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EPA'S IRIS PROGRAM: EVALUATING THE SCIENCE AND PROCESS BEHIND CHEMICAL RISK ASSESSMENT

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HEARING

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

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THURSDAY, JULY 14, 2011

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Serial No. 112-30

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Printed for the use of the Committee on Science, Space, and Technology

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C O N T E N T S

Wednesday, April 13, 2011

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Appendix I: Answers to Post-Hearing Questions

EPA'S IRIS PROGRAM: EVALUATING THE SCIENCE AND PROCESS BEHIND CHEMICAL RISK ASSESSMENT

THURSDAY, JULY 14, 2011

House of Representatives,
Subcommittee on Investigations and Oversight,
Committee on Science, Space, and Technology,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:04 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Paul C. Broun [Chairman of the Subcommittee] presiding.

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

hearing charter

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

SUBCOMMITTEE ON INVESTIGATIONS & OVERSIGHT

EPA's IRIS Program: Evaluating the Science

and Process Behind Chemical Risk Assessment

thursday, july 14, 2011
10:00 a.m. to 12:00 p.m.
2318 rayburn house office building

Purpose

On July 14, 2011, the Subcommittee on Investigations and Oversight will hold a hearing on the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS). There will be two panels at the hearing; the first panel will comprise of witnesses from EPA, the U.S. Government Accountability Office (GAO), and the National Academies' National Research Council. The second panel will include individuals and experts who will talk about their perspectives on IRIS.

In March of 2008, GAO reported that ``the IRIS database was at serious risk of becoming obsolete because EPA had not been able to

routinely complete timely, credible assessments. After subsequent reports, in January 2009 [GAO] added EPA's processes for assessing and controlling toxic chemicals to [its] list of areas at high risk for waste, fraud, abuse, and mismanagement or in need of broad-based transformation.'' \1\

\1\ David Trimble, Director, Natural Resources and Environment, Testimony before the Subcommittee on Investigations and Oversight, Committee on Science, Space, and Technology, July 14, 2011

As a result, the Subcommittee held several hearings on this subject. On May 21, 2008, the Subcommittee took testimony from Dr. George Gray, the then-Assistant Administrator for Research and Development at EPA, and Ms. Susan Dudley, the then-Administrator of the Office of Information and Regulatory Affairs (OIRA). Additionally, Mr. John Stephenson of GAO testified on findings regarding the lack of productivity in the IRIS process.

On June 12, 2008, the Subcommittee received testimony from Mr. Jerry Ensminger (U.S.M.C., retired), Mr. Lenny Seigel (Executive Director, Center for Public Environmental Oversight), and Dr. Linda Greer (Director of the Health Program at the Natural Resources Defense Council).

In 2009, the Subcommittee heard from Mr. John Stephenson again, and Dr. Kevin Teichman, the Deputy Assistant Administrator for Science at EPA's Office of Research and Development. They testified about the current IRIS process announced by EPA Administrator Lisa Jackson on May 21, 2009.

These prior IRIS hearings focused on the IRIS interagency review process, and delved into the role of the White House and other agencies, to determine the extent of their involvement in IRIS' chemical risk assessments. Today's hearing, prompted in part by the National Academies' National Research Council report on EPA's formaldehyde assessment, focuses on the process EPA uses to initially develop draft IRIS assessments, which is separate from the overall process that includes the multiple layers of review. The National Academy of Sciences' (NAS) report dedicated an entire chapter that reiterated several previous criticisms of EPA's IRIS process. In light of those criticisms, and recognizing that this is not the first time NAS has articulated them, the committee's goal is to better understand the process behind the development of IRIS' chemical risk assessments, whether EPA plans on adopting the NAS' recommendations, and whether or not EPA assessments are based on the best available evidence and evaluated in accordance with established protocols.

Background

IRIS was established in the 1980s as an internal EPA database to provide a single source of information on the risks associated with exposure to chemicals. The IRIS database provides a hazard identification and dose-response analysis, scientific information that when combined with estimates of exposure allow regulatory agencies to produce a risk assessment. Historically, entries to the database were the result of extensive in-house development by the science staff at EPA, peer review processes with experts from outside the agency, and opportunities for public input and comment.

By the early 1990s, the chemical database contained information on roughly 500 chemicals. However, as IRIS grew and gained more influence, EPA decided to restructure the IRIS process, which unfortunately led to the demise of the heretofore successful collaborative platform. This restructuring ultimately led to several reorganizations of the IRIS process (see Appendix B), with the most recent one announced by EPA Administrator Lisa Jackson on May 21, 2009.

In 2009, GAO testified before this Subcommittee that EPA ``has not been able to complete timely, credible chemical assessments or decrease its backlog of 70 [as of 2008] ongoing assessments.'' \2\ Further, GAO

reported, ``because EPA staff time was dedicated to completing assessments in the backlog, EPA's ability to both keep the more than 540 existing assessments up to date and initiate new assessments was limited. We found that 48 of the 70 assessments being conducted as of December 2007 had been in process for more than 5 years-and 12 of those, for more than nine years. These time frames have lengthened. Currently, of those 70 assessments, 58 have now been ongoing for more than 5 years-and 31 of those for more than 9 years.'' \3\

\2\ John B. Stephenson, Director, Natural Resources and Environment, Testimony before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, June 11, 2009

\3\ Ibid.

The IRIS database currently includes 554 chemicals. Since GAO last reported, EPA completed six assessments in 2009 and ten assessments in 2010. These numbers are far below the twenty assessments EPA planned to finalize in 2010. \4\ Moreover, 70 chemicals continue to remain in various stages of review.

