review of the Particulate Matter Standard directing specific attention to the $PM_{2.5}$ indicator, also referred to as the fine particle indicator. In the Proposed Rule (January 17, 2006), Administrator Stephen Johnson solicited comments on the setting of a $PM_{2.5}$ standard with a 24-hour averaging time in the range of 25-65 $\mu g/m^3$ and an annual standard in the range of 12-15 $\mu g/m^3$. The CASAC Particulate Matter Panel recommended that the 24-hour averaging time standard be set in the range of 30-35 $\mu g/m^3$ and the annual standard be set at 13-14 $\mu g/m^3$. I, and one other CASAC Particulate Matter Panel member, disagreed with the CASAC recommendation and offered dissenting views. In my opinion, the decision as to where to set the annual standard in the range of 12-15 $\mu g/m^3$ was a policy judgment and not a decision that could be made exclusively based on scientific information. I took strong

exception to the view that science, in the absence of judgment, would support a 14 $\mu g/m^3$ standard and not support a 15 $\mu g/m^3$ standard.

Ultimately, Administrator Johnson issued a Final Rule (October 17, 2006) reducing the 24-hour averaging time standard from 65 to 35 $\mu g/m^3$ and retaining the annual standard at 15 $\mu g/m^3$. In my opinion, this was a reasonable policy choice from among an array of acceptable science-based options. I was disappointed that some of the CASAC Particulate Matter Panel characterized Administrator Johnson's choice as being a political choice that ignored the science. In my opinion, the CASAC Particulate Matter Panel failed to recognize that the selection of a specific numerical standard for any criteria pollutant, including $PM_{2.5}$, reflects a policy judgment informed by science. The Panel's advocacy of an annual standard of 13-14 $\mu g/m^3$ represented their personal policy preferences, although they presented the choice as those it was compelled by the science.

Let me now turn to the role of science and judgment in the "Final Rule for the National Ambient Air Quality Standard for Ozone" announced on March 12, 2008 by EPA Administrator Johnson. This Final Rule revises the 1997 Standard and concludes a process begun in September 2000. Throughout the review process, there was debate over the numerical level of a revised standard. In my view, much of the debate was premature and focused on the desire of various parties for lowering of the standard even before the review of the science was complete. This resulted in a blurring of the boundary between the role of science and judgment in the setting of the standard.

As required by a Court Decree, the EPA published a Proposed Rule on July 11, 2007 and requested public comments on anticipated action in issuing a Final Rule for the ozone standard. Release of the Proposed Rule intensified the debate over the numerical level of the standard and continued to blur the distinction between the role of science and judgment in the setting of the standard. Numerous comments were submitted to the official ozone docket. I submitted my personal comments[1] to the ozone docket and also joined with 9 of my scientific colleagues in submitting a document[2] – "Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone" to the docket. The debate over the numerical level of the standard continues even today as evidenced by this Hearing.

Much of the debate fails to acknowledge that the setting of the standard involves policy judgments informed by science. The debate has included repeated reference to the CASAC Ozone Panel recommendation that the primary standard be set within a specific narrow numerical range, i.e. 0.060 – 0.070 ppm. In my opinion, the CASAC Ozone Panel moved from the Science arena into the Policy arena in advocating an upper bright line value of 0.070 ppm for the primary standard. That value represents the personal judgment of the Ozone Panel Members, not just their interpretation of the science. It is my opinion that the CASAC Particulate Matter Panel never adequately communicated the extent to which their opinions on the numerical level of the standard communicated to the Administrator represented both their interpretation of the science and their personal policy judgments on the numerical level of the standard.

The EPA Administrator, under the authority of the Clean Air Act, has the exclusive responsibility and authority for making policy judgments, informed by science, in setting the NAAQS for criteria air pollutants. Supreme Court Justice Stephen Breyer, in the landmark case, Whitman versus American Trucking Association (531 U.S. 457, 2001), offered "common sense" guidance for setting the standards for criteria pollutants such as ozone (Attachment 3). Justice Breyer expressed the opinion that while the Administrator cannot consider cost in setting air quality standards for the criteria pollutants, the EPA Administrator need not set standards at zero risk. He advised the Administrator to use judgment in a "comparative health" context when "deciding what risks are acceptable in the world in which we live."

In short, Justice Breyer recognized that every day life carries with it a variety of risks. Justice Breyer's opinion provides "common sense" guidance for deciding how low is low enough in setting air quality standards – the numerical level of the standard and the associated acceptable risk level, even if not specifically articulated, are policy judgments that should be informed by science. In my opinion, the Administrator could have made a policy judgment, informed by science, with selection of a numerical value for the ozone primary standard as high as the 1997 primary standard of 0.08 ppm. His selection of a lower value was consistent with the original advice of his own staff – 0.075 ppm up to a level slightly below the current standard.

In my own comments to the Ozone Docket[1], I reviewed the science available on the health effects of ozone. In my comments, I noted the substantial uncertainty and variability in the findings of an increase in common health effects with ozone exposure in the range of the current standard and below. These scientific uncertainties were also detailed in the comments[2] that I and nine of my colleagues submitted to the Docket. Both sets of comments emphasized that the selection of any specific numerical standard should be a policy judgment that is informed by science.

The CASAC Ozone Panel, in proposing a bright line upper limit of 0.070 ppm, offered their collective judgment on, in the words of Justice Breyer, – "what risks are acceptable in the world in which we live." That was their policy choice, it should not be postured as being exclusively science based. Science alone can never provide a basis for deciding how low is low enough, policy judgments are always required in deciding "what risks are acceptable." Any specific numerical value for the standard has an associated implied "acceptable risk value," even if the level of acceptable risk has not been explicitly stated.

The CASAC Ozone Panel's letter to the Administrator dated April 7, 2008, commenting on the Final Rule, continues to suggest that somehow science and scientists alone can establish the appropriate numerical level of the NAAQS for ozone. In that letter, the CASAC Ozone Panel again failed to clarify the distinction between their interpretations of the science and their policy judgment in offering an opinion on the numerical level of the ozone standard. The Panel should have clearly acknowledged that the numerical level they have advocated reflects their personal policy preferences. Likewise, in arguing for "further lowering the national ambient ozone standards," the

Panel fails to acknowledge that this is their collective policy outcome wish that goes well beyond considering just the available scientific information. How low is low enough for the ozone standard is ultimately a policy judgment informed by scientific information and analysis. The Clean Air Act clearly specifies that the EPA Administrator has the exclusive authority and responsibility for using judgment in the setting of the Standard.

Without question, the Administrator, in setting the standard, should consider scientific advice received from many parties, including the special advice provided by the Clean Air Scientific Advisory Committee. However, it is clear that the Clean Air Act calls for an Advisory Committee and not a Clean Air Standard Setting Committee. This places a special responsibility on the Committee to distinguish between their scientific advice and their personal policy judgments as to the numerical level of the Standard.

It is noteworthy that the Final Rule for the Ozone Standard states – "the Administrator observes that he reaches a different policy judgment than the CASAC Panel based on apparently placing different weight in two areas: --" The Final Rule goes on to detail these differences and states – "and fully considering the scientific and policy views of CASAC, the Administrator has decided to revise the level of the primary 8-hour O_3 standard to 0.075 ppm." Without question, the Final Rule Ozone Rule clearly acknowledges that the CASAC Ozone Panel offered both their scientific and policy views. It is unfortunate that the CASAC Ozone Panel did not make this important distinction in its communications to the Administrator in their public statements on the Final Rule.

In closing my testimony, I want to make several important points. As a scientist, I am a strong advocate of conducting research that will provide an improved scientific basis for the policy judgments that are essential in the setting of NAAQS for pollutants as well as many other policy decisions that have important implications for the health and well being of Society. However, I am concerned about the extent to which many scientists, and I should add, Special Interest Groups, frequently champion particular courses of action purporting that the course of action being advocated is being driven exclusively by the science. The Special Interest Groups range from environmental and disease-oriented groups to industry coalitions. Each group postures that good science is driving their advocacy position. Each group fails to recognize that science alone does not provide the answer, well-reasoned judgments are an essential ingredient for making decisions.

I am concerned as a scientist, and more broadly as a private citizen, that single issue science used as a tool for advocacy can lead to bad decisions that may not be in the best interest of Society as a whole. For example, when the Administrator makes decisions on air quality standards I would hope the Administrator is also considering the overall health of Society and not focusing exclusively on a single pollutant in isolation. In my opinion, the kind of "common sense" approach that Justice Breyer offered should be used. My concerns about the role of science and judgment in making policy decisions extends to a broad range of societal issues that are impacted by scientific information.

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ATTACHMENT 1

BIOGRAPHY

ROGER O. McCLELLAN, DVM, MMS, DSc (Honorary), Dipl-ABT, Dipl-ABVT, Fellow-ATS

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ROGER O. McCLELLAN is currently an advisor to public and private organizations on issues concerned with inhalation toxicology and human health risk analysis. He received his Doctor of Veterinary Medicine degree with Highest Honors from Washington State University in 1960 and a Master of Management Science degree from the University of New Mexico in 1980. He is a Diplomate of the American Board of Toxicology, a Diplomate of the American Board of Veterinary Toxicology and a Fellow of the Academy of Toxicological Sciences.

He served as Chief Executive Officer and President of the Chemical Industry Institute of Toxicology (CIIT) in Research Triangle Park, NC from September 1988 through July 1999. The CIIT continues today as The Hamner Institute. During his tenure, the organization achieved international recognition for the development of science under-girding important environmental and occupational health regulations. Prior to his appointment as President of CIIT, Dr. McClellan was Director of the Inhalation Toxicology Research Institute, and President and Chief Executive Officer of the Lovelace Biomedical and Environmental Research Institute, Albuquerque, New Mexico. The Institute continues operation today as a core element of the Lovelace Respiratory Research Institute. During his 22 years with the Lovelace organization, he provided leadership for development of one of the world's leading research programs concerned with the toxic effects of airborne radioactive and chemical materials. Prior to joining the Lovelace organization, he was a scientist with the Division of Biology and Medicine, U.S. Atomic Energy Commission, Washington, DC (1965-1966), and Hanford Laboratories, General Electric Company, Richland, WA (1959-1964). In these assignments, he was involved in conducting and managing research directed toward understanding the human health risks of internally deposited radionuclides.

Dr. McClellan is an internationally recognized authority in the fields of inhalation toxicology, aerosol science and human health risk analysis. He has authored or co-authored over 300 scientific papers and reports and edited 10 books. In addition, he frequently speaks on risk assessment and air pollution issues in the United States and

abroad. He is active in the affairs of a number of professional organizations, including past service as President of the Society of Toxicology and the American Association for Aerosol Research. He serves in an editorial role for a number of journals, including continuing service as Editor of Critical Reviews in Toxicology. He serves or has served on the Adjunct Faculty of 8 universities.

Dr. McClellan has served in an advisory role to numerous public and private organizations. He has served on senior advisory committees for 8 federal agencies. He is past Chairman of the Clean Air Scientific Advisory Committee, Environmental Health Committee, Research Strategies Advisory Committee, and Member of the Executive Committee, Science Advisory Board, U. S. Environmental Protection Agency; Member, National Council on Radiation Protection and Measurements; Member, Advisory Council for Center for Risk Management, Resources for the Future; a former Member, Health Research Committee, Health Effects Institute; and service on National Academy of Sciences/National Research Council Committees on Toxicology (served as Chairman for 7 years), Risk Assessment for Hazardous Air Pollutants, Health Risks of Exposure to Radon, Research Priorities for Airborne Particulate Matter, as well as the Committee on Environmental Justice of the Institute of Medicine. He has recently completed a term on the Board of Scientific Councilors for the Centers for Disease Control and Prevention for Environmental Health Research and the Agency for Toxic Substances and Disease Registry. He is currently serving on the National Institutes of Health Scientific Advisory Committee on Alternative Toxicological Methods and the National Aeronautics and Space Administration Lunar Airborne Dust Toxicity Advisory Group.

Dr. McClellan's contributions have been recognized by receipt of a number of honors, including election in 1990 to membership in the Institute of Medicine of the National Academy of Sciences. He is a Fellow of the Society for Risk Analysis, the American Association for Aerosol Research, the Health Physics Society, and the American Association for the Advancement of Science. In 1998, he received the International Achievement Award of the International Society of Regulatory Toxicology and Pharmacology of standing contributions to improving the science used for decision making and the International Aerosol Fellow Award of the International Aerosol Research Assembly for outstanding contributions to aerosol science and technology. He received the Society of Toxicology 2005 Merit Award for a distinguished career in toxicology. In 2005, The Ohio State University awarded him an Honorary Doctor of Science degree for his contributions to the science under-girding improved air quality. In 2006 he received the New Mexico Distinguished Public Service Award. He has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment and air pollution, and in the management of multidisciplinary research organizations. He is a strong advocate of risk-based decision-making and the need to integrate data from epidemiological, controlled clinical, laboratory animal and cell studies to assess human health risks of exposure to toxic materials.

ATTACHMENT 2

Setting National Ambient Quality Standards

Each NAAQS consists of four elements: (a) an indicator (such as ozone for photochemical oxidants, (b) an averaging time (such as 8 hours), (c) a numerical level (such as 0.08 ppm ozone averaged over 8 hours), and (d) a statistical form (such as the annual fourth-highest daily maximum 8-hour average concentration, averaged over 3 years.

Under the Clean Air Act, the EPA Administrator is required to review the NAAQS for the criteria pollutants at 5-year intervals to evaluate whether or not the four elements of the NAAQS are still deemed to be acceptable based on current scientific knowledge as it applies to the assessment of public health risks. In practice, the interval between reviews has been longer. The process for review and promulgation of a NAAQS, either continuation of the existing standard or establishing a new NAAQS, consists of multiple phases. The initial phase, which is obviously on-going, consists of conduct of research on the various criteria pollutants. This includes a broad spectrum of activities; understanding emissions of pollutants, transport and transformation of pollutants in the atmosphere, ambient measurements of pollutants, estimation of personal exposures to pollutants, assessment of toxic effects and mechanisms of action in cells, tissues and animals, conduct of controlled exposure studies to pollutants in human volunteers and epidemiological investigations of human populations. Most of the research is funded by the EPA, some in the Agency's own laboratories and some in academic and other laboratories, the National Institutes of Health and, to a modest extent, private industry. The dominance of federal government support of research on criteria pollutants relates to their effects being of broad societal concerns with the pollutants, by and large, having no unique industrial emission source.

The findings of this research are used by the EPA's Office of Research and Development to prepare a criteria document (CD). Each CD traditionally has been essentially an encyclopedia of everything known about a given criteria pollutant and is used as a basis of information for the preparation of a Staff Paper (SP) by the EPA's Office of Air Quality Planning and Standards. This is a Policy Assessment of Scientific and Technical Information; in short, an integration and synthesis of the information in the CD that is most relevant to setting the four elements of a NAAQS. In recent years, the Staff Papers have made substantial use of risk assessments for the criteria pollutant being considered. These risk assessments have been conducted by a single EPA Contractor organization. The various versions of the CD and SP are released to the public with an invitation to provide comments as a basis for improving the documents.

Throughout this process, a Clean Air Scientific Advisory Committee Panel, operating as an element of the EPA's Science Advisory Board, is involved in reviewing and advising on the scientific content of both the CD and the SP, including the related risk assessment. This has typically involved several revisions. Prior to the current cycle of ozone review, the CASAC Panel sent a closure letter to the EPA Administrator when

the CASAC was of the opinion that the revised documents were suitable for use by the Administrator in promulgating a NAAQS. In the current ozone review, the "closure letter" process was abandoned. Instead, the current CASAC Ozone Panel has focused on offering a consensus opinion.

At the next step, the Administrator proposes, via a Federal Register Notice, a NAAQS including specific proposals for each of the four elements of the NAAQS; the indicator, averaging times, numerical levels and statistical forms. Comments are solicited from the Public with the opportunity to submit written comments to a specific Docket. The Administrator, acting under a Consent Decree, signed a "Proposed Rule."

The next step is for the Administrator to promulgate a NAAQS consisting of the four elements discussed previously. I purposefully do not use the phrase – "final step," because the Courts may have a role in deciding whether the Administrator's proposed NAAQS for Ozone will stand. The NAAQS are to be based on the available scientific information reviewed in the CD and SP and summarized in the notice of proposed rules. The primary, health-based NAAQS are to be set at a level that will protect public health, including sensitive populations, with an adequate margin of safety. The Administrator is precluded from considering cost in the setting of the NAAQS.

At this point, I would like to emphasize that there exists no absolute and unambiguous scientific methodology that can determine which specific indicator, precise averaging time, numerical level or statistical form will be adequate to protect public health. The available scientific information can inform the NAAQS decisions, however, the Administrator must ultimately use policy judgment in making decisions on each of the four elements from among an array of scientifically acceptable options including consideration of their attendant scientific uncertainties. Beyond the language in the Clean Air Act, Justice Breyer in Whitman v. American Trucking Association (531 U.S. 457, 473) has given very useful guidance for the Administrator in exercising policy judgment in the setting of NAAQS (see Attachment 3).