\4\ ``Update on Integrated Risk Information System (IRIS) Program Activities,'' EPA, Office of Research and Development, National Center for Environmental Assessment (NCEA) (hereinafter NCEA IRIS document)

Further compounding the problem, EPA line offices are no longer required to concur with IRIS assessments and internal EPA comments are still not transparent. The quality of assessments being produced also continues to be an issue. Since 2005, five assessments have been referred to the National Academies' for evaluation. All of the NAS reviews have severely criticized EPA's assessments, and offered numerous recommendations, which EPA has yet to implement.

Issues

NAS: ``Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde''

On April 8 of this year, NAS published its long-awaited study on EPA's formaldehyde assessment. While NAS ``strongly questioned EPA claims that exposure to formaldehyde can result in increased risk of a leukemia and other cancers that had not previously been associated with formaldehyde, asthma, and reproductive toxicity,'' \5\ that is not the most compelling part of the document for the purposes of this hearing. Of interest is that the NAS panel ``strongly faulted EPA's methodology in crafting its draft assessment, warning of a pattern of problems in how the agency crafts assessments for its Integrated Risk Information System (IRIS) database that could continue to hamper future risk studies. `The committee is concerned about the persistence of problems encountered with IRIS assessments over the years, especially given the multiple groups that have highlighted them . . . If the methodologic issues are not addressed, future assessments may still have the same general and avoidable problems that are highlighted here.'' \6\

\5\ Maria Hegstad, ``NAS Sets Back EPA Proposal For Strict Formaldehyde Risk Assessment,'' Environmental NewsStand, April 8, 2011

\6\ Ibid.

In the summary of the report, the panel commented on the similarities in some of the problems with the IRIS assessment on formaldehyde, and those identified in other reports published by previous NAS panels:

``Overall, the committee noted some recurring methodologic problems in the draft IRIS assessment of formaldehyde. Many of the problems are similar to those which have been reported over the last decade by other NRC committees tasked with reviewing EPA's IRIS assessments for other

chemicals. Problems with clarity and transparency of the methods appear to be a repeating theme over the years, even though the documents appear to have grown considerably in length. In the roughly 1,000-page draft reviewed by the present committee, little beyond a brief introductory chapter could be found on the methods for conducting the assessment. Numerous EPA guidelines are cited, but their role in the preparation of the assessment is not clear. In general, the committee found that the draft was not prepared in a consistent fashion; it lacks clear links to an underlying conceptual framework; and it does not contain sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies, for critically evaluating individual studies, for assessing the weight of evidence, and for selecting studies for derivation of the RfCs and unit risk estimates.'' \7\

\7\ ``Review of the Environmental Protection Agency`s Draft IRIS Assessment of Formaldehyde,'' National Research Council of the National Academies, April 8, 2011 (hereinafter NAS Formaldehyde Report)

Please see Appendix A for detailed recommendations from the NAS report.

NAS: ``Science and Decisions: Advancing Risk Assessment'' \8\

\8\ ``Science and Decisions: Advancing Risk Assessment,'' National Research Council of the National Academies, 2009

Dr. Thomas Burke, associate dean of The Johns Hopkins Bloomberg School of Public Health, recently chaired an NAS panel on ``ways to improve EPA risk assessments.'' \9\ At a joint meeting of EPA's Science Advisory Board and EPA's Board of Scientific Counselors, Dr. Burke said, ``The sleeping giant is that EPA science is on the rocks . . . if you fail, you become irrelevant, and that is kind of a crisis.'' \10\ Referring to EPA's risk assessment process as the agency's ``Achilles heel,'' \11\ Dr. Burke's NAS panel suggested steps on how EPA could improve that process in a 2009 report titled, ``Science and Decisions: Advancing Risk Assessment.'' This report carries added weight in light of the NAS report on formaldehyde issued earlier this year with its chapter critical of EPA's IRIS process.

\9\ ``Key Advisor Warns EPA to Improve Agency Science or Face a -- Crisis,'' InsideEPA.com, July 8, 2011

\10\ Ibid.

\11\ Ibid.

NTP's RoC

The Department of Health and Human Services' (HHS) National Toxicology Program (NTP) publishes a report every Congress called the Report on Carcinogens (RoC). \12\ On June 10 of this year, the Twelfth RoC was released, and it elevated its classification of formaldehyde from `reasonably anticipated to be a human carcinogen' to `known to be a human carcinogen.' The report was published despite the NAS review. This is important because according to an analytic paper, NTP has:

\12\ Maria Hegstad, ``NAS Critique of EPA Formaldehyde Study Hampers HHS --Cancer` Report,'' Environmental NewsStand, April 26, 2011. ``Congress directed the program to prepare the report every other year, but due to concerns over the review process for the document, the last RoC was published in 2005. The RoC provides information on chemicals that NTP deems carcinogenic or reasonably anticipates to be human carcinogens, along with people's potential for exposure to them.''

``been reviewing the scientific data for formaldehyde in preparation

for a listing decision in the 12th Report on Carcinogens (RoC). EPA and the NTP have had available, reviewed and relied upon the same studies, reports and underlying data in conducting their respective hazard evaluations of the possible relationship between formaldehyde exposure and leukemia and other lymphohematopoietic malignancies. Therefore, the NRC committee's review of and conclusions concerning the draft EPA IRIS report are, with respect to lymphohematopoietic malignancies (including myeloid leukemia), directly applicable to the NTP's own review and conclusions--precisely because the draft EPA and NTP reports involve the same studies and data sets.'' \13\

\13\ ``National Research Council Report on Scientific Evidence Pertaining to the Relationship Between Formaldehyde Exposure and Leukemia: Implications for the National Toxicology Program's Listing of Formaldehyde in the 12th Report on Carcinogens,'' Environ International Corporation, April 22, 2011 (emphasis in original text)

Further:

``The NRC committee's opinion was that EPA's review of the scientific literature as presented in the draft IRIS assessment does not provide a sufficient scientific basis for concluding that there is a causal link between formaldehyde exposure and leukemia. The NRC committee's conclusions concerning EPA's assessment of leukemia apply as well to application of the `listing criteria' for formaldehyde in the NTP's 12th RoC. In particular, there is no reasonable basis for the NTP to conclude that formaldehyde should be listed in the 12th RoC as being either `known' or `reasonably anticipated' to cause myeloid leukemia or any other lymphohematopoietic malignancy.'' \14\

\14\ Ibid. (emphasis in original text)

The RoC's more serious listing of formaldehyde could possibly influence EPA's own assessment relating to formaldehyde and leukemia, despite NAS' comments. Conversely, if EPA reassesses its formaldehyde review and comes to a different conclusion, then that raises questions about conflicting information from two different government entities, which may cause confusion downstream as risk managers and regulators

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try to understand which determination is more reliable.

EPA's SAB

Under the current process, EPA's Science Advisory Board (SAB) is responsible for peer reviewing EPA's IRIS assessments. However, ``there have been questions in the past, including some raised by [EPA's] Inspector General about the independence of the SAB panels.'' \15\ (Second footnote from passage) \16\The charge questions that lead SAB peer reviews are ``written by the EPA office requesting the review and which industry says can narrow the focus of the reviews. Sources also say the panels do not include a broad-enough roster of experts. For example, the SAB panel that recently reviewed EPA's IRIS assessment for inorganic arsenic* * *did not include a statistician or a cancer modeling expert and only one epidemiologist.'' \17\

\15\ Aaron Lovell, ``Rebuffed by EPA, Industry Asks OMB, GOP to Fix Chemical Study Process,'' Environmental NewsStand.com, June 22, 2011 (hereinafter Lovell Article)

\16\ U.S. EPA Office of Inspector General, ``EPA can Improve its Process for Establishing Peer Review Panels,'' Evaluation Report No. 09-P-0147, April 29, 2009

\17\ Lovell Article, supra, note 11

IRIS Assessments are not Insulated from Risk Management

In the NAS' 1983 report, ``Risk Assessment in the Federal

Government: Managing the Process,'' the National Research Council panel identified four components of a complete risk assessment:

hazard identification;

dose-response evaluation;

exposure assessment; and

risk characterization. \18\

\18\ National Research Council, National Academy of Sciences, ``Risk Assessment in the Federal Government: Managing the Process,'' 1983

IRIS reflects science that addresses the first two conditions. In discussing the difference between risk assessment and risk management,

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the Academy panel wrote:

``Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision.'' \19\

\19\ Ibid.

This distinction is commonly cited when IRIS assessments are criticized. When assessments make determinations that safe levels are below background levels, the IRIS program can reasonably claim that such factors can be weighed later in the risk management process. In reality, IRIS assessments are usually adopted with no further consideration. ``[S]ome customers use IRIS because it is a useful source of information; while for other customers IRIS is mandatory, and those customers include state agencies. Customers who use IRIS for general information often rely upon other databases to complement an IRIS assessment. Other databases exist, which can provide some help, but for domestic regulatory purposes there is no satisfactory alternative to IRIS. And using an IRIS file as the scientific basis for a regulatory decision is expected and seldom challenged.'' \20\

\20\ Jim Solyst, 11Eyeballing IRIS,'' The Environmental Forum, March/April 2009, Vol 26, No. 2

Witnesses

Panel 1

The Honorable Paul Anastas, Assistant Administrator, Office of Research and Development, U.S. Environmental Protection Agency. Dr. Anastas will talk about EPA's efforts to implement the most recent revised IRIS process, provide a status of assessments, and discuss EPA's efforts to implement NAS' and GAO's recommendations.

Mr. David Trimble, Director, Natural Resources and Environment, U.S. Government Accountability Office. Mr. Trimble will provide an overview of IRIS, highlight previous GAO work on IRIS, and evaluate EPA's efforts to implement GAO's recommendations.

Dr. Jonathan M. Samet, MD, MS, Professor and Flora L. Thornton Chair, Department of Preventive Medicine, Keck School of

Medicine, University of Southern California; and Chair, Committee to Review EPA's Draft IRIS Assessment of Formaldehyde, National Research Council, The National Academies. Dr. Samet will highlight the NAS' recent work on IRIS, and detail NAS' recommendations contained in chapter seven of their recently release report on formaldehyde.

Panel 2

The Honorable Calvin Dooley, President and Chief Executive Officer, American Chemistry Council. Mr. Dooley will talk about IRIS and industry's perspective on the IRIS process.

Ms. Rena Steinzor, Professor, University of Maryland School of Law, and President, Center for Progressive Reform. Ms. Steinzor will talk about IRIS, and offer suggestions on how to improve it and remove it from GAO's high risk series.

Dr. Gail Charnley, Principal, HealthRisk Strategies. Dr. Charnley will talk about IRIS, offer suggestions on how to improve it and remove it from GAO's high risk series, and discuss the NAS' recommendations.

The Honorable J. Christian Bollwage, Mayor, City of Elizabeth, New Jersey. Mayor Bollwage will talk about how IRIS assessments impact local communities, particularly Elizabeth, New Jersey.

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Chairman Broun. The Subcommittee on Investigations and Oversight will come to order. Good morning, everyone. Welcome to today's hearing titled EPA's IRIS Program: Evaluating the Science and Process Behind Chemical Risk Assessment. You will find in front of you packets containing our witnesses'--our witness panels' written testimony, biographies, and truth in testimony disclosure.

I recognize myself for five minutes for an opening statement.

Good morning. I want to welcome our witnesses here today.