ATTACHMENT 3

Justice Breyer on Using Policy Judgment (from Whitman v. American Trucking Association, 531 U.S. 457, 473)

In setting standards that are "requisite" to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more or less stringent than necessary for these purposes. *Whitman v. American Trucking Associations*, 531 U.S. 457, 473. In establishing "requisite" primary and secondary standards, EPA may not consider the costs of implementing the standards. *Id.* At 471. As discussed by Justice Breyer in *Whitman v. American Trucking Associations*, however, "this interpretation of § 109 does not require the EPA to eliminate every health risk, however slight, at any economic cost, however great, to the point of "hurtling" industry over "the brink of ruin," or even forcing "deindustrialization." *Id.* At 494 (Breyer, J., concurring in part and concurring in judgment) (*citations omitted).* Rather, as Justice Breyer explained:

> *"The statute, by its express terms, does not compel the elimination of all risk; and it grants the Administrator sufficient flexibility to avoid setting ambient air quality standards ruinous to industry.*
>
> *Section 109(b)(1) directs the Administrator to set standards that are "requisite to protect the public health" with "an adequate margin of safety." But these words do not describe a world that is free of all risk – an impossible and undesirable objective. (citation omitted). Nor are the words "requisite" and "public health" to be understood independent of context. We consider football equipment "safe" even if its use entails a level of risk that would make drinking water "unsafe" for consumption. And what counts as "requisite" to protecting the public health will similarly vary with background circumstances, such as the public's ordinary tolerance of the particular health risk in the particular context at issue. The Administrator can consider such background circumstances when "deciding what risks are acceptable in the world in which we live." (citation omitted).*
> *The statute also permits the Administrator to take account of comparative health risks. That is to say, she may consider whether a proposed rule promotes safety overall. A rule likely to cause more harm to health than it prevents is not a rule that is "requisite to protect the public health." For example, as the Court of Appeals held and the parties do not contest, the Administrator has the authority to determine to what extent possible health risks stemming from reductions in tropospheric ozone (which, it is claimed, helps prevent cataracts and skin cancer) should be taken into account in setting the ambient air quality standard for ozone. (Citation omitted)/*
>
> *The statute ultimately specifies that the standard set must be "requisite to protect the public health" "in the judgment of the Administrator," § 109(b)(1), 84 Stat. 1680 (emphasis added), a phrase that grants the Administrator considerable discretionary standard-setting authority.*

The statute's words, then, authorize the Administrator to consider the severity of a pollutant's potential adverse health effects, the number of those likely to be affected, the distribution of the adverse effects, and the uncertainties surrounding each estimate. (citation omitted). They permit the Administrator to take account of comparative health consequences. They allow him to take account of context when determining the acceptability of small risks to health. And they give her considerable discretion when she does so.

This discretion would seem sufficient to avoid the extreme results that some of the industry parties fear. After all, the EPA, in setting standards that "protect the public health" with "an adequate margin of safety," retains discretionary authority to avoid regulating risks that it reasonably concludes are trivial in context. Nor need regulation lead to deindustrialization. Pre-industrial society, was not a very health society; hence a standard demanding the return of the Stone Age would not prove "requisite to protect the public health."

Responses by Roger O. McClellan to Additional Questions
From Senator Inhofe

1. Dr. McClellan, I am very interested in your comments on how "Many scientists, including special interest groups, frequently champion particular courses of action purporting that the course of action being advocated is being driven exclusively by science." I think that quote gets to the heart of the issue we are addressing here today, blurring the line between policy decisions and true science. How do you suggest the Agency better distinguish between the two?

Answer: An excellent starting point is for the U.S. Environmental Protection Agency to acknowledge that for all its activities that lead to regulatory decisions, such as the setting of National Ambient Air Quality Standards, the science should be integrated and synthesized to inform policy decisions. Moreover, it should explicitly acknowledge that the science alone is not sufficient for decision-making and, especially, the establishment of acceptable levels of risk. Judgment is inherently involved.

The Agency should clearly relate this fundamental concept to Advisory Committees and ask the Committees to clearly identify science-based conclusions and, if they offer either a personal or collective judgment as to regulatory actions, that these judgments be identified. The Agency should indicate its requirements for exposition of the science and at the same time make it clear that if personal or collective policy judgments are offered, the Agency will consider these advisory opinions that involve judgment but not be bound by them. In most cases, legislation requires that the Administrator make policy judgments – these judgments cannot be delegated to Advisory Committees.

2. Dr. McClellan, we have heard criticism of the EPA Administrator's use of the scientific recommendations of CASAC in setting the recent PM and ozone standards. Can you further comment on the role of CASAC as an Advisory Committee and not a Standard Setting Committee? Doesn't the Clean Air Act give the Administrator the exclusive authority and responsibility for using judgment in setting the standard?

Answer: The Clean Air Act (CAA) requires the Administrator to take a number of actions including the setting of National Ambient Air Quality Standards (NAAQS). The CAA explicitly identifies these actions as being the responsibility of the EPA Administrator and has no provision for delegating the responsibility of NAAQS to any

committee including the Clean Air Scientific Advisory Committee (CASAC). The CAA does require the Administrator to seek the advice of CASAC. In my opinion, the CASAC, in both the Particulate Matter and Ozone NAAQS setting processes, has over-stepped its statutory bounds by cajoling the Administrator when he did not precisely accept their advice which was a blending of science and their personal and collective policy judgments. CASAC is an advisory committee and not a standard setting committee.

3. Dr. McClellan, how does Dr. Thurston's testimony that the Clean Air Act stipulates the Administrator must choose a more stringent standard in the face of uncertainty to ensure a margin of safety square with Justice Breyer's common sense guidance that he outlined in the 2001 American Trucking case for deciding how low is low enough in setting air quality standards?

Answer: In my view, the thoughtful opinion of Supreme Justice Breyer should clearly take precedence over the personal opinions of individual scientists like Dr. Thurston. Dr. Thurston's views would appear to be influenced by the outcome he desires – a more stringent NAAQS for ozone rather than thoughtful interpretation of the Clean Air Act as offered by the distinguished Supreme Court Justice Breyer.

Senator WHITEHOUSE. Thank you, Dr. McClellan.
Dr. RHOMBERG.

STATEMENT OF LORENZ R. RHOMBERG, PH.D., PRINCIPAL, GRADIENT CORPORATION

Mr. RHOMBERG. Thank you for the opportunity to address the Committee. I am Dr. Lorenz Rhomberg, a Principal at Gradient Corporation, an environmental consulting firm based in Cambridge, Massachusetts.

I have been asked to address the use of science in the development of guidance for conducting risk assessments for children's exposures. In 2003, EPA came out with its draft supplemental guidance for assessing susceptibility from early life exposures to carcinogens and made that draft available for public comment. I was commissioned by a trade association to evaluate the scientific basis of the EPA's drafts and to make oral public comments at the SAB meeting in May 2003 at which that draft was reviewed. My comments were supportive of the EPA draft on some items, but also noted that what appeared to be technically inappropriate formulas that were used in some cases for calculating the observed differences in sensitivity between young animals and adults in chemical bioassay experience.

I suggested alternative approaches to this calculation. In the end, when the final revised document was published by EPA, my suggestions had been essentially applied, resulting, in my view, in a sounder scientific basis for the EPA policy decisions that resulted. But in that process, my comments, like those of the other public commenters, was not simply urging what the policy ought to be in the end, what the standard should be or what the final decision should be. Instead, it was a technical comment on how the available scientific information should be interpreted and brought to bear. My comments, as others, pulled out the scientific evidence to support those points so they could be debated.

But even with that scientific debate that occurred, there was no single best or correct scientific answer to the questions at hand that emerged in that debate, and no single answer was recommended by the SAB, because it couldn't be. The SAB members and later the EPA policy formulators that drew on those recommendations had to arrive at a policy about relative sensitivity assumptions to be applied to other chemicals, not the ones that were being examined in the SAB meeting. That policy had to be supported as well as possible by scientific understanding of the data at hand. That is, a policy guided by science but not, because it is rarely possible to do so, identified by science.

In the end, it is the collective judgment of knowledgeable and appropriately trained people, the whole span of the mainstream opinion of the field as a whole, that is what science has to say on a subject, and not the opinion of any individual scientist, no matter how well qualified that scientist may be, whether they are an EPA staff member or they are an EPA manager or a political appointee or an external scientist. What science has to say is not something that any one person dictates, it is what the science field as a whole thinks.

I would like to offer some general thoughts on the use of science in setting environmental standards. Many of our environmental laws are cast using the implicit presumption that there is a clear scientific answer to the key questions and that any competent scientist acting forthrightly and in good faith will look at the evidence and come to essentially the same conclusion.

In this setting, the agency scientists' evaluation serve as a surrogate for the opinions of the scientific world as a whole, presuming that any competent scientific investigation would yield a definitive answer that would be just about the same. Under this view, the science advisory board or other high level peer review is mostly to provide due process and oversight to ensure that the investigations and findings are indeed made competently and in good faith.

The difficulty with this view is that scientific answers to key questions are really not that clear, and different interpretations with very different risks of management consequences can be made. We always have to face the incompleteness and uncertainty in data, even contradictions among the data that we have to evaluate.

But the debate about these things is an inherent part of how science operates. It is not just a reflection of the failure of the science, we don't have the right things on the table or the motivation of the participants. It is the method of science to try to pick apart arguments, to separate what you think about things from the motivations and the status and the position of the person who is propounding them. In short, debate about science, its studies, their interpretations, their bearing on the risk assessment questions, is not evidence that the science is being manipulated. That is the science. That is the science happening. If you want science-based regulation, then we want that debate to occur.

The question then is how do we structure that debate to be helpful to the risk assessment policy process. There are two questions. One is, how to ensure that the debate focuses on legitimate scientific issues and not specious arguments, and the other is how to make decisions in the face of that. In my view, the way to do this is to have a very transparent debate, put things out on the table, including a separate step where the science is evaluated and there is a scientific advisory board review of the science that doesn't look at what the SAB thinks is the right standard to apply here, but rather has that assessment of the full body of opinion of science as a whole, with its alternatives and uncertainties in there, being put on the table. And then a second step where we decide to do that, justifying the choices that we make in view of those questions.

By putting these things on the table, the uncertainties in the first place and the justifications for decisions in the second place, so that they can be seen and criticized by others, it will be then hard to manipulate this process, because any manipulation would be evident.

Thank you.

[The prepared statement of Mr. Rhomberg follows:]

Written Testimony of

Lorenz R. Rhomberg, PhD
Principal, Gradient Corporation, Cambridge, MA

before the
Subcommittee on Public Sector Solutions to Global Warming, Oversight, and Child Protection
Senate Environment and Public Works Committee

Hearing entitled, *Oversight Hearing on Science and Environmental Regulatory Decisions*

May 7, 2008

I am Dr. Lorenz R. Rhomberg, a Principal at Gradient Corporation, an environmental sciences consulting firm based in Cambridge, Massachusetts. Gradient Corporation provides scientific analysis and technical consulting services to a variety of clients in the public and private sectors, including municipal and state government, the federal government, trade associations, law firms, and industrial companies. I should disclose that I have had several contracts with the US Environmental Protection Agency over the years to conduct scientific research and analysis, and I have two current open contracts with that agency. Today, I am appearing at the invitation of the Subcommittee, and I am representing solely my own point of view.

Before joining Gradient Corporation, from 1994 to 1999, I was on the faculty of the Harvard School of Public Health, doing research and teaching regulatory toxicology and risk assessment. Before that, from 1984 to 1994, I was a scientist at the US Environmental Protection Agency, first in the Office of Toxic Substances and later in the Office of Research and Development (in EPA headquarters in Washington) where I worked on chemical risk assessments and on risk assessment methodology improvement issues. I hold a doctorate in biology from Stony Brook University.

I am currently a member of the National Research Council's Standing Committee on Risk Assessment Issues and Reviews, and in the past I have served on several other committees convened by the National Academy, including as chair of the Committee on Strategies to Protect the Health of Deployed U.S. Forces. I was commissioned by the Presidential/Congressional Commission on Risk Assessment and Risk Management (which was mandated under the Clean Air Act Amendments of 1990) to write a report on differences among federal agencies in how human health risk assessments are conducted, addressing how such differences relate to differences the mandates of the various authorizing statutes. On several

occasions I have served as an *ad hoc* member of the EPA Pesticides Office's Scientific Advisory Panels. I am a past President of the Society for Risk Analysis New England Chapter and a past councilor of the national Society for Risk Analysis. I am the author or editor of several books and monographs and have published over 60 scientific papers and book chapters on the analysis of human health risks from environmental chemicals.

Children's Risk

I understand that today's hearing is an oversight hearing and that the general topic is the EPA's use of science in its regulatory decisions, and specifically whether undue influences exist on how that science is presented, or how it is used or not used in coming to conclusions about regulatory standards that the agency is charged with making. More specifically, I have been asked to address the use of science in the development of guidance for conducting risk assessments of children's exposures. I should say that this is not my main area of scientific focus, and my participation in the process of developing guidance has been limited. I have one technical paper, published in 2002, that investigates how the faster pace of physiological processes in children vis-à-vis adults affects the internal tissue levels of a chemical for a given amount of daily exposure; this paper was produced without any funding and at no one's behest, simply as a contribution to the field by writing up for publication a talk that I was invited to give at a scientific meeting on risk assessment issues convened by the University of Medicine and Dentistry of New Jersey.

In 2003, EPA came out with its draft *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposures to Carcinogens*, and made the draft available for public comment. I was commissioned by an industrial trade association to evaluate the scientific basis of the EPA's draft guidance and to make oral public comments during the public comment period of the EPA Science Advisory Board (SAB) meeting of May 13-14, 2003, at which the SAB reviewed the draft. My comments were supportive of the EPA draft on some items but also noted that what appeared to be technically inappropriate formulas were used in calculating the observed sensitivity differences to cancer induction in young experimental animals *versus* adults for the same chemical, especially when applied to bioassays that had exposure to young animals continued through adulthood. I suggested an alternative approach to this calculation. In the end, when the final revised document was published by EPA, my suggestions had substantially been applied, resulting (in my view) in a sounder scientific basis for the EPA's policy decisions on how to treat early-life exposures to potential carcinogens in the risk assessment process.

This is not to say that I agree with every use of science in the final Supplemental Guidance document, for there are parts of the analysis with which I would continue to take issue. Quite a few other commenters, from all quarters, also made comments and presented their scientific arguments for them, and there was debate among the members of the Science Advisory Board about the merits of the various arguments, with evidence and counter-evidence discussed publicly. There are several points about this process that bear comment.

First, each comment was not simply an urging on what the final policy decision should be; instead, each was a technical comment on how the available scientific information should interpreted and brought to bear. Each commenter supported his or her proposal by adducing scientific evidence and conducting analysis, and the discussion focused on the strengths and weaknesses of this support and the consideration of the scientific plausibility of alternative explanations for the same scientific data that would imply different policy consequences.

Second, even with the scientific debate that occurred, there was no single evident "best" or "correct" scientific answer to the questions at hand (about relative sensitivity of young individuals and adults to carcinogenic chemicals). Extracting an unambiguous measure of relative sensitivity from the data that are available is not straightforward; many of the studies are ill suited to separate such sensitivity differences from the potential contribution of other factors, and in any case, data are available on a limited number of chemicals, with different chemicals showing different results. The SAB members – and later, the EPA policy formulators who drew on the SAB recommendations – had to arrive at a policy about relative sensitivity assumptions to be applied to *other* chemicals not among those with current data, and that policy had to be reasonably likely to be approximately correct and as well supported as possible by the scientific understanding of the data at hand – that is, a policy supported by science, but not (because to do so is not possible) identified by science.

Third, not all the alternative interpretations were equally supportable. Some proposals by commenters were rejected by the SAB as insufficiently supported, even though no single best answer was available. Deciding which interpretations are sufficiently supported is a matter of scientific judgment, which in this case was invested in the SAB and ultimately in the EPA policy formulators, acting on the SAB recommendations.

Fourth, individual participants in the debate, including the public commenters and the SAB members, had differing views on the relative bearing of different studies and the relative merits of the alternative scientific arguments. I presume they were acting in good faith, and this shows that it is the *collective* scientific judgment of knowledgeable and appropriately trained people – the span of mainstream opinion of the field as a whole – and not any individual's scientific judgment (no matter how well qualified the individual scientist may be) that characterizes "what science has to say" on the issues. I would venture that no participant in the SAB meeting at which I commented, especially including the SAB members, would be entirely satisfied with the document that resulted, because each individual view of what constitutes the "best" scientific interpretation will vary in some regard. That is, every participant probably felt, to some smaller or larger degree, that his or her expertise was not sufficiently heeded and that the collective judgment was not the "best" one, defining "best" as the one that one would have made oneself.

General Thoughts on the Use of Science in Setting Environmental Standards

I would like to offer some general thoughts on the use of science in setting environmental standards. They stem from the above observation that science often cannot provide a definitive answer to the questions asked by the regulatory process. Because of this, scientific judgment is necessary, and so the question arises how to make a process that weighs the evidence and comes to those judgments in a way that evaluates the scientific uncertainties in good faith in a way that will be broadly acceptable and seen as legitimate.

Many of our environmental laws are cast using the implicit presumption that there are clear scientific answers to its key questions, and that any competent scientist, acting forthrightly and in good faith, will look at the evidence and come to essentially the same conclusion. This presumption leads to mandates that scientific "findings" by the Administrator of EPA (or other responsible official) that a chemical or exposure "may pose an unacceptable risk to human health or the environment" trigger some regulatory action "to protect the public health with an adequate margin of safety" (to use approximate language that many environmental statutes employ, with some variations). In such a setting, the agency scientists' evaluations serve as a surrogate for the opinions of the scientific world as a whole – presuming that any competent scientific investigation will yield a clear and rather definitive answer that all would agree upon. Under this view, the role of the Science Advisory Board or other high-level external peer review is

mostly to provide due process and oversight to ensure that the investigations and findings are indeed made competently and in good faith.