This hearing continues the committee's work on EPA's Integrated Risk Information System or IRIS. The committee has held a number of hearings over the last few years on IRIS's ability to produce risk assessments associated with exposure to chemicals. In 2009, GAO placed the program on its High Risk Series because EPA was unable to complete timely, credible chemical assessments or decrease its backlog of ongoing assessments.

Over the last decade, the IRIS Program has gone through a number of changes, particularly to the process by which its assessments are reviewed. These changes were meant to address the inappropriate influence of the White House, regulated agencies, and industry on the IRIS process; the argument being that these entities were preventing assessments from being finalized. Despite these changes, the process implemented by EPA in 2009 still allows for White House input, and the program still has a backlog of over 70 assessments, unchanged from the previous Administration.

While EPA seems to be taking steps to adopt the recommendations of GAO regarding outside review, they have uniformly ignored the recommendations of another body, the National Academy of Sciences. For several years now they, too, have offered recommendations related to IRIS. These recommendations, however, did not focus on the review process but rather on how EPA develops the draft assessments in the first place. Time and time again, draft assessments were sent

to the NAS for review, only to be severely criticized. Rather than adopting the recommendations of the Academy and updating their processes, EPA continued to churn out assessments that were summarily rebuked.

As I stated at our 2009 hearing, ``The competing priorities of issuing assessments in a timely manner and producing assessments that are scientifically credible are central to the problems we face today.'' That statement remains just as true today as it did two years ago. Up until now, EPA has blamed outside forces for the failures of the program. In reality, they, too, are to blame. The program's credibility is threatened when it continually puts forth assessments that fail to address fundamental issues raised by reviewers. If, as the old adage goes, the definition of insanity is doing the same thing over and over and expecting a different result, then this program needs some therapy.

Adopting the NAS recommendations is the first step to restoring the program's credibility. EPA's announcement 2 days ago is a step in the right direction, but the program's success hinges on its implementation. As the Academy noted in its formaldehyde report, many of the concepts and approaches they recommended are elementary and already exist in EPA's guidelines. They went on to state, ``The current state of the formaldehyde draft IRIS assessment suggests that there might be a problem with the practical implementation of the guidelines in completing the IRIS assessments.''

Following through is the key here. It is up to the EPA to not only adopt the NAS recommendations but to also follow its own existing guidelines. This committee will continue its oversight of the IRIS program to ensure that EPA not only adopts the NAS recommendations, but that it follows guidelines already in existence and continuously seeks to employ the most modern, credible methods and protocols to assess chemical risks.

I have a lot of questions about this program and where it is headed. As GAO stated in their testimony in 2009, ``EPA needs to hold itself more accountable to the public and Congress for carrying out this important component of its mission, especially since the IRIS program is discretionary.''

As a physician myself, I understand the stakes that we are dealing with, particularly for sensitive populations such as children, pregnant women, and the elderly. I want to make sure that they are protected from undue harm. I also am aware of the damage caused by overly-conservative measures that scare our citizens without reason, ultimately doing nothing to advance safety. The opening line of the NAS's report titled, ``Science and Decisions,'' stated, ``Virtually every aspect of life involves risk.'' It is how we assess and manage that risk that ensures our safety.

[The prepared statement of Mr. Broun follows:]

Prepared Statement of Chairman Paul Broun

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implemented by EPA in 2009 still allows for White House input, and the program still has a backlog of over 70 assessments--unchanged from the previous administration.

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As I stated at our 2009 hearing, ``[t]he competing priorities of issuing assessments in a timely manner and producing assessments that are scientifically credible are central to the problems we face today.'' That statement remains just as true today as it did two years ago. Up until now, EPA has blamed outside forces for the failures of the program. In reality, they too are to blame. The program's credibility is threatened when it continually puts forth assessments that fail to address fundamental issues raised by reviewers. If, as the old adage goes, the definition of insanity is doing the same thing over and over and expecting a different result, then this program needs some therapy.

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I now recognize the Ranking Member from Maryland for her opening statement.

Chairman Broun. Now I recognize the Ranking Member from Maryland for her opening statement. I recognize Ms. Edwards for five minutes.

Ms. Edwards. Good morning, and thank you, Mr. Chairman.

For 50 years the tobacco industry has waged an organized campaign to cast doubt on the health risks of smoking cigarettes. They invented the effort to use science to fight science, to harness industry-funded research and public

relations efforts, and to use friendly, public officials and FORA to point to these manufactured uncertainties in opposing any effort to protect the public.

During that entire time public health experts have known absolutely that smoking causes cancer and that smoking remains in the words of the surgeon general, ``the single most important preventable cause of death in our society.'' This model of industry-funded science is being used to generate uncertainty and postpone even minor regulatory steps, regardless of the effects on public health and repeated with gusto by other industries.

A similar campaign is being waged by the fossil fuel industry to cast doubt on the science of climate change, and today we are going to see some of this unfolding, surrounding EPA's science-based efforts to develop risk assessments related to health consequences of chemicals that Americans are exposed to commonly.

Industry tends to push for two things in the realm of science and regulation. First they demand that we must have certainty before any action can be taken, and second, they point to studies that suggest there is uncertainty. What they don't mention quite so prominently is that the industry funds the production of studies designed to so doubt. That manufactured doubt is then used to justify inaction because obviously, there is no certainty. The result is gridlock. The country ends up in an endless loop of science, research, science, research that is expensive and counterproductive and making it almost impossible to ever make a statement about the harm of anything.

With enough money and enough willing researchers, there is always money and there are always willing payees. Industry can be certain that there is always another study just around the corner, no matter the chemical or the consensus regarding its harm with the industry, generally hoping that the study will show no harm.