The difficulty with this view is that, in fact, the scientific answers to the key questions are not that clear, and different interpretations – with very different risk management consequences – can be made of the available data. We should distinguish between the hard facts of science – the particular data items that can often (but not always) be measured with objectivity and precision – from the application of those facts to make the generalizations and conclusions that constitute our overall scientific understanding of a chemical's potential toxicity in exposures as people actually experience them. We can say that 5 of 40 rats given 100 milligrams of a chemical per kilogram of body mass every day for 2 years developed kidney tumors, but it is very different to conclude from such data that we know the daily dose that humans would need to have in order to have a lifetime cancer risk increase of one in a million. A large part of the problem is that, from a regulatory policy point of view, we are interested in knowing about very low risks from very low exposures, and we want to characterize the levels where adverse effects do *not* happen. We cannot generally find these things out by direct observation, and so we use inferences from animal data on relatively small numbers of subjects at what are generally very high doses. It is not just that we need to extrapolate; we routinely have data that are incomplete and that contain apparent contradictions (*e.g.*, tumors in rats but not mice – should we suppose that humans are like the rats or the mice?).

The public health sciences are not the only sciences that have this distinction between the firmness of the component facts and the more debatable interpretation of those facts. Every scientific endeavor has as its aim not just the accumulation of facts but the synthesis of those facts into an understanding of the fundamental causes of the phenomena that are measured and the broader general laws that allow the facts to be used to project understanding to other instances of those phenomena. And there is always debate about those inferences. When I was a graduate student studying evolutionary biology, there was a torrid debate in the field between two schools of thought – the pheneticists and the cladists – regarding how the classification system for all the species of animals and plants should be constructed. There were fierce rivalries, institutions that were hotbeds of one or another school of thought, sparring over research funding, accusations of underhandedness in peer review and research funding, and so on. And this is a field with virtually no public policy importance or really much at stake beside academic rivalry; there was no industry interest, no NGOs, no regulators. This illustrates that the scientific controversies and questions about whose judgment is being applied exist *before* the question of stakes in the outcome is

introduced. It is not for nothing that furious debates about matters with little consequence are called "academic." But when there are stakes in the outcome, and different interested parties with different primary concerns, these pre-existing and fundamentally scientific debates get caught up with questions about the motivation of the debaters.

The debates are an inherent part of science and how it operates. They are not just a reflection of failure to get needed data or of personal pettiness or motivations of the participants. It is the method of science to be skeptical of conclusions, not accepting findings on the basis of the authority of the author but expecting to see the evidence and reasoning, and trying to pick apart that reasoning or find alternative explanations. The important point is that such actions should not automatically be ascribed to an attempt to manipulate the findings. Science depends on such skeptical inquiry to sort out the ideas that stand up to scrutiny from those that do not.

Science can and does suspend judgment on a question that is incompletely resolved, recognizing a range of tenable interpretations in view of what is known and what can be inferred. This is not to say that any alternative interpretation is equally accepted, but the array of possible interpretations, and the plausibilities assigned to them, can be maintained and continue to be addressed with further inquiry.

In sum, when the regulatory process expects science to produce clear or at least non-contentious "findings" that can be acted upon, findings that would be equally attested to by any trained investigator, and instead encounters factious debate about what the scientific data should be interpreted to mean, problems can ensue. Scientists who see the problems one way or the other tend to gravitate to the institutional places where their points of view are valued and where there is attention to seeing that certain parts of the spectrum of valid and tenable scientific opinion are not undervalued. In the resulting debate, then, arguments about the scientific status of different parts of the spectrum of interpretation -- arguments that can be and ought to be legitimately scientific -- can seem to be attempts to manipulate the outcome that would be triggered by the choice of which part of the spectrum of legitimate interpretation gets recognized as the "finding."

The question then is how can we structure the process of characterizing this more complex understanding of the findings of science in a way that informs the process of regulatory decision-making, exploring the varieties of legitimate scientific interpretation of the data at hand while preventing actual or perceived manipulation of the characterization or misrepresentation of the weight of scientific opinion.

One way to look at this is to ask who should have the ultimate say on how the span and thrust of legitimate scientific opinion is to be characterized? Should it be the individual agency scientist? No, since as I have argued, any single observer tends to have a view different than the collective opinion of the field as a whole, and it is that collective opinion that best characterizes what "science" has to say on the matter. This is not to say that the individual scientist is not entitled to his or her view. I am in favor of publication policies that allow individual agency scientists to express their views, as long as those views are clearly characterized as personal and not official. Even though this can prove awkward and can be exploited by those who want to argue that the agency is "going against its own scientists," I think it is necessary to ensure against the formation of agency "orthodoxy" and to expose any attempt to narrow the range of opinions on a question. But while individual agency scientists should expect to be heard, they should not expect to be heeded. That is, no one person has dispositive power over scientific interpretation. Unfortunately, there have been scientists in parts of the agency who see themselves as arbiters of particular issues and expect their personal expert opinions to be the sole basis of the agency's finding. No one, at any level in the agency, should have that role, and failure of the agency exactly to follow any one scientist's views should not be constituted as ignoring or silencing that person, especially when the avenue of personal publication is open.

Should the agency scientific apparatus as a whole be entrusted with the ultimate say on the characterization of science? This would entail some mechanism of internal debate and deliberation among many agency scientists and the forging of some kind of consensus that is then reported. Some such process is necessary, but in view of the hierarchical nature of the institution it would be hard not to have such a process perceived as a product of the agency's scientific management. Moreover, the span of opinion and perspective within the agency is still incomplete vis-à-vis the field as a whole. The agency has a natural set of interests and concerns, and it tends to put a big premium on precedent and consistency, which can tend to ossify its approaches to risk questions into a kind of orthodoxy. As toxicology gains more and more insight into modes of toxic action and increasingly depends on new experimental technologies, the agency's internal resources alone may have difficulty giving newer approaches their due.

There is value in getting input from the wider scientific community early on in the assessment process. Various ways to do this have been explored, such as special scientific meetings, peer-consultations, and in the case of the trichloroethylene carcinogenicity reassessment, an "external involvement group" that

included academics and industry scientists discussing advances in the science and their interpretation before the agency undertook its synthesis and characterization of the science. One need not be too afraid of including interested parties in such processes, because the purpose is to put relevant data on the table and debate it scientifically, not to come to any findings. Indeed, there is value in assuring that all points of view that will be of special concern to the various interested parties at the end of the process get put on the table for examination early on.

I would favor such an approach, with the further proviso that the agency explicitly takes on the goal of creating a characterization of the view of the scientific issues that spans the range of scientifically supportable views of the field as a whole. That is, rather than the agency scientists being presumed to embody the judgment of the large scientific world in its own internal deliberation (the model used now), the agency's task would be to anticipate how a larger deliberation of the whole of scientific opinion would characterize the science. Whether the agency has succeeded in this attempt would be judged in the first step of the peer review (as expanded upon below).

One could also assign the ultimate judgment about what science has to say on a topic to the Science Advisory Board or to another group constituted of outside experts. Currently, such groups serve mostly to review and advise, not to create. Sometimes, on particularly thorny issues, the matter has been entrusted to a committee convened by the National Research Council. But this is an inefficient and expensive process, and it raises the further issue of how such a group is to be constituted. It may be better to have a process in which the SAB has as its initial charge the process of evaluating whether the science characterization assembled by the agency is indeed a thorough and comprehensive assessment of the scientific judgments of the field as a whole. Only after this is established would the agency go back and consider how to apply this characterization of the science to the assessment of the potential hazards in question. The model here is like the one in which a separate staff paper on the scientific issues is prepared for criteria air pollutants, and the deliberation of possible regulatory actions is an explicitly separate step.

Finally, assessment of risks and consideration of potential regulatory actions that could be taken in the face of the scientific uncertainties previously characterized can then be examined. There is no getting around the fact that developing regulatory options and making decisions is more difficult when the full complexity and variety of the viable scientific interpretations are considered. But this would avoid the problem of pretending that science has dictated the specific actions when in fact it is usually

insufficiently precise in its answers to do so. It would be important for transparency and legitimacy of the decisions that the reasoning for the assessment approach and regulatory options chosen be thoroughly laid out, not just in a formulaic way, but fully attending to the possible impacts of alternative choices and the specific interpretations of evidence that support each possibility. These assessments and regulatory choices would then also be subject to SAB review.

The overarching theme of the approach I outline above is that it is good fully and transparently to lay out the entire complexity of the scientific questions that are driving a regulatory effort, and to do so before the regulatory analysis itself is conducted, so that one can avoid the tendency to narrow the view of the scientific interpretation to include only what corresponds to and (artificially) appears to point to a particular regulatory option. The guard against manipulation or undue influence in such a process is in its openness not only about the data and the process, but especially in its requirement that the reasoning and justification behind judgments be explicitly laid out for scrutiny and debate by all. Whenever a party can simply declare its judgment and expect to have the final say, there is opportunity for actual or perceived manipulation behind the scenes. An open process that is continually scrutinized and subject to criticism derives its legitimacy from the cogency of its arguments, and any misrepresentation or selective use of science to support a position is evident for all to see and hence ineffective.

There are those who would protect the integrity of the scientific deliberation by isolating it from outside influences and entrusting it only to those deemed to have pure motives and no biases. But such ideal judges do not really exist and the isolation itself leads to a narrow and unrepresentative set of interpretations. It is better to let interested parties contribute to the debate and have the ultimate review focus on whether the full complexity of the science and its alternative interpretations has been well represented in the public process.

Senator WHITEHOUSE. Thank you, Dr. Rhomberg.
Our final witness, Dr. John Balbus.

STATEMENT OF JOHN M. BALBUS, M.D., MPH, CHIEF HEALTH SCIENTIST, ENVIRONMENTAL DEFENSE FUND

Dr. BALBUS. Thank you very much for inviting me to provide testimony and bat cleanup for these very loaded bases we have this morning.

My name is John Balbus. I am the Chief Health Scientist for the Environmental Defense Fund. EDF is a non-partisan, science-based, environmental non-profit organization that partners with Government, industry and communities to find practical solutions to environmental problems. I am a physician and public health professional, a member of the board on environmental studies and toxicology at the National Research Council and a current member of NRC committees on risk assessment and nanotechnology. Since 2004, I have also been a member of EPA's Children's Health Protection Advisory Committee.

Prior to joining EDF, I was a faculty member at The George Washington University Schools of Medicine and Public Health, where I founded the Center for Risk Science and Public Health and co-founded the Mid-Atlantic Center for Children's Health and the Environment, one of 10 pediatric environmental health specialty units in the United States.

So my testimony this morning comes from the perspective of a children's environmental health advocate and member of EPA's Federal advisory committee on children's health protection. I am going to provide examples of what I consider repeated failures of the agency to use scientific evidence of children's risks from environmental agents to craft standards and procedures that adequately protect children.

The recognition of children's unique susceptibilities have led to the development of special protection for children's environmental health. President Clinton signed Executive Order 13045 in 1997 and as part of its implementation, Administrator Browner chartered the Children's Health Protection Advisory Committee in 1998. The CHPAC provides advice to EPA on science and policy issues that affect children, providing recommendations directly to the Administrator in the form of consensus letters. One of its more unique features is that this consensus is achieved among technical and policy experts from all sectors, including representatives of a variety of industries.

In my written testimony, I describe how EPA decisions on ozone and fine particulate matter standards discounted the expert advice regarding the State of the science from the EPA's advisory committees, the CASAC and the CHPAC. I also describe the lack of the scientific rigor and the justifications provided for such, and how the resulting standards failed to provide adequate protections for children.

In the interest of time, we have heard a lot about that, I won't go into more detail in these two examples.

The CHPAC has been urging the EPA since its inception to improve the understanding and management of chemical exposures in children. The Committee wrote a letter to the Administrator recom-

mending that the agency begin to gather the needed data to determine whether exposures to these chemicals are harming America's children, starting with prioritization of the inventory of chemicals in commerce under the Toxic Substances Control Act, or TSCA.

While the agency has begun to analyze data collected through the high production volume chemical challenge program and the inventory update rule to provide understanding of risks posed by existing chemicals on the market, these data are very limited in their ability to assess children's risks, and the use and interpretation of these data by the agency to date has been highly questionable. I provide more details on this in my written testimony.

Another area, starting with a pilot project in 2000, the voluntary Children's Chemical Evaluation Program's stated goal is to ensure that there are adequately publicly available data to assess risks from chemicals known to be of concern for children. Eight years now after the pilot program's initiation, of the 23 chemicals nominated for the pilot, not a very large number, because there was clear demonstration of children's exposure to these 23, 3 were never sponsored by industry, 5 never had data submitted by the industry, 3 had data but no decision on data needs has yet been made by the EPA and roughly half, 12, have completed the first tier of the program 8 years in.

A mandatory review of the pilot took place in the fall of 2006 with a summary of the mostly critical comments published in March 2007. Since then, now over a year later, there is still no indication of EPA's plans to revise, resume or replace this program. CHPAC's comments on the weaknesses of this program have not been addressed formally by the EPA. It lies fallow.

Finally, exposures to cancer-causing chemicals during childhood may sow the seeds for the development of cancer later on in life. A growing body of scientific evidence documenting this window of greater susceptibility in children led EPA scientists to recommend adjustments in the way risk assessments are performed for cancer-causing chemicals that account for this enhanced potency during this time.

But a subsequent EPA document providing more specific guidance on just how to conduct cancer risk assessments has ensured that vanishingly few cancer-causing chemicals will ever meet the criteria to be treated as more potent in children. By using the narrowest possible definition of one particular mechanism of causing cancer, the agency has in fact strayed from usual risk assessment practices and backed off from providing greater protection for children in accordance with their greater susceptibility.

Taken as individual phenomena, none of these examples might stand out as remarkable. They could be considered just the process of science. But when considered as a whole, a picture emerges of an agency whose senior leadership has repeatedly chosen to stray from the clear and science-based recommendations of expert advisory panels, public health organizations—we heard the list that wrote on the air standards—and in some cases, even its own career staff scientists in order to make policies and decisions that fall short of adequately protecting children as well as the general public.

In some cases these policies and decisions are justified on the basis of arguments that run counter to established scientific principles and the judgments of the most prominent experts in the Country. In other cases, these policies are made really with little justification whatsoever.

I applaud this Committee for its effort to shine a light on the science within EPA and greater transparency in agency decision-making. Greater adherence to the recommendations of the agency's scientific experts will help bolster public trust in the agency and lead to greater protection of children's health.

Thank you very much.

[The prepared statement of Dr. Balbus follows:]

ENVIRONMENTAL DEFENSE FUND

finding the ways that work

Testimony of John M. Balbus, MD, MPH
Chief Health Scientist
Environmental Defense Fund

Before the
Public Sector Solutions to Global Warming, Oversight, and Children's Health Protection Subcommittee
of the U.S. Senate Environment and Public Works Committee

At an Oversight Hearing on Science and Environmental Regulatory Decisions

May 7, 2008

Introduction

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A lack of care and precaution regarding the exposure of fetuses and children to potentially toxic substances has resulted in serious and at times tragic consequences, including the birth defects caused by thalidomide, cancers from diethylstilbestrol (DES), and the nearly universal lead poisoning of the 1970's and before, when the average child's blood lead level far exceeded the current CDC action level. Over this time, environmental health professionals have gained much greater awareness of the unique susceptibilities of children to environmental toxins. This awareness has been augmented by products of several dedicated research programs for children's environmental health that were funded during the 1990's and this decade.

While children are not universally more susceptible to toxic exposures than adults, several key features of their physiology and behaviors make them particularly vulnerable, especially at certain critical points in their development. Because young children's intake of air, water, and food are relatively larger than an adult's when measured per unit of body weight, they receive a greater dose of air pollution or ingested toxins than adults in the same situation. Children's organs, especially the brain, lungs, and reproductive system, undergo dramatic growth and differentiation, which leaves them more vulnerable to disruption from toxic exposures. Children typically engage in behaviors that put them in greater contact with many harmful substances, whether that means sticking their hands in their mouths, crawling on the floor, exploring dangerous environments without the maturity to recognize those dangers, or simply spending more time running around outdoors. Finally, fetuses and very young children have immature metabolism and excretion systems that can lead to unique susceptibility to certain toxic substances.

The recognition of children's unique susceptibilities, as well as the simple truth that healthy children are the foundation of a healthy and prosperous future, has led to the development of special protections for children's environmental health. President Clinton signed Executive Order 13045 in 1997 to assure that greater attention was paid to the protection of children from toxic environmental agents. Subsequently, Administrator Browner chartered the Children's Health Protection Advisory Committee (CHPAC) in 1998. The CHPAC is a body of university, state government, and industry scientists, pediatricians and nurses, environmental non-governmental organizations, and children's advocates who advise EPA on science and policy issues that affect children, providing recommendations directly to the Administrator in the

form of consensus letters. One of its more unique features is that this consensus is achieved among technical and policy experts from all sectors.