In this world the scientists being paid say 325 bucks an hour, by the way, who work for industry, are not working to understand a problem but to provide answers that their clients want to use for their public relations campaigns. In 1983, the National Academy of Science has issued a red book on risk assessment. For almost 3 decades that has been the Bible on how to conduct a risk assessment. The report was motivated in part by a desire to try to set the science of assessing risk outside the political environment that surrounded decisions about what to do about those risks.

But deep pockets readily use the report to see science as a fertile ground for fighting regulation. Industry learned that they can forestall any movement out of the realm of risk assessment and into the realm of risk management by manufacturing doubt, a process institutionalized by the NAS book. Not by NAS but by those who used it.

Now the Academy has marched again into a situation that they may not have fully anticipated. The NAS report on EPA's draft formaldehyde assessment contains a very useful roadmap for how EPA should undertake reorganizing their IRIS assessments to make them more comprehensible and transparent, and though Dr. Anastas has embraced those recommendations, embraced the recommendations, the industries that most worry about IRIS assessments has seized on the language of the NAS report to try to claim that EPA cannot be trusted to do the science. That is not the message of the NAS report not the intention of the Academy panel.

Under the Bush Administration that so crippled the EPA through a broken program with interference by OMB, that agency was able to finalize only a couple of IRIS assessments a year.

EPA Administrator Lisa Jackson put in place a new process that severely cut back on OMB and polluting agency interference.

So today we are going to hear from industry prescribers that go back to this kind of OMB-dominated system in which there is a suggestion that no assessment can ever be finalized without the Academy peer review of the draft assessment and then another peer review of the redrafted assessment.

Instead I suggest that we follow the National Academy's advice. All the EPA the time to institute the kind of changes proposed in the formaldehyde review. Dr. Anastas has already proposed an initiative tied to the Academy roadmap that appears to be responsive and robust. It seems clear to me that to allow EPA to do their job with the advice from the Academy and not get captured by the endless science of the doubt machine is the direction that we should go.

I look forward to hearing from our witnesses today to cast light on this process and to ensure that we have agencies that are actually working in the public interest and not in the private interest.

Thank you, and I yield.

[The prepared statement of Ms. Edwards follows:]

Prepared Statement of Ranking Member Donna F. Edwards

For fifty years the tobacco industry has fought a campaign to cast doubt on the health risks of smoking cigarettes. They invented the effort to use ``science'' to fight science; to harness industry-funded research for public relations campaigns; and to use friendly public officials to point to these manufactured uncertainties in opposing any effort to protect the public.

And during that entire time, public health experts have absolutely known that smoking causes cancer, and that smoking remains--in the words of the Surgeon General--``the single most important preventable cause of death in our society.''

That model of industry-funded science being used to generate uncertainty and postpone even minor regulatory steps--regardless of the effects on public health--has been taken up with gusto by other industries. A similar campaign is being waged by the fossil fuel industry to cast doubt on the science of climate change. And today we are going to see some of this unfold surrounding EPA's science-based efforts to develop risk assessments of the health consequences of chemicals to which Americans are commonly exposed.

Industry tends to push for two things in the realm of science and regulation: first they demand that we must have certainty before any action can be taken, and, second, they point to studies that suggest there is uncertainty. What they don't mention quite so prominently is that they fund the production of studies designed to create doubt. That manufactured doubt is then used to justify inaction because, obviously, there is no certainty.

The country ends up in an endless science loop that makes it almost impossible to ever make a statement about the harm of anything. If an agency tries to take a position, industry argues that there is ``another study'' just around the bend for which the agency should wait. With enough money and willing researchers, industry can guarantee that there is always another study just around the corner no matter the evidence regarding its harm.

Of course the science that industry funds is specifically aimed at producing studies that show no harm from their products. In this world, the scientists who work for industry are not working to honestly understand a problem, but to provide answers that their clients want to use for their public relations campaigns. And make no mistake, no one pays you $325 an hour to produce science that isn't useful to their interests.

The National Academy of Sciences has not been blind to this development in America's science and regulatory landscape. In 1983, the National Academy of Sciences issued the ``red book'' on Risk Assessment. For almost three decades that has been the bible on how to

conduct a risk assessment. The report was motivated, in part, by a desire to try to set the science of assessing risks outside the political environment that surrounded decisions about what to do about those risks--a process they labeled risk management. The Academy, perhaps naively, hoped that all the struggles over regulatory decisions would be focused on risk management.

What the Academy did not anticipate was how readily those with deep pockets would see science as fertile ground for fighting regulation. Industry learned that they can stall any movement out of the realm of risk assessment by manufacturing doubt, and the NAS red book helped institutionalize this system.

And now the Academy has again marched into a situation that they may not have fully anticipated. The NAS report on EPA's draft formaldehyde assessment contains a very useful ``roadmap'' for how EPA should undertake reorganizing their IRIS assessments to make them more comprehensible and transparent. To his credit, Dr. Anastas has embraced those recommendations. But the industries that most worry about IRIS assessments have seized on the language of the NAS report to try to claim that EPA cannot be trusted to do science.

That is not the message of the NAS report nor the intention of the Academy panel.

If the Academy panel thought EPA could not institute effective changes, they would not have suggested EPA undertake them.

If the NAS panel did not think IRIS assessments were needed or could be produced to a high quality, they would not have advised EPA to continue to put out those assessments even as they work to incorporate changes to that process as recommended by the Academy.

If the panel did not trust EPA's ability to make appropriate changes to the draft-formaldehyde assessment, they could have recommended that EPA return to the Academy for a second review of that assessment. They did not make such a recommendation.

Yet we will have testimony today from an industry-funded scientist that goes so far as to say that in light of the Academy study, the IRIS program should be killed.

The IRIS program was a broken program during the Bush Administration. By 2006-2007, interference by OMB and endless science challenges by industry and polluting agencies that did not want to clean-up their messes--such as those documented at Camp LeJeune--had so crippled EPA that they were able to finalize only a couple of IRIS assessments a year.

Pressure from this Subcommittee helped inspire GAO to put IRIS on their high risk watch list and inspired the new Administrator of EPA, Lisa Jackson, to put in place a new process that severely cut back on the opportunities for OMB and polluting agencies to interfere with EPA's production of IRIS assessments.

It is too soon to know whether these steps will bear fruit, but we do know this: every IRIS assessment that the Academy has reviewed in the last half-dozen years, including the formaldehyde assessment, was largely a result of that broken process whereby OMB dictated to EPA much of the content and organization of those assessments. I would suggest that if the reports lacked coherence or clear communications perhaps it is because they were heavily interfered with by these non-EPA parties who insisted on new chapters, new sections, new issues and new articles being added.

And the cure that industry prescribes for improving IRIS reports? Why, go back to the OMB-dominated system that produced them in the first place! Mr. Dooley sent a letter making just such a suggestion to Jack Lew. They further advocate that no assessment ever be finalized without an Academy peer review of the draft assessment and then another peer review of the redrafted assessment.

Could the intent to slow roll action be any more transparent? And

in the years between Academy reviews, just imagine how many new industry-funded studies might be created to throw up ever more science chaff in the path of EPA? These are not cures that will heal the IRIS program, but are designed to bleed it to death.

Instead, I suggest that we follow the National Academy's advice. Allow EPA the time to institute the kinds of changes proposed in the formaldehyde review. Dr. Anastas has already proposed an initiative tied to the Academy roadmap that appears responsive and robust. And there is a new director of the IRIS program, Dr. Cogliano, who has been recruited to do for IRIS what he did for the International Agency for Research on Cancer risk process.

We have good people in place and good advice from the Academy. Let us allow them to do their job and not get captured by the endless science doubt machine.

Chairman Broun. Thank you, Ms. Edwards. If there are Members who wish to submit additional opening statements, your statements will be added to the record at this point.

Now, before we begin, let me note that, again, testimony from the EPA was not received within the timeframe established in our committee rules. Testimony was not received until 2:47 p.m. yesterday, with additional supplements trickling in at 5:45 p.m. yesterday.

Committee rule 7(B)(1) states that, ``Insofar as is practicable, no later than 48 hours in advance of his or her appearance each witness who is to appear before the committee shall file in printed copy and in electronic form a written statement of his or her proposed testimony and the curriculum vitae. Late testimony inhibits the committee's ability to fully evaluate the matter before it. Late delivery of testimony could set the stage for the committee to refuse to accept the written testimony of or hear from a witness.''

In this instance it is imperative that EPA testify, but EPA has once again obstructed the committee's ability to conduct legitimate oversight. EPA provided late testimony to the fiscal year 2012 budget hearing on March 10, late testimony to the May 11 hearing on hydraulic fracturing, and late testimony for the E-15 hearing on July the 7th .

Additionally, questions for the record from the fiscal year 2012 budget hearing were due on March 24, yet the committee only received responses 2 days ago, almost 4 months late.

This is intolerable. The committee provided EPA a heads up on this hearing almost 2 months ago, providing ample time for OMB to review EPA's testimony. Dr. Anastas, this is unacceptable, and I expect EPA's testimony to be on time so that this committee can execute its responsibilities, and I hope in the future that we can count on you to do so and other officials with EPA to do so, and I would appreciate a very prompt response to our request.

At this time I would like to introduce our first panel of witnesses. Dr. Paul Anastas, Assistant Administrator for the Office of Research and Development at the U.S. Environmental Protection Agency. Mr. David Trimble is the Director of Natural Resources and Environment at the U.S. Government Accountability Office. Dr. Jonathan Samet, is that correct? Samet. Okay. Samet, MD, served as Chair of the National Research Council's committee to review EPA's draft IRIS assessment of formaldehyde. Dr. Samet also previously chaired the National Research Council's Board on Environmental Studies and Toxicology, where he evaluated the EPA's reassessment of dioxin and related compounds.

As our witnesses should know, spoken testimony is limited to five minutes each, after which the Members of the committee will have five minutes each to ask questions. Your written testimony will be included in the record of the hearing. It is

the practice of the Subcommittee on Investigations and Oversight to receive testimony under oath. Do any of you have any objection to taking an oath?

Let the record reflect that all witnesses are willing to take an oath. They indicated that by shaking their head from side to side, even though we heard no rattles. I saw it.

You all may also be represented by counsel. Do any of y'all have counsel here today? Y'all is Southern for you all.

Let the record reflect that none of the witnesses have counsel. They again indicated by the shake of their head, indicating no. If all of you would please stand now and raise your right hand, do you solemnly swear or affirm to tell whole truth and nothing but the truth, so help you God?

Let the record reflect that all witnesses participating have taken the oath. Please take your seat.

Now I recognize our first witness, Dr. Anastas.

TESTIMONY OF THE HONORABLE PAUL ANASTAS,

ASSISTANT ADMINISTRATOR, OFFICE OF RESEARCH

AND DEVELOPMENT, U.S. ENVIRONMENTAL PROTECTION AGENCY

Dr. Anastas. Good morning, Chairman Broun, Ranking Member Edwards, and other Members of the committee. I am Paul Anastas. I am the Assistant Administrator for the Office of Research and Development at the U.S. Environmental Protection Agency and the Agency's Science Advisor.

Before I begin let me make a personal statement to this committee, and I think this committee appreciates the amount of respect that I have for this committee, and I want to give a personal apology to this for the tardiness of today's testimony. I do believe it was prepared promptly, and my apologies for the clearance process that may have delayed that. So that is something that I think is important and that I take seriously personally.