Over the past four years, the CHPAC has made recommendations to the Administrator on a number of science issues regarding the protection of children that have not been followed by the agency. These include recommendations for setting the level of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter (PM) and Ozone, relying on a voluntary program to obtain critical information on children's risks through the Voluntary Children's Chemical Evaluation Program (VCCEP), and implementing EPA's 2005 Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens in an expeditious and health-protective manner. This testimony reviews in more detail the CHPAC recommendations and their scientific basis, and the specific EPA actions that were in conflict with those recommendations. It also highlights examples of lack of care and attention to children's susceptibility to toxic insults demonstrated by recent risk characterizations of specific chemicals.

Setting the PM NAAQS to Protect Children's Health

EPA revised the NAAQS for particulate matter on October 17, 2006. The CHPAC wrote two letters to the Administrator in 2005 and 2006 calling on him to consider the health effects in children and set the standard at a level sufficient to protect them. In addition to breathing more air per pound of body weight than adults, children experience higher levels of particle deposition in their airways, which are smaller than adult airways. Thus, the dose of fine particles to the lung is likely greater in children than adults for a given concentration in the air, particularly as they are more active. The CHPAC letters documented the health effects of particulate matter on children, including exacerbation of asthma, reduced lung function, increased chronic respiratory symptoms, infant mortality, and adverse birth outcomes. These health effects had been observed in a number of studies at exposure levels near and below the proposed standards.

The final standards selected by the Administrator for annual and daily concentrations of fine particulate matter were well above those recommended by the CHPAC, and indeed, above the range recommended by the Clean Air Scientific Advisory Committee (CASAC), the federal committee charged with evaluating EPA's assessment of the science behind the standards. In justifying the selection of these higher standards, the Administrator dismissed the agency's own

quantitative risk assessment as being inappropriate for the setting of a standard. Instead, the Administrator replaced the expert judgment of the CASAC and the agency's own risk assessment with a judgment that was not science-based that the average PM air pollution concentrations in studies where health effects are observed provide the most valid basis for setting a standard. The Federal Register notice discusses in some detail the comments from the medical and public health community that urge the Administrator to set a lower standard on the basis of greater certainty and more robust data on health effects at levels below the current standard, and the opposing comments from the business and industry groups that emphasized the uncertainty inherent in the data. In justifying his decision, the Administrator reiterated the concerns of the business and industry groups, claiming that below the mean of observed concentrations, the dose response was uncertain, without specifying how far below the mean that might occur. The Agency ultimately set standards that do not provide an adequate margin of safety for infants and children.

Setting the Ozone NAAQS to Protect Children's Health

As is the case with PM, children are uniquely vulnerable to the effects of ozone air pollution because they breathe more air per unit of body weight, roughly 80% of their lung development occurs after they are born, and they typically spend much more time outdoors, often engaged in active play. The CHPAC sent two letters to Administrator Johnson that reviewed children's unique susceptibility and reviewed some of the scientific literature that provided a basis for setting a standard that would be protective of children. The letters emphasized the special susceptibility of the nation's six million children with asthma to ozone air pollution, and cited numerous studies documenting adverse effects of ozone on this vulnerable group.

The CHPAC urged the Administrator to set the ozone standard at the bottom of the range (0.060 parts per million) indicated by the CASAC. In addition, the CHPAC noted that a number of child-specific outcomes were omitted from consideration of the benefit of reducing the ozone standard, including school absences, doctor visits, medication use, and decreased resistance to infections. Furthermore, risks to children under age five were not well considered. These effects contribute to the physical and economic burden associated with children's exposure to ozone. The CHPAC asked the Administrator to consider these uncounted benefits of lowering the ozone

standard in his final decision, in order to lend more weight to the need to choose a more protective standard.

Once again, the Administrator set the ozone standard well above the CHPAC's recommended level and above the range recommended by the CASAC. The justification for doing so, published in the Federal Register on March 27, 2008,[1] was again based in part on discounting the epidemiologic evidence of harmful affects in children at levels below the revised standard. The Administrator claimed that his choice of an appropriate level to protect public health differed from the CASAC's because of the latter's overreliance on evidence from a single clinical study and the EPA risk assessment. In fact, the CASAC's letter of October 24, 2006[2] criticized the EPA staff for not paying enough attention to the epidemiologic evidence for serious health effects occurring at low levels of exposure:

"Agency staff's analyses placed most emphasis on spirometric evidence and not enough emphasis on serious morbidity (e.g., hospital admissions) and mortality observed in epidemiology studies."

While the background justification for the standard includes studies demonstrating effects in children, the Administrator, in strong disagreement with his expert advisory panel, discounts their results. He concludes:

"A standard set at a level lower than 0.075 would only result in significant further public health protection if... the reported associations observed in epidemiological studies are, in fact, causally related to O3 at those lower levels."[3]

In other words, the Administrator, going against the recommendations of the leading air quality and public health experts on his advisory committees, concluded that the substantial body of evidence from epidemiologic studies showing ozone effects at levels below 0.075 parts per

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[1] Federal Register, Volume 73, Number 60. Final Rule: National Ambient Air Quality Standards for Ozone, Environmental Protection Agency (March 27, 2008), 16435-16514.
[2] Clean Air Scientific Advisory Committee (CASAC). Letter to EPA Administrator Stephen L. Johnson, October 24, 2006. Re: Clean Air Scientific Advisory Committee's Peer Review of the Agency's 2nd Draft Ozone Staff Paper.
[3] Federal Register, Volume 73, Number 60. Final Rule: National Ambient Air Quality Standards for Ozone, Environmental Protection Agency (March 27, 2008), 16435-16514.

million could not be trusted. This results in a standard in which there is no margin of safety to protect children from ozone's damaging effects.

Protecting Children from Toxic Chemicals – the Voluntary Children's Chemical Evaluation Program and Current Chemical Risk Management Practices

The EPA is responsible for protecting the public, including the developing fetus, infants, and children, from exposure to toxic chemicals in the environment. The main regulatory authority for this responsibility comes from the 1970 statute, the Toxic Substances Control Act (TSCA). However, the large number of chemicals already in commerce before 1970 was allowed to stay on the market without any additional review or consideration. And while TSCA gives the EPA the authority to screen all new chemicals before they can be commercially sold, the reality is that this screening is limited, because there is no requirement that companies generate toxicity data before submitting these chemicals to the EPA for approval. The EPA has limited ability to request toxicity data and also has very little ability to collect data on where and how chemicals are used. While this is a problem for the general public, it is a particularly critical situation for protecting children. A number of chemicals can now be routinely found in our bodies and the bodies of children. Lead, brominated flame retardants, fluorotelomers, and bisphenol-A are well known examples. Children's health problems like autism, attention-deficit disorder, obesity, asthma, and certain cancers have risen over the past few decades, and while specific chemicals have been linked to some of these problems, there is still great uncertainty as to just what children are exposed to and what those exposures may be doing to children's health.

The CHPAC has been urging the EPA since its inception to improve the understanding and management of chemical exposures in children. The committee wrote a letter to the Administrator recommending that the Agency begin to gather the needed data to determine whether exposures to these chemicals are harming America's children, starting with prioritizing the inventory of chemicals under TSCA. While the agency has begun to analyze data collected through the High Production Volume (HPV) Chemical Challenge program and the Inventory Update Rule (IUR) to improve understanding of risks posed by existing chemicals on the market, these data are very limited in their ability to assess children's risks, and the use and interpretation of these data by the agency to date has been highly questionable. For example, under the IUR, the chemical manufacturers only need to report "readily obtainable" information on potential

exposures of children or adults to their chemicals. Manufacturers may simply state that the data were not readily obtainable, and they have no further obligations. Moreover, the Agency only asks manufacturers whether products made from their chemicals are intended for use by children. The CHPAC notes in its letter that the IUR will not provide information about early life exposures, because infants and fetuses are more likely to be exposed inadvertently through their parents' use or through the ambient environment. Information on movement of chemicals from products into the environment is also needed to improve our understanding of both exposure potential and risk. The letter notes that EPA's existing exposure screening tools are not predictive of child-specific pathways, and recommends that the Agency adapt exposure tools to encompass child-specific exposure routes and pathways (e.g., mother's milk, mouthing of objects, household dust).

Under the HPV program, manufacturers volunteered to provide a minimum base set of hazard data on chemicals produced in quantities over one million pounds. Shortcomings of the information generated include the fact that industry was allowed to group chemicals into categories and provide estimated values of hazard indicators by extrapolating from tests done on other chemicals within the category. With respect to toxicity to children, data were limited to fairly basic tests of reproductive and developmental toxicity, which are far from adequate to determine the potential for many types of effects on children and their development. EPA's new Chemical Assessment and Management Program (ChAMP) is starting to produce screening risk characterizations and prioritizations, specifically including risks to children, using the data obtained from the IUR and the HPV program. The purpose of such efforts is to prioritize the thousands of chemicals on the market for more thorough scrutiny, testing and assessment. With any screening process, to be protective of public health, it is important to avoid mislabeling a situation as safe when in fact it is not, as this stops the process of determining more definitively whether or just how harmful the situation (in this case, the chemical exposure) actually is. In particular, it is critical that any decision to place chemicals into low-priority categories be based on solid information, and that chemicals for which there is poor information upon which to base a decision be maintained as higher priority until such information can be reliably obtained. These basic scientific and public health principles are being violated by the Agency in their initial risk characterizations and prioritizations under the ChAMP.

Environmental Defense Fund (EDF) has carefully reviewed the first eight such risk documents made available by EPA. As noted above, the IUR is a problematic source of exposure data for these characterizations, especially for children, because of its voluntary nature and the limited scope of information relevant to children's exposures. Some examples of poor protection of children based on limitations of the data include the following:

- For n-butyric acid, the EPA notes that "*n*-Butyric acid is used as an intermediate, food additive, and ingredient in varnish, cosmetics and detergents." However, the company(ies) providing data under the IUR apparently stated that all production was used solely as a chemical intermediate. On the basis of this, the EPA concludes, "The IUR-based ranking for children is low due to the assumption that these chemicals will not be present in products intended for use by children." Thus, *despite clear recognition that this chemical is used as a food additive and consumer product ingredient, the EPA dismisses the possibility of exposure based on one year's worth of production and use data.*
- In its characterization of a group of dibasic esters, the EPA notes that publicly available sources state that one of the compounds is used as a food additive and all of the group are components of paint strippers, polishes, and lacquer thinners. Nonetheless, the agency concludes: "Based on IUR data, the likelihood that DMS, DMA and DMG will be used in products intended for use by children is low. Therefore, the IUR-based ranking for exposure to children is low." *EPA ignores the food additive use altogether and dismisses the paint stripper use with one sentence*: "The paint stripping consumer use described above is not likely to involve children." This claim fails to recognize that children will be exposed to chemicals in paint strippers and other products even if they do not directly use them.

These two examples highlight not only the statutory limitations restricting EPA's ability to gather necessary information, but also the insufficient rigor in EPA's efforts to protect children's health. Instead of addressing these concerns, as raised by the CHPAC, EPA has pointed to a very blunt tool, the IUR, as a sufficient way to address children's exposures. EPA must more transparently acknowledge the inadequacies in the data supplied by the IUR on children's exposures and commit to using all available sources of data in its characterizations. The agency

is also not exercising its existing authority under TSCA Section 8 reporting rules to gather the necessary data to assess children's exposures and risks more thoroughly.

In a separate effort to collect and assess the scientific information needed to protect children's health, the EPA initiated the Voluntary Children's Chemical Evaluation Program, starting with a pilot project in 2000. Its stated goal is to ensure that there are adequate publicly available data to assess risks from environmental exposures to chemicals known to be of concern to children, and the pilot project was intended to quickly pave the way for a more comprehensive review program. Eight years after the pilot program's initiation, progress is meager at best. Of the 23 chemicals nominated for the pilot because of clear demonstration of children's exposure:

- 3 were never sponsored by industry;
- 5 never had data submitted by industry;
- 3 had data submitted by industry, but no decision on data needs has yet been made by EPA;
- 12 have completed at least the first tier of the program.

There is still no user-friendly source of VCCEP information that the general public can access to find out about potential risks to children. The public may download reports one chemical at a time and read them, or travel to Washington, DC to read these documents in the EPA's Reading Room. At this rate of 1.5 chemicals per year making it through just the first tier of three within the program, the EPA does not appear to be placing adequate priority on assembling the scientific data needed to determine and then act upon chemical risks to children. This is underscored by the fact that the program appears to have ground to a complete halt at present. A mandatory review of the pilot took place in the Fall of 2006, with a summary of the (largely critical) comments received published in March of 2007. Since then, over a year later, there still is no indication of EPA's plans to revise, resume, or replace this inadequate program. The CHPAC's comments on the weaknesses of this program have not been addressed by EPA.

EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposures to Carcinogens

The rapid turnover and differentiation of their cells make children more susceptible to developing certain types of cancer. It can also enhance the effect of cancer-causing chemicals, making them relatively more potent in children than in adults. Thus, exposures to cancer-causing chemicals during childhood may sow the seeds for the development of cancer later in life. A growing body of scientific evidence documenting this window of greater susceptibility in children led EPA scientists to recommend adjustments to the way risk assessments are performed for cancer-causing chemicals that account for this enhanced potency. But a subsequent EPA document providing more specific guidance on the conduct of cancer risk assessments has ensured that vanishingly few cancer-causing chemicals will ever meet the criteria to be treated as more potent in children. By using the narrowest possible definition of one particular mechanism of causing cancer, the agency has strayed from usual risk assessment practices and backed off from providing greater protection for children in accordance with their greater susceptibility. The following paragraphs tell this story in greater detail.

In March 2005, EPA issued new guidelines for assessing the risk of cancer from exposure to chemicals in the environment. The guidelines were accompanied by a supplement describing the assessment of cancer risk when exposure occurs during infancy and childhood. The agency was not talking strictly about childhood cancers, but rather the risk of developing cancer over a lifetime due to exposures that occur early in life. The EPA staff scientists thoroughly analyzed the available information on the effects of cancer-causing chemicals given to immature animals versus mature animals. They also looked at the available evidence in humans. Their analysis indicated that many cancer-causing chemicals produced worse results – that is, higher tumor incidence – when the exposures happened before the animals matured. Standard cancer risk assessment practices are based on toxicological studies that only expose animals after maturity.

Chemicals can cause cancer a number of ways: by directly damaging DNA, by causing DNA damage indirectly, or by changing the expression of DNA. The EPA report noted that cancer-causing chemicals were most potent in early life if they acted by causing DNA damage in the form of mutations, although there was uncertainty about whether other types of carcinogens would also be more potent in children. The Agency decided that exposures occurring in infancy and childhood should be considered more dangerous only when there was evidence for mutations and declined to consider the chemicals that caused cancer by other means. This decision leaves out chemicals like DES, which acts via hormonal mechanisms but clearly still displays increased

potency with early life exposures. For DNA damaging chemicals, the guidelines require the risk assessor to apply a potency factor of 10 for exposures occurring between birth and 2 years of age, and a 3 fold increase in potency between 2 and 15 years of age. The CHPAC closely followed and made recommendations on the development of the SG in 2004 and 2005.

The Agency subsequently wrote a document to guide their staff in implementing the SG by more precisely defining the mutagenic "mode of action" (MOA) for cancer. Unfortunately, this framework greatly restricts the implementation of child-specific potency factors. The Agency asserts that data showing the chemical is mutagenic is not sufficient to use the child protective factors. Rather, the Agency proposal requires very detailed information on how a chemical reacts with the DNA and where in the process of tumor formation this interaction occurs. These data are almost never available. In fact, these data are not available for most of the chemicals that the staff scientists used as examples to document increased potency in early life. Thus, the Framework greatly restricts the application of the extra potency factors for early life exposures. This has the effect of not taking into account children's unique susceptibility to carcinogens in regulatory pollution limits that affect air, water and soil.

The CHPAC wrote a letter to the Administrator recommending that the Agency not further delay implementation of the 2005 SG for children and re-draft this framework in a manner that is more consistent with standard risk assessment practice and with the underlying science. EPA's sent their guidance to a Peer Review panel, which met on April 4, 2008. This panel had similar concerns to those expressed by CHPAC. In the meeting, the panel stated that the Agency should use the children's potency factors with all carcinogens until the data are available showing the factors are unnecessary. The EPA has not adequately addressed the CHPAC concerns and still appears to intend to create a high burden of proof to apply the potency factors. This not only is inadequate to protect public health, but it also creates a strong disincentive for industry to do key testing on children's vulnerabilities.

Conclusion

Taken as individual phenomena, none of these examples might stand out as remarkable, but when considered as a whole, a picture emerges of an agency whose senior leadership has repeatedly chosen to stray from the clear and science-based recommendations of expert advisory

panels, public health organizations and advocates, and in some cases even its own career staff scientists, in order to make policies and decisions that fall short of adequately protecting children as well as the general public. In some cases, these policies and decisions are justified on the basis of arguments that run counter to established scientific principles and the judgments of the most prominent experts in the country. In other cases, these policies and decisions are made with little justification whatsoever. I applaud this committee for its effort to shine a light on the misuse of science within the EPA. Greater transparency in agency decision-making and greater adherence to the recommendations of the agency's scientific experts will help bolster public trust in the agency and lead to greater protection of the public's health.

Senator WHITEHOUSE. Thank you, Dr. Balbus.

I am pleased to announce that we have been joined by Senator Baucus of Montana, the chairman of the Senate Finance Committee. I would invite him to make a statement, if he would like.

STATEMENT OF HON. MAX BAUCUS, A UNITED STATES SENATOR FROM THE STATE OF MONTANA

Senator BAUCUS. I thank the Chairman.

I would like to add my voice to urging the EPA to return much more to science-based decision, and away from decisions which, in my judgment, are based more on politics. I would like to begin with a quote from the President's father. President George Herbert Walker Bush said in 1990, that "Science, like any field of endeavor, relies on freedom of inquiry. And one of the hallmarks of that freedom is objectivity. Now more than ever," the President continued, "on issues ranging from climate to AIDS research to genetic engineering to food additives, the Government relies on the impartial perspective of science for guidance."

All those of us who are public servants have recognized this principle, that the science behind our environmental decisions must be objective, impartial and free of politics. Sadly, this principle has been abandoned, in my judgment, by the current Administration and the corrupted results are real. They have real effects, they are hurtful, they are harmful and sometimes tragic.

Unfortunately, in my home State of Montana I see this, especially in the town of Libby. In Libby, Montana, people have been living with the consequences of 70 years of asbestos contamination, most of it caused by W.R. Grace. It is a small town, over 200 people have died from asbestos-related diseases there. In the early part of the current Administration, the scientists at EPA and the Agency for Toxic Substance and Disease Registry determined that a public health emergency should be declared in Libby, so that greater resources and expanded authorities could be brought to bear.

In other words, the effect of that would be the removal of asbestos-contaminated foam insulation in Libby homes as well as attending to asbestos contamination in other parts of the Country. The EPA said no, they put that science aside, made the political judgment to not declare a public health emergency. That is a decision that greatly benefited W.R. Grace, but to the detriment of the people of Libby, Montana.

In Libby, EPA management has even drug its heels for 6 years in one of the most basic aspects of any of its Superfund clean-up, that is, determining the level of toxicity, what is the toxicity of a contaminant. Because without this information, EPA cannot tell the people of Libby whether or not their homes are clean, what is the level of toxicity. They wouldn't make that determination.

In response to pressure from me and others, EPA management relented and agreed to conduct the necessary toxicity assessments in Libby, which will ultimately lead to a science-based position, not one based on politics. I am not hopeful, though, that the current Administration will follow the science enough and do the right thing enough, not when recent guidance issued by EPA enables secrets, influenced by OMB and other agencies, as well as the industries they advocate for, on purely scientific assessments of the tox-

icity of chemicals. Nor of the new phrases, such as science policy, that are used to disguise, in my judgment, old, corrupt practices that ignore science and put politics before public health.

I feel strongly we need to find a way to get EPA to turn much more to the principles of objective and impartial science, science-based decisionmaking. Because that, after all, is the common denominator, it is the common language, it is basic science upon which we all can then make subsequent decisions. We must first know the science. We can then make other decisions. But at least we need to know the science and the science cannot be corrupted.

So Mr. Chairman, I join you in finding ways we can help accomplish that objective, because I think it is so important. It also gets to the question of American credibility of decisions made by their public servants in Washington, DC, whether elected or whether appointed. Thank you.

Senator WHITEHOUSE. Thank you, Senator Baucus.

Let me start with a good, solid Rhode Island question for Dr. Thurston. We have significant senior population in Rhode Island. You indicated in your testimony that using young, healthy adults for testing for the ozone standard may not fully take in the consequences on various populations that may be more vulnerable. You mentioned infants and children and people with respiratory illness. Would the elderly also qualify as a like more vulnerable population?

Mr. THURSTON. Well, certainly yes, that is what studies have shown. Let me just mention, as a born and bred Rhode Islander myself, I want to thank you for your service on this Committee and showing such an interest in the environment and the health of Rhode Islanders, where I have family members.

Certainly, saying, older adults, I prefer older adults, actually, to seniors. I am getting too close to the category.

Senator WHITEHOUSE. They get younger all the time.

[Laughter.]

Mr. THURSTON. I am glad to hear that. But older adults are far more susceptible to environmental insults, because many times they have pre-existing disease. And when you have a pre-existing disease, that makes you more vulnerable to some other insult, like an environmental insult, exacerbating your disease situation and therefore, you are much more likely to suffer major consequences, from an exposure to things like air pollution.

Senator WHITEHOUSE. Because what we see far too often in Rhode Island is, on a summer day, a notice broadcast over the radio that it is not safe for infants and young children or older Americans to go out of doors because the ozone contamination in the air is so high.

I come from a State that is on the Atlantic Ocean. We get fresh air blowing off the cool Atlantic all summer long. If we have this problem in Rhode Island, I can only imagine what it is like in other States that don't have that kind of advantage from the point of view of our environment. It strikes me that it is important to remember that as we are discussing those sort of abstract numbers and these scientific determinations and these process questions, that when Administrator Johnson is done saying that 0.075 is OK, despite the fact that not a single member of either of his panels

was willing to go to that number, that has real consequences for real people, and it means that they have to stay indoors trapped by that decision, they can't go outside. And it means that if they do, they faced increased risks of the kind of medical problems that you have described.

Let me also ask Dr. Balbus, you said that individually versus taken as a whole, there are conclusions that one can draw from the sort of repeated instances that you have chronicled under this EPA leadership. Could you, do you have any either sense or calculation as to, on those occasions, when EPA strays from what its own science indicates is the proper answer, is it easily balanced or do they tend to veer more toward protection of the environment and public health or more toward industry? Are there any patterns or trends that you have established in the occasions when EPA departs from the range supported by its own scientific evidence?

Dr. BALBUS. In each of the examples that I provide in the testimony, these were examples where existing standards or procedures were being strengthened in order to afford greater protection of public health. In each of these examples, the decision that was made was always in the direction to not go as far.

Senator WHITEHOUSE. Always.

Dr. BALBUS. In the examples that I provided and in the examples that I am aware of. I am not aware of an example——

Senator WHITEHOUSE. You are not aware of a single example?

Dr. BALBUS. I am not aware of an example where the Administrators have chosen to err on the side of greater public health protection when any of their science advisory panels have advised, in the last, since I have been with EDF for the last 7 years.

Senator WHITEHOUSE. Dr. Gilman, under Administrator Johnson's tenure, are you aware of any times when he has departed or used the uncertainty principle to depart from scientific recommendations in the direction of greater environmental or public health?

Mr. GILMAN. I am not as great a student of Administrator Johnson's tenure. I can speak to one, actually, one that the representative of the Environmental Defense stated was the most significant public health measure taken since we took lead out of gasoline, which is of course the Diesel Rule that was further promulgated under this Administration. I don't think there are too many people who would argue with that characterization.

Senator WHITEHOUSE. My time has expired. Senator Alexander?

Senator ALEXANDER. Thank you, Mr. Chairman, and thank you for the hearing. Let me thank the witnesses for what they have said.

Let me see if I can derive a constructive suggestion for what to do about this black hole that has been talked about today. Dr. Gilman, Dr. Michaels paid you a nice compliment. What was your job with the EPA? When were you there?

Mr. GILMAN. Actually, I was going to say at the start of my testimony, I can't understand anyone who would ever take the job that Dr. George Gray had. That was the job I had while I was at the EPA. I was both the Assistant Administrator for the Office of Research and Development and the Science Advisor.

Senator ALEXANDER. Is it your understanding of the law that the science advisory committee, such as the one that made the ozone recommendation are purely advisory?

Mr. GILMAN. The CASAC is actually a statutorily established committee. And there are burdens placed on the Administrator in terms of receiving that information. I haven't read the statute as closely, I think probably George had it up on the internet during the first part of the testimony.

Senator ALEXANDER. Well, let me read you Section 109 of the Clean Air Act. The air quality standards, "In the judgment of the Administrator, based on such criteria in allowing an adequate margin of safety that are requisite to protect public health." So has it been the practice at the EPA for the Administrator under that provision of law to make the final decision about ambient air standards?

Mr. GILMAN. Yes.

Senator ALEXANDER. And as I mentioned earlier, and I won't ask you about this, I will just make my own observation, in this case, the advisory committee recommended a range of .06 to .07, the Administrator chose .075. So the way I look at it, the Administrator disagreed with them less than they disagreed among themselves in terms of the range. In other words, they didn't recommend to the Administrator, and I am making this observation myself, that he would pick .065 or .063 or .067. He went above that. And then he published, under the law, the recommendations of the science advisory committee are public, and we have asked that they be a part of this record.

Then the Administrator made his decision. He is obligated to explain why he made his decision, apparently, and I have asked for that to be made part of the record.

But the problem seems to be this black hole, this interagency review. When did interagency reviews of EPA decisions begin, do you know?

Mr. GILMAN. They probably have happened in ad hoc basis through time. Obviously somewhat in the past informal, now being proposed much more formally. During my tenure at the agency, we tried to make it a practice of informing other agencies that we were about to begin an assessment of a particular compound, to alert them to the fact that we were going to be doing that work, and invited them to participate in the process that was in place for getting their views and any information they might want to share.

Senator ALEXANDER. The interagency review occurred during the Clinton administration?

Mr. GILMAN. I can't speak to whether it happened on an ad hoc basis or a more formal basis. But in my experience, and I actually served at OMB for a period of time, the interagency process happened sometimes in a very informal way, it happened sometimes at the very end of the process. I wouldn't be surprised at all if there were occasions when there was an interagency review.

Senator ALEXANDER. My understanding is that it did. This is my last question. The way I look at this, if the advisory committee is advisory and if the Administrator has a judgment to make and he makes it based on the criteria, the court can decide whether he was within the criteria, some of us might have made a different deci-

sion, I might have frankly, on ozone, made a different decision than the Administrator did. But I think he was within his right to do it.

And if his recommendation is public and if the scientific recommendation is public, that is a lot of transparency. It seems to me the so-called black hole is the issue here. And could you suggest to us, I mean, I can think of a lot of reasons why discussions of our staff, executive sessions of this Committee, members of the President's staff, the decisionmaking, those things aren't public. They are part of the process.

But can you suggest to us ways that the interagency review could be improved so it would build confidence in the process that science is being respected in the decision that is being made about public health?

Mr. GILMAN. Yes. I would agree with you that there are times when those kinds of deliberations should be private. But I do think in this case, frankly, it would serve the best interests of the OMB, the best interests of the EPA and best interests of the process, the results, the credibility of that, if indeed we returned to what was the practice before the most recent policy, which is that the various Federal agencies should actively participate in the public process, the very public process all the way from the nominating of compounds into the IRIS system, all the way through the process of taking in information, putting it through peer review, responding to the peer review. The peer review process provides an opportunity for other Federal agencies, other entities, interested parties, to participate, add their comments and the like.

I do think that was the process that provided both the opportunity to be heard and the transparency that improves credibility.

Senator ALEXANDER. Thank you, Dr. Gilman. Thanks to the other witnesses. Please excuse me.

Senator WHITEHOUSE. I understand that Senator Alexander has other commitments. We will continue with Senator Boxer.

Senator BOXER. Yes, Senator, before you leave, I just want to tell you that you seem to be, well, going back to the—to the whole point of whether or not the Administrator acted in a lawful manner. What I want to put in the record, and I hope you will read it, is the ten times that this Administrator has been just overruled by the courts. And some of the most conservative courts, Janice Rogers Brown was one of those justices.

And I am just going to quickly tell you what they are. And how you could say he was within the scope on some of these things, when he was clearly outside the scope, you know, people might not like it, Dr. McClellan was annoyed, but too bad, you weren't on that particular advisory board and you were overruled. So that is life.

The fact is, here is when they were overturned: Massachusetts v. EPA. Supreme Court rejected EPA's argument that greenhouse gases are not air pollutants. In New York v. EPA, EPA's interpretation that substantial plant modifications did not come within the scope of physical change would make sense only in a Humpty-Dumpty world. This is the court speaking.

Another one, EPA rules seeking to reverse controls on mercury from power plants was unlawful on its face. Another one, this is

all the Bush administration, not, Mr. Gilman, going back. D.C. Circuit chastising EPA for taking an unlawful approach to emission standards. EPA's efforts to exempt whole categories of toxic pollutants from regulations violated its clear statutory obligation under the law. Portions of EPA's smog rule unlawfully evaded the plain language of the Clean Air Act.

If EPA disagrees with the Clean Air Act, it should take its concerns to Congress. In the meantime, it must obey the Clean Air Act. And this one, NRDC, EPA incinerator rules violated the clear and unambiguous language of the statute. Another one, EPA's attempt to create a low-risk subcategory of manufacturing facilities exempted from the Clean Air Act was an unlawful attempt to sidestep what Congress prohibited.

So the point I want to make, before you left, and I am so sorry I kept you here, is that all of this is a pattern. We already know there is a lawsuit filed against the small particulate matter. I believe that will be another slam dunk for the people fighting on the side of science and health. And there is going to be a lawsuit filed on ozone, because you went outside.

So when Justice Scalia clearly states unambiguously that the California Clean Air Act says that you cannot put in any other implications, cost or anything else, that is the end of it. But yet this Administration keeps doing it time and time again. They are losing battle after battle. The people are wining this battle. And I don't understand why this Committee can't be united in saying that this is wrong. I don't think you can defend the indefensible. I know that you and I have great respect for each other, but I don't see how you can he acted within what the scientists recommended when the scientists had a range, then he went outside the range.

And this whole uncertainty, uncertainty, which one of you was talking about the tobacco companies? Yes. Dr. Michaels reminded us, the tobacco companies, well, we really don't know that smoking causes cancer, we really can't prove it, and years and years of that stuff. And it goes on. Just watch for this word uncertainty, how many times the witnesses who here are connected with some of these organizations use it. It is the new buzz word, uncertainty. And I don't think that we were born yesterday and we get it.

But I want to say to Dr. Gilman, thank you for bringing up all those headlines from years past. Good for you. Because this is a battle that is not part of it. Let's put up these headlines on more time. This is what we are facing here. And I don't care who does it. I don't care if it is a Democratic President, a Republican President, an Independent President. If they are going to hurt my people and my kids in my State can't breathe, too bad for them, you are wrong. And that is it. And I am going to fight.

And here you go. White House meddling hobbles EPA, EPA's staff are discussing the issue. Look at this. This is sick. And then you have all these decisions by the court which just are unequivocal. One after the other after the other after the other. So it is really a time for us to act, and that is why we are so proud that Senator Whitehouse actually recommended this hearing, and that is why he is chairing it.

I wanted to say to Dr. McClellan, you said that you were very angry at this ozone deal. And you put a statement into the record

at the time stating your point of view at what the level ought to be. And you base it——

Mr. MCCLELLAN. Excuse me, Senator. I did not, enter into the record a recommendation as to a numerical standard. That is a misstatement that the record should show clearly is a misstatement.

Senator BOXER. OK, is this really, because, I think this is in your statement, isn't it from your statement? OK, this is what you had in your statement: "I submitted my personal comments to the ozone docket, and I also joined with nine of my scientific colleagues in submitting a document called Critical Considerations in Evaluating Scientific Evidence of Health Effects of Ambient Ozone to the docket." You are saying you did not do that?

Mr. MCCLELLAN. Absolutely, that is the document, I think it is a seminal piece of——

Senator BOXER. OK.

Mr. MCCLELLAN [continuing].—scientific review. But if you will carefully read that document, if your staff will read it, you will not find a specific recommendation as to the numerical standard.

Senator BOXER. OK.

Mr. MCCLELLAN. I stand by my statement.

Senator BOXER. Fine. Fine.

Mr. MCCLELLAN. Science alone cannot set the standard.

Senator BOXER. Sir, sir, I am not asking your opinion. You gave your opinion. I am trying to read this to you from your own words that you submitted this document into the record, which is fine. And by the way, it was your total right.

Now, who funded that study?

Mr. MCCLELLAN. The Rochester report, which was prepared by myself and nine colleagues, was funded by the American Petroleum Institute.

Senator BOXER. Thank you. I wanted to get at that. Special interests funded the study. Let's get it straight here. When I hear from witnesses, Mr. Chairman, I want to know where they are coming from. Thank you.

Mr. MCCLELLAN. That is why we made a special effort to make certain the report clearly states who sponsored the review and the independence of the scientists in preparing the report.

Senator WHITEHOUSE. Senator Alexander, did you want to put something into the record?

Senator ALEXANDER. Thank you, Mr. Chairman. I will be glad to read the cases that Chairman Boxer offered of the number of times that the Supreme Court has overruled the EPA during the Bush decision, if she will read the number of times the Supreme Court and other courts have overruled the Clinton EPA Administration. I would ask unanimous consent to put into the record a list of those cases where the courts have overruled decisions by the Administrator of the EPA during the 8 years of the Clinton administration.

Senator WHITEHOUSE. We ordinarily close the record of the hearing within a week after the hearing. So the sooner you can get it in.

Senator ALEXANDER. We will summarize it and we will do it properly.

Senator WHITEHOUSE. You have unanimous consent.

[The referenced material was not received at time of print.]

Senator BOXER. And let me say, I fully support that. You know, this is the point I made to Dr. Gilman, this is a battle that rises above politics. This is about the health of our people. I don't care who does the wrong thing. They better protect the health of the people. I don't care who they are. And I will fight against them if they are in my own party or in anything else, if they don't.

Senator WHITEHOUSE. If I could ask just a few more questions. Let me start with Dr. Grifo. You have looked into this fairly considerably. A number of witnesses have mentioned the concern about the black box. When you have OMB with the ability to have secret meetings in the science stage of the EPA determination, and inject its point of view, what safeguards are you aware of in the process that, in the absence of any transparency, that would restrict the OMB input to what might be called pure and legitimate science, as opposed to put it bluntly, shilling for special interests that might have access to the White House, of which OMB is a part.