Chairman Broun. Accepted and I greatly appreciate that. We look forward to having the testimony presented in a timely manner in the future. Thank you, and I am going to expect that, and I think you are a man of your word, and I appreciate that assurance that we can have that. Thank you.

Dr. Anastas. Thank you, and thank you for the opportunity to be with you here today to discuss the EPA Integrated Risk Information System, otherwise known as IRIS. EPA plays a critical role in providing high quality health information on chemicals of concern. The agency's IRIS Assessment Program is a key part of this effort. It includes human health assessments on more than 540 chemical substances. These assessments provide the sound scientific basis for EPA decisions and are widely used by risk assessors, health professionals, state and local governments, as well as international governments.

EPA is committed to upholding the highest standard of scientific integrity in all of its activities. This means constantly seeking to improve, strengthen, and enhance our scientific work to reflect the best available information. Continuous improvement of the IRIS Program is an important part of this effort.

The EPA recently announced changes to the IRIS Program that will ensure we continue to use the best and most transparent science to pursue our mission of protecting human health and the environment. The new changes build upon the significant improvements initiated by Administrator Lisa Jackson in 2009.

For example, since 2009, EPA has completed 16 IRIS assessments, more than the total number of assessments that were completed in the previous four years. We have cut down the

average timeframe for completing assessments from between 3 and four years to within two years, and reduced the backlog of assessments in the pipeline, and yes, new assessments have been added to that pipeline, so that may be why the number looks to be the same.

These improvements have been accompanied by a strong and continued emphasis on independent peer review of the IRIS Program. In April of this year EPA received a report from the National Academy of Sciences on their review of EPA's draft IRIS assessment on formaldehyde. EPA welcomes and accepts the recommendations of the NAS on the formaldehyde assessment and will incorporate these recommendations in the revision of the assessment.

In the report the NAS also suggested ways to improve the IRIS process in two primary areas; accessibility and transparency. Because EPA is constantly seeking feedback from credible, independent scientific sources, we welcome these suggestions and are incorporating them fully into the IRIS Program.

The new IRIS assessment documents will be shorter, clearer, more concise, and more transparent. IRIS users can expect to see a reduced volume of text and increased clarity and transparency of data, methods, and decision criteria. IRIS documents will rigorously be edited to eliminate any inconsistencies and redundancies and will include more graphical and tabular representations of the data.

Related discussions will be consolidated into concise, narrative descriptions, and references to all studies used in the assessment development will be posted online. To make the scientific rationale of IRIS assessments as transparent as possible, the EPA will evaluate the strengths and weaknesses of critical studies in a more uniform way. We will also clearly indicate which criteria were most influential in weighing scientific evidence, supporting its choice of toxicity values. EPA is working closely with the Agency's Science Advisory Board to focus its expertise on how to best respond to the NAS suggestions.

In addition, we continue to be committed to full consultation with scientists throughout the government and carefully consider and respond to their input. We will add a peer consultation step to the early stages of major IRIS assessments to assure that the scientific community can provide input as we make critical design decisions for individual assessments.

These changes will be implemented over the coming months in a tiered approach, with the most extensive changes applied to those assessments in the earlier stages of development. These improvements are part of the natural evolution that accompanies all rigorous scientific work. We will continue to consider information and perspectives from independent scientific sources and pursue improvements in an ongoing basis.

Thank you. I will be happy to answer any questions at the appropriate time as the chair directs.

[The prepared statement of Mr. Anastas follows:]

Prepared Statement of The Honorable Paul Anastas, Assistant Administrator, Office of Research and Development, U.S. Environmental Protection Agency

Good morning Chairman Broun, Ranking Member Edwards and other Members of the Committee. My name is Paul Anastas. I am the Assistant Administrator for Research and Development (ORD) at the Environmental Protection Agency and the Agency's Science Advisor. It is a pleasure to be here with you this morning to discuss EPA's Integrated Risk Information System (IRIS).

Background and Description of IRIS Program

EPA recognizes the critical role we play in disseminating timely, high-quality and accessible human health risk information on environmental contaminants that may endanger the health of the American public. Central to this aspect of EPA's mission is its Integrated Risk Information System, commonly called the IRIS program, which provides health effects information on chemicals to which the public may be exposed from releases to air, water, and land and through the use and disposal of products. IRIS assessments provide a scientific foundation for EPA decisions to protect public health across EPA's programs and regions under an array of environmental laws. While not regulations, IRIS assessments are critical to many Agency decisions. IRIS is also a resource for risk assessors and environmental and health professionals in state and local governments and other countries. After becoming Administrator in early 2009, Administrator Jackson reviewed the IRIS program and asked the Office of Research and Development (ORD) in May 2009 to implement a new IRIS process that would revitalize the program and make it more responsive to the needs of the Agency. The aim of the new process was to ensure the highest level of scientific quality, integrity, transparency, and timeliness.

EPA's Actions to Implement the 2009 IRIS Process

EPA undertook several actions to implement the new IRIS process in 2009. EPA regularly solicits public comments on the IRIS agenda, and ORD works directly with program and regional offices to ensure that IRIS assessments meet their needs. To ensure that IRIS assessments are focused on the highest priority needs, EPA expanded the role of the program and regional offices in nominating and prioritizing chemicals for assessment.