What prevents this from being a back door through which a political interest can get to the White House, the White House can give OMB instructions, and the instructions can meet with EPA, and because it is all secret, nobody ever knows that there is in fact the rankest kind of political influence, direct monied political influence, being brought to bear. What are the structural protections that prevent that from happening?

Ms. GRIFO. There is not much, nothing that I am aware of. I think what is really important here is this issue of those documents as they go into OMB are considered pre-decisional. I think the problem with that is it means that those of us on the outside wanting to see them, wanting to understand them, can't access them through the Freedom of Information Act. They are off limits to us.

And I think we have seen instances where they are clearly predecisional for a very, very long time. They do not move at an adequate pace through the system. And I think today, we have talked about numerous examples of this. I think what we would like to see is a more consistent effort to put those documents out there, because I think we have all said, sunshine is the best disinfectant. If the documents are out, we can look at them when they go in, we can look at them when they come out, and we can know what happened.

But right now, your Committee has had trouble accessing these documents. Other committees have had trouble accessing. And those of us that are limited to the powers of FOIA have had trouble accessing these documents.

Senator WHITEHOUSE. Dr. Michaels, as you have looked at some of the institutional forces that have been brought to bear to twist the science on various issues, particularly in the research for your book, but in whatever forum, there are sort of the legendary ones, like the American Tobacco Institute and the American Lead Institute, which I had the great pleasure and privilege of actually putting out of business.

Have you ever come across this Annapolis Center to which Mr. Gray belonged for those five or 6 years? And in the scheme of things between truly solid, legitimate scientific institutions and

phony fronts for industry advocacy, where along the spectrum would you place that outfit?

Mr. MICHAELS. Senator Whitehouse, thank you for asking that question. I am glad I brought my book along, because in fact, I address that very question here. The Annapolis Center was started by a vice president of the National Association of Manufacturers for, among other purposes, fighting the EPA's clean air standards. There is documentation from the Wall Street Journal some time in the 1990's on that.

It is heavily funded by ExxonMobil, from whom it received about $700,000 between 1998 and 2005; and by large coal-burning utilities like the Southern Company Corporation, which gave it more than $300,000. It produced a series of reports which just say, frankly, there is too much uncertainty, we can't move forward. That is their mantra. We see it again and again, there is no science there. This is tobacco's strategy of saying, "there is too much uncertainty, we can't move forward," and applying it to pollution.

Unfortunately, what we are seeing now is that there is a whole industry, the product defense industry, which is made up of for-profit corporations that are run by scientists or consultants and some of these supposed think tanks that defend every product when they are facing regulation. It is ludicrous; the indoor tanning association is out there questioning the science around ultraviolet radiation and skin cancer. You can always find someone who appears to be a scientist to say, there are questions.

Then we hear the phrase, sound science, when there are attacks on this regulation, but really what it is is something that sounds like science. They pull this stuff out to slow down the regulators. And unfortunately in this Administration, it works.

Senator WHITEHOUSE. With respect to another similar organization that Dr. Gray was also associated with, the Foundation for Research on Economics and the Environment, did that one come up in your——

Mr. MICHAELS. I haven't seen that one, but there are lots of these organizations. It sounds reasonable on the face, the clean water program is set up by some of the polluters who are responsible for putting perchlorates in our aquifers.

Senator WHITEHOUSE. It is their purpose to sound reasonable on their face, otherwise they wouldn't be effective at misleading the public, correct?

Mr. MICHAELS. That is correct.

Senator WHITEHOUSE. All right. You mentioned also that people have been cleared out of various positions on advisory and scientific boards. I assume one of the people you are referring to is Deborah Rice?

Mr. MICHAELS. Yes.

Senator WHITEHOUSE. I found it interesting that the putative basis for removing her from her position, talk about Orwellian, not only did they remove her from her position, they went back and scrubbed the record of anything she had ever said. They sort of tried to disappear her as a person, a novel administrative procedure, from my perspective anyway. The reason was an asserted conflict of interest. And the conflict of interest was, the asserted

one, was that she had stated her professional view on a particular issue on behalf of the State of Maine in a regulatory proceeding.

I guess I would ask you if you think having an opinion, a scientific opinion, is what is ordinarily understood in the scientific community as a conflict of interest. Because in the legal and political communities that I am familiar with, you are supposed to have opinions all day long, you can cite for the things you believe in based on facts. A conflict of interest is when you have an association with industry, a financial link, a true sort of conflict of interest as opposed to just a conflict of opinion.

And what is your evaluation of Ms. Rice's situation? And I ask this for a particular reason because as we were preparing for this hearing, we have a number of people, scientists either at EPA or on EPA panels, who said to us, I would love to come forward and testify, Godspeed with what you are doing, this is really important, the place is not what it appears and what it should be, but I don't dare come forward now, because I fear retaliation and her name was invoked as the, I don't want to be the next Deborah Rice.

Mr. MICHAELS. You are absolutely right, it is truly Orwellian. In the view of the scientific community, scientists are supposed to have opinions. Our job is not just to produce science, but to synthesize, to integrate the scientific studies and come out with some judgments. She was on this committee because she was able to do that, and Dr. Rice is a very well-known and respected toxicologist working for the State of Maine.

The people we are particularly concerned about are people with financial conflicts of interest, because we know from study after study that, in fact, a financial relationship can clouds someone's judgment. And the most tragic example probably is Vioxx. We know now that Vioxx greatly increases the risk of heart attacks. Somewhere in excess of 80,000 heart attacks among Americans were caused by Vioxx. If you go back and look at the studies that were done five, 8 years ago, we can see that the evidence was there from the very beginning that Vioxx increases the risk of heart attacks.

But numerous scientists paid for by the manufacturer of this drug couldn't see it. They said, when they looked at the evidence, well, there is some other reason for these heart attacks, it is the other drug people are taking, it can't really be true that Vioxx was cuasing the heart attacks. We are paying the price now with many deaths as a result.

The answer is to make sure that people on these advisory committees have opinions and are good scientists, but have no financial conflict of interest. In fact, the International Agency for Research on Cancer, which is the World Health Organization's branch that classifies carcinogens, introduced a very successful policy about 3 years ago that if you have any financial relationship to the issue under question, you can't serve on one of their panels. You can be an esteemed representative to testify, as Dr. McClellan might have been at their meetings, but you can't be part of their deliberations, because that financial conflict of interest clouds your judgment. We should be doing that here at EPA as well.

Senator WHITEHOUSE. My time has expired. Senator Boxer?

Senator BOXER. I just want to again thank you so much, Mr. Chairman, for your work. This is important work. And what saddens me is to see the Environmental Protection Agency become a shadow of its former self and have people who I think should know better say, oh, it is fine. It is not fine. And I guess each of us sees our job through our own experience and how things impacted us.

I remember myself, as a much, much younger person, learning about the Pinto, Ford Pinto, and learning about that case. And learning that the maker of that automobile actually knew exactly what was wrong. And in the discovery part of the lost case, we all learned that they put a number to the problem of this engine problem and they said, you know what, it is cheaper for us to simply, rather than change it, have these lawsuits, X number of people will die, but it will be cheaper for us. It is a disgrace. It is a sin, in my view, to have that attitude.

And I believe that attitude prevails inside the Environmental Protection Agency. I do. I believe that our children's health is expendable to these folks in there who are working at the behest of the special interests. I believe it. Just as I believe the tobacco companies knew what they were doing and made this whole uncertainty, uncertainty, uncertainty. No, they knew.

And this committee has a job to do. It is not always pleasant. But it is very important to blow the whistle when we see these things happening. And we see people who are in there, trying to fight the good fight get kicked out for no other reason that they will not be cowed, they will not come to heel and carry out a political agenda for the special interests. We have seen it time and time and time and time again.

Mr. Johnson refuses to come up here. I know it is unpleasant for him. And let me say to him through this day, it is unpleasant for me. I don't like having to argue with him. Because I think it is an argument that never should have to take place. We are supposed to be doing what is right for the people. That is why we are here. And I think as we do what is right for the people, via the environment by the way, I think we help business, Mr. Chairman. Because if our workers get sick, they can't go to work. And the cost of health care on a lot of our businesses is skyrocketing.

We are going to take up some bills next week, I am very excited about them, really, to protect the quality of the air around ports. We have ships coming into port that are filthy, using bunker fuel, coming into your ports, coming into my ports, getting people very, very, very sick for no reason when there is an alternative that would barely add pennies to a pair of NIke shoes, if that.

So this hearing, to me, is really the heart of why I got into public life in the first place. And I just want to commend you, and I do have just a couple of quick questions for our wonderful panel. I would say, Dr. Thurston, you mentioned that the American Lung Association, the American Medical Association, the American Academy of Pediatrics, the American Public Health Association and many other medical associations led a "consensus in the scientific community" that EPA should follow CASAC's recommendations on the ozone standard. Please tell us why you believe the science is strong supporting the need for this stronger standard, and what

the health effects are that CASAC and the experts are so worried about.

Mr. THURSTON. Well, there are just hundreds of studies that have been done since the first time that I testified before this Committee, which is 1996, that demonstrate effects below the level that the Administrator is trying to set the standard. So many of those are epidemiological studies that show these effects. And I gather there is a bit of an argument about the controlled exposure studies and trying to point to those and saying, well, maybe they're definitive or not.

But as I mention in my testimony, that these controlled exposure studies don't always show all of the effects. In 1984, we at NYU and researchers at Harvard did a study where we followed children in western New Jersey. We demonstrated that as one function decrements, decreasing their ability to inhale and exhale air, at levels well below the 100 ppb 1 hour standard. At that time, a 100 ppb ozone level. At that time, the standard was 120 for a 1-hour. And they had done controlled exposure studies that failed to demonstrate lung function decrements at 120, below 120. So they said, well, basically your epidemiology study must be wrong, because you must have a confounder you haven't considered or something, because we have these controlled exposure study.

But we said, well, but the reality is, these kids are exercising and they are also exposed, not just to 1 hour, but to multiple hours. So then they went back and they re-did the controlled exposures studies where they had people exercise and expose them to 8 hours. And in fact, what they found, they confirmed our epidemiology that there were effects well below what the controlled exposures studies showed us. And the epidemiology was right, but the standard was lowered as a result.

And we have pretty much the same situation today that we are seeing in the epidemiology, which is real people, getting real exposures in the real world. There are just many studies below the standard that the Administrator is proposing that show just these kinds of effects. And we are seeing severe effects of hospital admissions and now the studies clearly show what I said in 1996, which was that there are mortality effects of ozone. The EPA is somewhat still in denial about this. They actually did a risk analysis, they considered a case where there are no mortality effects of ozone, and they pointed to those, and those are the EPRIA. Then that is considered by OMB in doing the standard.

And that is a ridiculous case. Because we know, and now the National Academy of Sciences has finally confirmed something we scientists have known for a decade, that there are mortality effects of ozone. And yet, they considered this ridiculous case of no mortality effects from ozone exposures and I think that that may influence, I know that economics can't be considered, but OMB does consider this and the RIA. And that should not really be in the RIA, but that case apparently is.

So I think the epidemiology speaks strongly for the fact that what the Administrator has set as a standard is not the appropriate one.

Senator BOXER. Right. And I would predict right here and now a lawsuit on this. And the people will win it, very clearly. All you have to do is look at what Justice Scalia wrote.

Last question is to Dr. Balbus, and thank you for being here. Could you describe in a little greater detail your concern with EPA's management of the children's chemical evaluation program?

Dr. BALBUS. This relates to our discussion of science, because this is a premier means of getting detailed scientific evidence on the effects of chemicals on children. The intent of this was to look at chemicals that were found in children's bodies through bio-monitoring or well-known to be in products to which children are exposed. So already a select group of chemicals of higher risk for children or greater concern for children. And then to get much more detailed toxicity information than we usually get for chemicals on this subset out of a concern for protecting children.

Environmental Defense Fund was involved in the development of this program from the start, and its structure. They were highly critical of the way it was structured, which was a multi-tiered system that would not start out with a full set of data, but would start out with a partial set of data and use that to make a decision to go further.

So this pilot study started in 2000. I was part of the original peer review expert panel, consultation panel that looked at the submissions from industry. There were issues that I don't have time to go into with regard to the voluntary nature of it and the way that the actual documents were developed or written. But we worked through those.

The major issue with this program is just its incredibly slow pace and the fact that it seems to have been completely abandoned. There was an evaluation that was supposed to happen a couple of years ago. The evaluation process, after a delay, got started, and there has been no feedback to the Children's Health Protection Advisory Committee or to the public that I know of as to the current status of the program.

Senator BOXER. So not much is happening, is what you are saying. It has sort of been a slow walk.

Dr. BALBUS. It has been a slow walk that has ground to a halt.

Senator BOXER. OK, a slow walk ground to a halt. Now, I said it was my last question, but I found one other. And the Chairman said I could do this.

The EPA's chemical assessment management program, there is a North American Competitive Council which recommendations actions for this program. Do you know about that?

Dr. BALBUS. I am well aware of this, yes.

Senator BOXER. I just wanted to say for the record who is making these recommendations, who is on this North American Competitive Council regarding EPA's Chemical Assessment Management Program. They are, among others, Chevron, General Electric, General Motors and Lockheed Martin. Now, the last time I checked, their mission, their first mission was not protecting the health of our kids and of our citizens. They have other missions. Fine. Fine. But a mission shouldn't be confused with protecting our people. I wonder if you agree with that.

Dr. BALBUS. I have to confess, I don't know exactly what their role is. So I can't really address exactly what it is that they are contributing to the ChAMP.

Senator BOXER. Well, we know that they recommend actions for the EPA's Chemical Assessment Management Program. It is concerning to me because, again, our role is to balance everything. We find out what the scientists say, we find out what the economists say, we do all this. EPA has a different function, thank God, underscored by the Supreme Court. I say that because otherwise, what would we do? We would never do the right thing when it comes to protecting health, because there is always a special interest that is going to say, I am going to lose X jobs.

By the way, I think this whole issue of environment versus economics is wrong on its face. I can point to my own State of 38 million people now, Senator, 38 million in my State, and I think it must be nice to be able to know everyone in your State like you can.

[Laughter.]

Senator BOXER. But 38 million people, a huge economy, I don't know, fifth or sixth largest GDP in the world, moving forward, the best per capita energy use of any State, a job creator, the home of the Silicon Valley and the computers and the biotech and tours and agriculture and you name it, it is there, entertainment, you know all that, it is all there, fishing, recreation. Now I sound like the chamber of commerce.

The point I am making is that we have to do all that economic expansion while keeping our people healthy. And we are certainly not perfect, I know I stayed on that, we are not perfect here in this Country, but the one thing that Senator Whitehouse and I and others on this Committee want to make sure of is that the EPA wakes up in the morning thinking about how they can protect the health and safety of the people of this Nation, particularly the most vulnerable. Because the good news is when you protect these kids and by the way, gentlemen and lady, and I know the doctors know this, if they are medical doctors, but if you are not, if you have never seen a child suffering from asthma or gasping for breath, before you criticize a tough standard, go see it, OK? Go see it. That is what the EPA is supposed to do.

And yes, Senator Alexander is right, you are going to put everything into the mix at the end of the day, but the EPA, when they deal with these pollutants in the air, by law, they must only consider the health of the people.

So I just want to say, we are in trouble here at this EPA. There are whistleblowers hurting because of this EPA. I want to send another message to the workers over there, change is coming. Change is coming. Do not give up, do not worry, change is coming. You are going to be able to do your work, you are going to be able to be proud once again, and that time is coming soon. I thank you very much.

Senator WHITEHOUSE. Thank you. Let me take this occasion to thank all the witnesses for their time and trouble in coming here. It has been a pleasure for me to hear from all of you. I want to express my particular gratitude to Chairman Boxer for allowing me to go forward with this hearing, to chair this hearing. She has been

an example to me as a new Senator, watching her lead this Committee, her passion, her desire to get it right, her energy, it is just phenomenal. We have seen it again in this hearing, where I have been in the unaccustomed position of actually having to hit the gavel hammer for my Chairperson.

Senator BOXER. You did it well, but don't do it too much. I am worried here.

[Laughter.]

Senator WHITEHOUSE. I think we learned a lot today. I just have an awful lot of alarm bells that are ringing right now. From the substantive aspect, for instance, an ozone standard, which means a lot to my State, that appears to have, at least as of today, no visible means of support, certainly no visible means of support from within the scientific community EPA itself relied on for expert judgment. If you take that to something that is writ larger and you look at I think all of the occasions when EPA has departed from its own scientific advice, it is always, infallibly on the side of the industry.

I think, Dr. GIlman, you made a good point by raising the diesel emissions. That was a good step that EPA took. I don't think they departed from their scientific standards in doing so. I think when they have departed from their internal scientific standards, it has always been toward industry, at least it certainly appears that way. I would love to have the record corrected if that is not the case.

On a more systemic basis, what I see is an EPA that has systemically and deliberately exposed itself to political influence in ways that are new. One is the question of the stacked scientific panels. I would note that in contrast to Dr. Rice, who was thrown off for having expressed an opinion contrary to where, I guess, EPA wanted to go, we have Robert Shatner, who is an employee of ExxonMobil, who served on the expert panel to assess the carcinogenicity of ethyl oxide, which is a chemical manufactured by ExxonMobil; James Cloneg, who served on the ethyl oxide panel after receiving research support from Dow Agro, a manufacturer of ethyl oxide, and the American Chemistry Council; Dale Sickles, who sits on the EPA acrylamide panel that has received research funding from American Cyanamid, the manufacturer of acrylamide, and Cytec, a marketer of acrylamide.

So it doesn't seem that there is a particularly high standard for conflict of interest for people who, there seem to be different standards for conflict of interest depending on where the EPA administration seems to want to go.

And then this whole OMB arrangement is a directly fabricated vector to bring political influence into EPA determinations. If that was what you wanted to do, you couldn't come up with a better strategy.

And finally, I think the lack of candor that we have seen from the EPA witnesses here, I have to applaud Dr. Gray for his ability to say what I found to be preposterous things with a completely straight face throughout. It is a skill but it is not what I look for from people who we entrust with substantial public responsibilities that affect the health of Americans across this Country and affect our children.

So to me this has been a very useful hearing. I have been a witness, it is a lot of trouble to come here, it takes a lot of time out of your day, you only get a few minutes to say your piece. But it has been very helpful, and I appreciate it very, very much.

So unless there is anything further, the record of this hearing will stay open for another week, if anybody would like to propose anything to be supplemented. And we will stand adjourned.

[Whereupon, at 1:20 p.m., the committee was adjourned.]

Statement of the American Lung Association

SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

SUBCOMMITTEE ON PUBLIC SECTOR SOLUTIONS TO GLOBAL WARMING, OVERSIGHT, AND CHILDREN'S HEALTH PROTECTION

"OVERSIGHT HEARING ON SCIENCE AND ENVIRONMENTAL REGULATORY DECISIONS"

MAY 7, 2008

The American Lung Association was deeply disappointed that EPA failed to provide the kind of protection from the nation's most widespread air pollutant that the public is legally entitled to expect when it issued the final EPA ozone standards in March 2008. Pushing aside clear and powerful recommendations from his expert scientific advisors on the Clean Air Scientific Advisory Committee, the Administrator chose instead to construct weak arguments that would justify more pollution. While the final standards of 75 ppb are an improvement over the prior standards, they fall short of the Clean Air Act's mandate to protect the health of the public. The American Lung Association does not agree with the Administrator's view of a "sufficient level of public health protection." If EPA had followed the law, we could have cut the risk of life-threatening pollution to millions of Americans nationwide.

The Clean Air Act requires EPA to review the National Ambient Air Quality Standards (NAAQS) every five years to ensure that the standards reflect the latest scientific and medical evidence. Primary standards must be set at levels that will protect the health of the public with an adequate margin of safety, including the health of vulnerable populations such as children with asthma or people with chronic bronchitis or emphysema. In 2001 the Supreme Court unanimously ruled that clean air standards must be based strictly on what is necessary to protect public health.

Ozone air pollution causes serious adverse health effects. Many groups face higher risk from ozone, in particular children and teens, seniors and people with lung diseases like asthma and emphysema. These well-documented health effects include compromised lung function, worsened respiratory symptoms such as cough, worsened asthma, inflammation of the lining of the lungs, heightened susceptibility to respiratory infections such as colds and flu, as well as an increase in hospital admissions and emergency room visits. Most recently, evidence has shown that ozone can kill.

The American Lung Association has closely followed the EPA review of the National Ambient Air Quality Standards for ozone. We sued EPA over its failure to meet the mandatory 5 year deadline for the completion of the review. We have been following and participating in every step of the review process for the primary standards including

the review of multiple drafts of the Criteria Document, Staff Paper, risk assessment, and the proposed rule. We have attended each meeting of the Clean Air Scientific Advisory Committee's multi-year review of these documents.

Scientific evidence accumulated over the last ten years clearly indicates that adverse health effects occur at lower levels. Since 1997, when EPA previously revised the ozone NAAQS, more than 1,700 peer-reviewed studies examining the health effects of ozone have been published. Extensive reviews of this new body of evidence by EPA staff scientists and by EPA's Clean Air Scientific Advisory Committee (CASAC) have confirmed that the current primary ozone standard is set at a level that is not sufficient to protect public health with an adequate margin of safety.

Recent epidemiologic studies have demonstrated a range of adverse respiratory health effects at levels below the current 8-hour standard of 0.08 ppm, including increased hospital admissions and emergency room visits, respiratory symptoms in infants and children, asthma exacerbations, school absenteeism, and increased risk of premature death. [1]

A recent report of the National Academy of Sciences confirms the link between short-term exposures to ozone air pollution and premature death, even at concentrations below the final standard.[2]

The epidemiologic evidence is further supported by a number of controlled human exposure studies that have shown that some healthy adults experience reductions in lung function, increased respiratory symptoms, heightened susceptibility to respiratory infection and lung inflammation following just 6.6 hours of exposure to ozone at concentrations of 0.08 ppm.[3] More recent studies have demonstrated effects on lung function and respiratory symptoms down to 0.06 ppm.[4] It is important to emphasize that the respiratory effects observed in these chamber studies occurred in healthy young adult subjects and would likely be more severe among more vulnerable groups, such as children, seniors, or people with asthma or other lung diseases.

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[1] Comments of the American Lung Association, Environmental Defense, and Sierra Club on the U.S. Environmental Protection Agency's Proposed Revisions to the National Ambient Air Quality Standards for Ozone. October 9, 2007.

[2] National Research Council. Estimating Mortality Risk Reduction and Economic Benefits from Controlling Ozone Air Pollution. April 2008.

[3] Devlin RB, McDonnell WF, Mann R, Becker S, House DE, Schreinemachers D, Koren HS. Exposure of humans to ambient levels of ozone for 6.6 hours causes cellular and biochemical changes in the lung. *Am J Respir Cell Mol Biol* 1991; 4: 72-81; Hortstman DH, Follinsbee LJ, Ives PJ, Abdul-Salaam S, McDonnell WF. Ozone concentration and pulmonary response relationships for 6.6 hour exposures with five hours of moderate exercise to 0.08, 0.10, and 0.12 ppm. *Am Rev Respir Dis* 1990; 142: 1158-1163; McDonnell WF, Kehrl HR, Abdul-Salaam S, Ives PJ, Folinsbee LJ. Respiratory response of humans exposed to low levels of ozone for 6.6 hours. *Arch Environ Health* 1991; 46: 145-150.

[4] Adams WC. Comparison of chamber and face-mask 6.6 hour exposures to ozone on pulmonary function and symptoms responses. *Inhalation Toxicol* 2002; 14: 745-764; Adams WC. Comparison of chamber 6.6 h exposures to 0.04-0.08 PPM ozone via square-wave and triangular profiles on pulmonary responses. *Inhalation Toxicol* 2006; 18: 127-136.

Never before has there been such a strong, broad, and unanimous consensus that the standards needed to be significantly strengthened in order to protect public health and to provide a margin of safety as required by the Clean Air Act.

The Clean Air Scientific Advisory Committee (CASAC) is chartered under the Clean Air Act to advise the EPA Administrator on the review of the NAAQS. The CASAC ozone panel was comprised of 23 distinguished scientific experts from a variety of disciplines and perspectives. This panel was composed of the nation's leading experts in ozone air pollution science and health. The panel met at least six times over the course of the review and submitted detailed oral comments and seven sets of written comments totaling 500 pages on the review plan, the exposure and risk assessments, and the draft and final Criteria Document and Staff Paper.

After reviewing the at least two drafts of the Criteria Document and the Staff Paper, the 23-member CASAC ozone panel reported to EPA these unanimous recommendations:[5]

- The current standard fails to protect public health from the harmful effects of ozone, the nation's most widespread outdoor air pollutant.
- EPA should set the 8-hour ozone standard much lower—in the range of 0.060 to 0.070 parts per million (ppm)—to adequately protect public health.
- EPA should eliminate the "rounding" loophole that weakens the current standard and leaves millions of Americans unprotected.

CASAC restated its original recommendations in a follow-up letter to EPA after reviewing the final ozone Staff Paper, and added an additional recommendation:

- EPA must explicitly account for a "margin of safety" in setting the ozone standards.[6]

Then CASAC panel took the unusual step of reiterating its position in a letter sent to the EPA Administrator upon issuance of the final rule.[7] A strongly worded letter to the EPA Administrator stated:

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[5] Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, re Clean Air Scientific Advisory Committee's (CASAC) Peer Review of the Agency's 2nd Draft Ozone Staff Paper, EPA-CASAC-07-001, October 24, 2006.

[6] Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, re Clean Air Scientific Advisory Committee's (CASAC) Review of the Agency's Final Ozone Staff Paper, EPA-CASAC-07-002, March 26, 2007.

[7] Letter from Dr. Rogene Henderson, Chair, Clean Air Scientific Advisory Committee to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, re Clean Air Scientific Advisory Committee Recommendations Concerning the Final Rule for the National Ambient Air Quality Standards for Ozone, EPA-CASAC-08-009, April 7, 2008.

> "*...the members of the CASAC Ozone Review Panel do not endorse the new primary ozone standard as being sufficiently protective of public health.* The CASAC -- as the Agency's statutorily-established science advisory committee for advising you on the national ambient air quality standards -- *unanimously recommended* decreasing the primary standard to within the range of 0.060-0.070 ppm. It is the Committee's consensus scientific opinion that your decision to set the primary ozone standard above this range fails to satisfy the explicit stipulations of the Clean Air Act that you ensure an adequate margin of safety for all individuals, including sensitive populations."

EPA's Children's Health Protection Advisory Committee (CHPAC) endorsed a standard at the lower end of the CASAC-recommended range.[8]

> "As pediatricians, public health and environmental professionals drawn from academia, government, industry and public interest organizations, we would like to again express our unanimous opinion that the 8 hour ozone standard should be set at the lowest level offered by the Clean Air Scientific Advisory Committee (CASAC), 0.060 ppm, in order to adequately protect the health of children with an appropriate margin of safety (CHPAC letter, March 23, 2007). This opinion is based on the existing scientific studies of children, which demonstrate serious adverse health effects of ozone exposure, including exacerbation of asthma with attendant increases in medication use, hospitalization, and missed school days, and impairment of normal lung development. It is also based on consideration of the evidence that disruption of lung development may result in permanent health consequences in children exposed to ozone."

This consensus has been endorsed by over 100 leading independent air quality scientists and physicians.[9] Moreover, mainstream medical and public health organizations including the American Medical Association, the American Academy of Pediatrics, the American Public Health Association, the American Nurses Association, the American Thoracic Society, the American Heart Association, the American College of Chest

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[8] Letter from Melanie A. Marty, Ph.D., Chair, Children's Health Protection Advisory Committee, to Stephen L. Johnson, Administrator, U.S. EPA, re: Review of the NAAQS for Ozone: Policy Assessment of Scientific and Technical Information, March 23, 2007; and Letter from Melanie A. Marty, Ph.D., Chair, Children's Health Protection Advisory Committee, to Stephen L. Johnson, Administrator, U.S. EPA, re: Proposed NAAQS for Ozone, 4 September, 2007.

[9] Letter to U.S. EPA Administrator Stephen Johnson re Broad Scientific Consensus to Lower the Ozone Air Quality Standard and Close the Rounding Loophole, from Jonathan I. Levy, Sc.D., Associate Professor of Environmental Health and Risk Assessment, Harvard School of Public Health; Kent Pinkerton, Ph.D., Director of the Center for Health and the Environment, University of California at Davis; and William Rom, M.D., M.P.H., Sol and Judith Bergstein Professor of Medicine and Environmental Medicine and Director of the Division of Pulmonary and Critical Care Medicine, New York University School of Medicine, and over 100 other air quality scientists and physicians, April 4, 2007. Available at: http://www.cleanairstandards.org/wp-content/uploads/2007/04/final-ozone-scientists-sign-on-letter-4-5-07.doc

Physicians and many others have recognized the need for ozone air quality standards consistent with the CASAC recommendations.[10]

The recommendations of these prominent scientific and medical panels are more than just optional advisories: they represent repeated peer review and assessment of the scientific research by recognized authorities. The fact that they arrive at similar and unanimous conclusions bears witness to the strength of the underlying science. Unfortunately, EPA's final standards are weaker than those recommended by CASAC, CHPAC, the World Health Organization, and numerous public health and medical organizations. They are weaker than the standards adopted by the State of California and many other countries including Canada and the United Kingdom.

In the face of this strong consensus, it is untenable to cite "uncertainty" as a rationale for failing to promulgate tighter standards. Indeed, EPA mentions uncertainty no fewer than 100 times in the preamble, despite the massive accumulation of new evidence published since EPA's last review. EPA's claims that uncertainty justifies less protective standards than recommended by CASAC are both unfounded and one-sided. EPA's uncertainty claims lack rational support, and arbitrarily ignore uncertainties that favor more protective standards. For instance, controlled human exposure studies typically use healthy young adults as test subjects. This creates uncertainty about what the results would be on infants, or children, or children with severe respiratory disease. When Congress wrote the Clean Air Act, scientists testified that we would never have absolute knowledge: that we would learn more and improve our ability to assess dangers, but that we would always need to protect the public even when we lack full knowledge. Congress included a simple phrase in the Clean Air Act, in the requirements for setting standards, to direct the EPA to include an "adequate margin of safety" to provide a cushion of protection. The Clean Air Act requires that the EPA address such uncertainty in favor of more public health protection, not less.

The American Lung Association was deeply disappointed that the final EPA ozone standards issued in March 2008 failed to follow the recommendations of the Clean Air Scientific Advisory Committee. While the final standards of 75 ppb represent an improvement over the prior standards, they fall short of the Clean Air Act's mandate to protect public health with an adequate margin of safety.

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[10] Letter to EPA Administrator Stephen L. Johnson, re: Science Compels Stricter NAAQS for Ozone, from the heads of the American Lung Association, American Academy of Pediatrics, American Public Health Association, Asthma and Allergy Foundation of American, and 16 national health and environmental organizations, April 16, 2007. Available at: http://www.cleanairstandards.org/wp-content/uploads/2007/04/ltr-from-public-health-environ-groups-on-ozone-naaqs-04-16-07.pdf; letter to EPA Administrator Stephen L Johnson re: Proposed National Ambient Air Quality Standards (NAAQS) for Ozone--Docket ID Number EPA-HQ-OAR-2005-0172, October 5, 2007 signed by American Heart Association and 9 other national health organizations; and Letter from the American Thoracic Society, American Medical Association, American College of Chest Physicians, American College of Preventive Medicine, American College of Occupational and Environmental Medicine, American Association of Cardiovascular and Pulmonary Rehabilitation and National Association for the Medical Direction of Respiratory Care to Stephen L. Johnson, Administrator, Environmental Protection Agency. October 9, 2007.

Furthermore, the American Lung Association was greatly dismayed by Administrator Johnson's call for legislative changes to the Clean Air Act's standard-setting provisions.

The great value of the current approach is that the air quality standards, the goals, are strictly science-based. Americans have a right to know if the air they breathe is safe or not. They need clear, unbiased, health-based National Ambient Air Quality Standards that are unalloyed by cost, feasibility, risk, or other considerations. They need standards that are reviewed every five years to ensure that the goals are based on current information -- that children are not born and raised before the standards are updated.

The present Clean Air Act allows ample opportunity for cost, feasibility, timelines and other considerations to be taken in account -- during the implementation phases.

The Clean Air Act has been extremely effective in driving down emissions of air pollution, while accommodated economic growth.[11] Its technology forcing provisions have been a great success story. The air quality standards are central to this success.

We urge this Committee to hold EPA accountable for its final decision on the ozone air quality standard.

Attached is a list of the medical societies and the public health groups who supported an ozone standard in the range that the CASAC recommended.

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[11] U.S. EPA. Air Quality and Emissions: Progress Continues in 2006. http://www.epa.gov/air/airtrends/econ-emissions.html

BEFORE THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON SECTOR SOLUTIONS TO GLOBAL WARMING, OVERSIGHT, AND CHILDREN'S HEALTH PROTECTION

"OVERSIGHT HEARING ON SCIENCE & ENVIRONMENTAL REGULATORY DECISIONS"

STATEMENT FOR THE RECORD
OF THE
AMERICAN CHEMISTRY COUNCIL
May 14, 2008

I. Introduction

The American Chemistry Council (ACC) appreciates the opportunity to provide this statement to the Subcommittee regarding the crucial role of science in environmental regulatory decision-making. The Subcommittee's hearing provides a timely opportunity to address an issue that is vitally important to the public interest.

ACC represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer, more energy efficient and more convenient. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $635 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure. ACC's member companies share the objective of meeting consumer, scientific and industrial demands for products and processes that protect human health and the environment. Our industry's technological innovation and progress help protect children from illness and injury, through products such as life-saving vaccines, child safety seats, and bicycle helmets, to name but a few.

Chemistry is a science-based industry. Virtually all of our products are the result of extensive research by skilled chemists who strive continuously to develop new molecules that perform needed functions, and sophisticated work by chemical engineers who design processes that make these products more safely and efficiently. The business of chemistry in the United States invests $26 billion in research and development annually, more than any other industry. It is a domestic leader in invention, receiving nearly 11% of all U.S. patents. The result of this research is innovation in chemistry that provides a constant stream of new, breakthrough products that steadily increase the quality of life in an ever-more competitive, global marketplace. This research fosters innovation and increased productivity, particularly innovation

in the downstream industries that use the products of chemistry. Indeed, a significant policy objective for the U.S. should be to assure that the chemical regulatory system does not stifle innovation, but rather spurs the technological advances for which U.S. businesses are known.

Industry research also promotes improved environmental practices by our industry. Indeed, our practices have led to a nearly 75 percent reduction in Toxic Release Inventory emissions since 1988 and decreases in absolute greenhouse gas emissions by 12.5 percent between 1990 and 2006.

In the balance of this statement, ACC discusses the crucial role that science must play in environmental regulatory decision-making and ACC's views on several issues involving science and environmental regulation.

II. The Crucial Role of Science in Environmental Regulatory Decisions

The decision-making process established by federal environmental laws has two main components.

Federal environmental laws embody a range of decisions by Congress about when agencies can or must act, when parties must do or stop doing something, and when other factors should or must be taken into account. Sometimes these standards are technology based; for example, requiring EPA to set emission standards for major sources of hazardous air pollutants that represent use of "maximum achievable control technology."[1] Other standards are risk-based; for example, allowing EPA to issue an order to prohibit or limit the manufacture of a chemical that "may present an unreasonable risk of injury to health or the environment" until the manufacturer provides data sufficient to evaluate those risks.[2] These standards also determine how conclusively a risk must be established before action is warranted or required.

Under technology-based standards, scientific and technical information generally represents the performance of control or treatment technologies in real-life settings. Under risk-based standards, this information reflects the findings of toxicologists, epidemiologists, and other health and environmental scientists regarding the inherent hazards of substances, the extent to which people or other receptors are exposed to them, and the resulting possibility or likelihood of adverse effects. Most often, toxicity testing data for human health hazards derive from controlled laboratory studies using animal models with high doses of substances to increase the likelihood of detecting potential effects. As a result, these studies require data interpretation to extrapolate (i) from high doses to low, environmentally relevant exposures that humans may experience, and (ii) from lab animals to humans. Interpretation of such data can be challenging, even for highly trained and experienced professionals, and differing expert perspectives are common. Such science-based interpretations are essential, however, to enable EPA and other agencies to make statutorily-required findings about risk.

In the case of risk-based regulatory decision-making, all stakeholders agree it is essential for agencies to use:

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[1] Clean Air Act Section 112(d)(2), 42 U.S.C. § 7412(d)(2).
[2] Toxic Substances Control Act Section 5(e)(1)(A), 15 U.S.C. § 2604(e)(1)(A).

- **The best available science**. Science evolves continuously, as newer research improves on prior understandings and knowledge advances. It is a basic tenet of the scientific process, and federal administrative law, that science-based decision-making should rely on the best science available at the time the decision must be made.[3] Better science can mean less uncertainty, and less need to rely on default assumptions.
- **Weight of evidence analysis**. While this phrase has several meanings,[4] scientists generally agree that science-based decision-making ought to take into account all available, relevant information. No research or analysis should be excluded *a priori*; rather, questions about the quality of the work ought to affect the weight that is given it, so that the best science is weighted most heavily.[5]
- **Peer review**. Historically, the scientific community has relied upon probing analysis by other knowledgeable scientists as the best means of assessing the merits of a scientific work in the short term (i.e., before enough time has passed to see if the work can be replicated). Peer review has been well-established at EPA for many years,[6] and since 2005 has been required at all federal agencies.[7]

ACC not only endorses these views, but has also made a substantial financial commitment to research and testing, both within our member companies and through contract research organizations and academic labs. ACC and its members devote considerable resources to (i) increasing the level of scientific certainty about whether their products pose hazards or risks; (ii) determining what conditions of use or exposure are of concern in order to protect workers, the public and the environment, and (iii) assuring that products can be used safely for their intended purpose. Conducting research and testing products is central to regulatory compliance and is also a foundation of product stewardship under ACC's Responsible Care® program. ACC's efforts include:

- **The Long-range Research Initiative (LRI)**. LRI is a multiyear commitment to fund basic research on the issues where better scientific understanding is most needed to do the job of protecting human health and the environment. To assure the credibility of the resulting research, ACC implemented cutting-edge practices such as (i) contractually-guaranteed researcher independence (researchers own the data they generate and are free, indeed required by terms of their contracts, to publish the results of their work without editorial control by ACC); and (ii) disclosing the fact of ACC's funding in publications.
- **High-Production Volume (HPV) Program**. The HPV Program is an unprecedented initiative to make publicly available uniform health and environmental screening

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[3] *See, e.g.*, the Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(3)(A)(i); OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 8457 (Feb. 22, 2002); EPA, *Role of Science at EPA* (concluding paragraph), *available at* http://www.epa.gov/osp/science.htm.

[4] *See* Douglas L. Weed, *Weight of Evidence: A Review of Concepts and Methods*, 25 RISK ANALYSIS 1545 (Dec. 2005).

[5] *See, e.g.*, EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, § 1.3.3 (EPA/630/P-03/001B, March 2005).

[6] EPA Science Policy Council, PEER REVIEW HANDBOOK (3d ed. 2006).

[7] OMB, *Final Information Quality Bulletin for Peer Review*, 70 Fed. Reg. 2664 (Jan. 14, 2005).

information on high production volume[8] (HPV) chemicals. More than 300 sponsoring manufacturers volunteered to provide hazard-screening information on 2,222 HPV chemicals, representing 90-95% of the chemicals in U.S. commerce by volume. As of April, 2008, initial submissions (containing a robust data summary and a recommended test plan to fill data needs) have been made by sponsors on 97% of the HPV chemicals. All of the information collected under the HPV Program is important and relevant for evaluating a chemical's potential impact on human health and the environment. Additionally, tests for genotoxicity, acute, developmental and reproductive toxicity are specifically relevant to protecting children's health. EPA is using the HPV data to make decisions on priorities for further review under the agreement concluded last year with the Canadian and Mexican governments. All HPV data – which was always intended for screening purposes and not as a complete data set – will be assessed under EPA's new program, called the Chemical Assessment and Management Program (ChAMP), established by the Agency's Office of Pollution Prevention and Toxics.

- **EPA's Voluntary Children's Chemical Evaluation Program (VCCEP).** This pilot program was developed to assess an innovative, science-based process for EPA and chemical company sponsors to evaluate the ability of a tiered, risk-based framework to determine whether risks to children have been adequately characterized. By focusing on risks, and not just potential hazards, the VCCEP pilot has led to significant advances in child-focused exposure assessments and to development of a scientific basis for distinguishing gaps in data or information from actual data needs – where data needs are the specific information or results required to reduce uncertainty and to characterize children's risk with an adequate degree of scientific confidence. ACC provided further information on the VCCEP program and its benefits in advancing science in our written statement filed for the record of the Senate Environment and Public Works Committee's April 29, 2008 hearing on toxics policy.

In addition to these initiatives, ACC member companies routinely evaluate their own products for potential health and environmental risks. Key components of the industry's commitment to product stewardship include guidelines for product stewardship, sharing best practices within the chemical industry and with customer industries; a tiered process for completing risk characterization and risk management actions for chemicals in commerce; and ways to make relevant product stewardship information available to the public.

ACC companies do not wait for inquiries about their products before they seek to understand the potential hazards or risk of such substances. Nor do they limit themselves to challenging the assessments that others conduct. The chemical industry understands it has a responsibility to generate the high-quality scientific information that federal agencies need to make environmental regulatory decisions and that companies need for first-rate product stewardship.

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[8] High Production Volume (HPV) chemicals are those substances manufactured in or imported into the United States in amounts greater than 1 million pounds per year.

III. Current Issues on Science in Environmental Regulatory Decision Making

A. U.S. Laws Are Precautionary

U.S. laws are precautionary,[9] and the risk assessment methodologies used by EPA and other agencies are inherently health protective and conservative, embodying safety and uncertainty factors that frequently result in estimated risks for regulatory purposes that are orders of magnitude greater than most likely values. This health protectiveness is commonly built into federal environmental statutes, for example, the Clean Air Act's requirement of "an adequate margin of safety" in setting national ambient air quality standards[10] and the Federal Food, Drug & Cosmetic Act's standard of "reasonable certainty of no harm" from pesticide residues on food.[11]

In general, current laws authorize EPA to act when the Agency has information about potential harm, rather than requiring certainty. The Toxic Substances Control Act (TSCA) requires EPA to have "a reasonable basis" to conclude that a chemical presents an unreasonable "risk" of injury to health or the environment – not "certainty."[12] Further, EPA need only find that a chemical "may present" such a risk before EPA can order manufacturers of that chemical to provide it with test data to allow it to make a more informed decision.[13]

Hazard alone – rather than risk – is generally an insufficient basis to regulate under current law, and properly so. Risk-based evaluations are needed to understand the conditions of exposure that may result in harm and, thereby, to enable risk-based decision-making to restrict or control such uses/exposures so that substances may be used, when appropriate, in a safe manner. Where difficult decisions involving risk/risk tradeoffs are necessary, an appropriate scientific framework is necessary to guide analysis and decisions.

B. How Much Evidence is Enough?

Underlying the legal question of what level of hazard or risk warrants regulation is the question of how much science is required before an agency decides that a given chemical causes a particular hazard or risk. Answering this question requires application of the scientific principles discussed above: weight of evidence, peer review and best available science. Related to the latter principle is the question of when an agency should act versus waiting for new data. In general, EPA should allow significant research or testing already underway to be completed, and take it into consideration – unless, of course, solid scientific data indicates risk sufficient to support or require immediate Agency action. Prematurely closing the door on an issue does not serve the cause of science and can have major economic consequences. As the sponsors of extensive research and testing, ACC supports programs that take that ongoing work into account.

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[9] OMB explains why this is so in Chapter Three of its report entitled: INFORMING REGULATORY DECISIONS: 2003 REPORT TO CONGRESS ON THE COSTS & BENEFITS OF FEDERAL REGULATIONS AN UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES (2003), *available at* http://www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf.

[10] 42 U.S.C. § 7409(b)(1).

[11] 21 U.S.C. § 346a(c)(2).

[12] 15 U.S.C. § 2605(a).

[13] *Id.* §§ 2603(a)(1), 2604(b)(4).

C. Industry Funded Science and Industry Scientists

The chemical industry takes seriously its central responsibility to conduct or fund research and testing of chemicals for use in the risk assessment processes. This scientific work has an important and appropriate role in the development of health and environmental information. Industry scientists can and do serve important and legitimate functions on scientific advisory panels. Frequently, they provide unique knowledge and insight concerning the chemical in question or related substances and thus promote the public's interest in having the best available scientific experts participate in the process. Therefore, they should not be unjustifiably prevented from contributing to the work of such panels.

Scientific studies conducted or funded by the chemical industry have long been acknowledged by government agencies, non-governmental organizations, and the scientific community at large as necessary and valuable contributions to the understanding of potential public health and environmental effects related to the manufacture and use of chemicals. These same groups generally also recognize that the costs associated with conducting chemical product testing have been and will be borne largely by industry, not the public sector. A wide variety of mechanisms exist by which policymakers and the public they serve can assure themselves that studies performed by or funded by industry (i) are identified as such, (ii) meet high scientific standards, and (iii) are not suppressed when their findings are adverse to industry's interests. These practices and standards include:

- The ability of research sponsors to contractually authorize investigators – regardless of the results – to submit the investigators' findings for publications in the peer-reviewed scientific literature without sponsor approval.
- The practice of virtually all scientific journals to require disclosure of affiliations and funding sources.
- Peer review, which both government agencies and private entities may conduct or fund.
- Environmental Protection Agency (EPA) requirements that all studies required to be submitted in connection with chemical regulation and pesticide statutes be conducted in accordance with EPA Good Laboratory Practice (GLP) regulations, which require (i) use of EPA-approved guidelines for test protocols; (ii) use of standard operating procedures; and (iii) full availability to government authorities of the raw, quality-assured data files for review and audit.[14] Research required to be submitted to regulatory agencies in member countries of the Organization for Economic Cooperation and Development likewise must follow OECD *Principles of Good Laboratory Practice*, which serve to substantiate the high quality and validity used for determining the safety of chemicals and chemical products in those countries.[15] Notably, most academic laboratory research does not follow GLP rules.
- Information Quality Act guidelines, issued by all federal agencies, which require scientific data to meet applicable standards for accuracy, reliability and lack of bias, and which require supporting data and models to be documented and made available. These

[14] *See* 40 C.F.R. Parts 160 (pesticide GLP regulations) and 792 (TSCA GLP regulations).
[15] The OECD Principles of Good Laboratory Practice are available at http://www.oecd.org/document/63/0,3343,en_2649_34381_2346175_1_1_1_1,00.html.

guidelines apply to privately-generated information when agencies rely on it for regulatory purposes.[16]

- EPA requirements under TSCA and the federal pesticide statute (FIFRA),[17] and similar global equivalents, that chemical manufacturers and pesticide registrants provide EPA and its equivalents with timely notification of any adverse effects findings.
- The prospect of tort liability for suppression of adverse research findings.
- Finally, and most fundamentally, the scientific process itself, through which different investigators attempt to reproduce the findings of others.

The more a given study follows the first four practices and standards listed above, the more confidence one can place in it – regardless of who funded it.

The chemical industry's commitment to scientific research and product testing includes engaging the highest quality scientists. Our scientists have national and international stature in the scientific community, as reflected by their inclusion on such authoritative bodies as the National Academies' Board on Environmental Studies and Toxicology and EPA's Science Advisory Board. These scientists have expert knowledge of the chemicals their employers manufacture, and fully appreciate the value of their contributions – as objective, trained scientific experts – to the development and interpretation of the science needed to evaluate the health and environmental effects of their products. As members of professional associations like the Society of Toxicology, industry scientists adhere to both personal and professional commitments to act in accordance with the codes of ethics of their professions.

Some have argued that scientists employed or funded partially by industry should not be permitted to serve on governmental review panels or similar bodies. Federal rules issued under the Ethics in Government Act provide that true conflicts of interest in such cases are limited to instances where a panel is considering a "particular matter" that "will have a direct and predictable effect" on an entity in which the person has a current, concrete financial interest, typically through stock ownership rather than employment.[18] Importantly, these government ethics rules still allow for a person with such a financial interest to serve where "the need for the individual's services outweighs the potential for a conflict of interest."

Similarly, some bias (or "partiality," under government ethics rules[19]) is unavoidable and therefore generally should not be considered as a basis for disqualification unless a person has demonstrated that he or she has already made up his or her mind regarding an issue at hand. As the National Academies explain, bias derives from "points of view or positions that are largely intellectually motivated or that arise from the close identification or association of an individual with a point of view of a particular group."[20] However, the NAS goes on to state that bias should be grounds for disqualification if a person "is totally committed to a particular point of

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[16] EPA's Information Quality Guidelines are available at http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.
[17] 7 U.S.C. § 136d(a)(2) (FIFRA), 15 U.S.C. § 2607(e) (TSCA).
[18] *See* 5 C.F.R. Part 2635, Subpart D, esp. § 402(b)(2), example 2.
[19] *Id.* Subpart E.
[20] National Academies, *Policy on Committee Composition and Balance and Conflicts of Interest* (May 12, 2003) at 3, *available at* http://www.nationalacademies.org/coi/bi-coi_form-0.pdf.

view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary."[21]

Finally, any evaluation of the role of industry scientists in governmental processes must take into account the Administrative Procedure Act, which empowers interested persons to have input into agency rulemakings,[22] and the Federal Advisory Committee Act, which requires advisory committees to be "balanced,"[23] and thus should prohibit both exclusion of, as well as domination by, any interest.

Expertise is the touchstone that guides the procedures followed by both the National Academies and EPA's Science Advisory Board. The National Academies' current policy[24] is a particularly useful and appropriate statement of the relevant issues, as it:

- Emphasizes that knowledge, training and experience are the foremost considerations, and that no one should be appointed to a panel to represent a particular point of view or special interest;
- Clarifies that, "[f]or some studies . . . it may be important to have an 'industrial' perspective or an 'environmental' perspective," not because these "sides" need to be represented, but "because such individuals, through their particular knowledge and experience, are often vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee."
- Notes that "conflict of interest" ordinarily refers to "financial interests," and that these can arise from any quarter, including regulated entities, the government and non-governmental organizations.
- Explains that biases should not be disqualifying – even where a person works for a company with "a general business interest in" the subject of the panel – unless the person "is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary."

OMB's peer review guidelines agree with NAS and EPA that "the most important factor in selecting reviewers is expertise: ensuring that the selected reviewer has the knowledge, experience and skills necessary to perform the review."[25]

Consistent with these authoritative sources, scientists employed or funded by industry should be eligible to participate in peer review panels and similar bodies just like any other scientists, based on the knowledge, training and experience they bring to the body. All participants in such bodies should disclose sources of potential biases and conflicts, and potential biases should be considered in seeking a balanced panel. Disqualification should be reserved for current, concrete financial conflicts of interest (as defined above) and biases indicating a totally closed mind, except where either is outweighed by the need for a person's services.

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[21] *Id.* at 4.
[22] *See* 5 U.S.C. § 553(c).
[23] *See* 5 U.S.C. App. 2, § 5(b)(2).
[24] *See* note 20 *supra.*
[25] *See* OMB Peer Review Bulletin, *supra* note 7, 70 Fed. Reg. at 2669.

IV. Conclusion

Science plays an indispensible role in environmental decision making, providing the content needed for responsible product stewardship by companies and the data and information needed to implement the risk (and technology)-based statutes that govern regulatory decision making. ACC and its members have devoted substantial resources, particularly in the last decade, to improving the quality and quantity of that science to enhance scientific certainty, improve risk-based decision-making, and promote the public interest. We look forward to continuing this progress, through the work of our scientists, and the research we fund, which in turn will continue the improvement in quality of life that our products make possible.

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