EPA also has increased efforts to work with other agencies to share data and avoid duplication of effort. For example, ORD has a new Memoranda of Understanding with the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment in addition to an existing Memoranda of Understanding with the Agency for Toxic Substances and Disease Registry. These efforts help to increase efficiency and assessment output. The Agency is also working closely with its Science Advisory Board on how to bring to bear its expertise on an ongoing basis to focus on the quality, transparency, and scientific rigor of IRIS assessments and guide EPA's response to the NAS recommendations. We will add a peer consultation step to the early stages of major IRIS assessments to assure that the scientific community can provide input as we make critical design decisions for individual assessments. The Agency also created an IRIS logistics team to coordinate all administrative support to improve efficiency and place increased emphasis on the scientific quality of assessments by allowing scientific staff to focus on the science. In addition, EPA developed the Health and Environmental Research Online database, referred to as HERO, which promotes transparency in risk assessments by capturing the literature used in EPA's health and environmental assessments and making the scientific studies used to develop assessments available to the public. The HERO database is web-based and accessible to everyone.

These actions, collectively, have led to improved results in the IRIS process. Specifically, EPA has completed 16 assessments since 2009, more than the number of assessments that were completed in the previous four years. EPA has reduced the IRIS backlog and is currently working on over 70 assessments. In 2010, EPA released nine assessments, seven of which were major assessments, for external peer review and public comment. Overall the new 2009 process resulted in greater involvement of EPA scientists and the public in the process.

In summary, there have been many improvements to the IRIS program since 2009 to provide high quality assessments in a timely fashion. Assessment development time was shortened to 23 months for most assessments, which will speed the availability of IRIS assessments for

use by the risk assessment community and public. The IRIS program is now entirely managed by EPA and EPA strives to ensure that all of its science assessments undergo rigorous, open and independent external peer review and that multiple opportunities exist for public review and comment. Additionally, changes in IRIS assessments that occur during the interagency and public process are documented and explained, ensuring a transparent final product.

IRIS Process and the NAS Review

In April 2011, the NAS released its review report of EPA's draft IRIS risk assessment of formaldehyde and included comments and recommendations to improve the IRIS process. EPA welcomes those recommendations and will be addressing all of them in a phased-in fashion. We note that the NAS specifically focused their comments on the development of draft IRIS assessments and did not recommend changes to the steps that occur later in the process. Additionally, the NAS recognized that EPA's implementation of their suggested changes would require a multiyear process. A summary of the NAS overall recommendations and EPA's responses to them are described below. \1\

\1\ 1 Full text from p. 152 of the final published NAS report.

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

1. NAS recommended that EPA rigorously edit documents to reduce the text volume and address redundancies and inconsistencies.

To respond to this recommendation, EPA is rigorously editing our assessment documents to substantially reduce the volume of text and address redundancies and inconsistencies; building on the existing IRIS guidelines and process to enhance the clarity and transparency of data evaluation and the presentation of findings and conclusions; consolidating related discussions to eliminate redundancies; increasing the use of tables and figures to improve communication of information; and providing reference information on the IRIS website for all studies considered.

2. NAS recommended that EPA include a fuller discussion of methods and develop concise statements of the criteria used to exclude, include and advance studies for hazard evaluation and derivation of toxicity values.

In response to this recommendation, EPA is providing a fuller discussion of the methods used in our assessments, along with concise statements of the criteria used to exclude, include, and focus on the highest quality studies for hazard assessment and for derivation of toxicity values.

3. NAS recommended standardized evidence tables for all health outcomes.

EPA is working towards replacing text descriptions of the studies with standardized evidence tables that provide the methods and results of each study for all health outcomes; and including text that will accompany evidence tables to present the criteria used to include or exclude studies.

4. NAS recommended that EPA provide a clearer articulation of the rationale and criteria for screening studies.

To accomplish this, EPA is enhancing our sequential approach for progressively focusing on the most pertinent information, including: searching the literature, identifying the pertinent studies, and evaluating study characteristics; evaluating the overall weight of evidence for each health outcome; identifying plausible approaches for developing toxicity values; selecting the most pertinent data and developing toxicity values for each health hazard; and portraying toxicity information graphically.

5. NAS recommended that EPA use uniform approaches to thoroughly evaluate the strengths and weaknesses of critical studies, summarize findings in tables, and clearly articulate the rationale for the studies used to calculate toxicity values.

To respond to these two suggestions EPA is streamlining IRIS assessment documents and more fully document our approach for assembling and evaluating the range of scientific data. As the NAS report indicated, we have already made similar changes to how we present the scientific evidence on the criteria air pollutants in our Integrated Science Assessments, and we are confident we can make comparable improvements in how we present our analysis of health study findings for chemicals evaluated in the IRIS program. EPA is also implementing a more uniform approach to our evaluation of the strengths and weaknesses of critical studies to increase the clarity of the rationale for selecting the studies used to calculate toxicity values. Lastly, we are increasing the use of evidence tables that summarize the factual details of pertinent studies for each health hazard and developing standardized language to describe study strengths and limitations.

6. NAS recommended that EPA provide descriptions to indicate various determinants of weight of evidence to promote understanding of what elements were emphasized in synthesizing the evidence.

In response, EPA is augmenting its current analysis of data to indicate which criteria were most influential in evaluating the weight of evidence.

Timeline for Responding to NAS Recommendations

EPA's overarching goal is to continually improve our IRIS assessments, recognizing that these improvements will have a greater impact on our new assessments as opposed to those already in the pipeline. It is important to note that the NAS report viewed the implementation of their recommendations as a multi-year process. For example, the NAS stated `it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach.'' To that end, EPA is doing the following:

Assessments that have already been peer-reviewed or released for peer review: We are revising these assessments to address peer review comments, especially those that call for increased transparency of study selection and evidence evaluation.

Assessments currently under development but not yet released for peer review: We are re-examining these assessments to ensure that the rationale for study selection and evidence evaluation is clear. These assessments will also be edited to reduce redundancy.

New assessments that have not yet been started: We will fully implement the NAS recommendations for new assessments, including a tighter document structure, evidence tables to summarize details from pertinent studies, greater transparency in study selection and evaluation criteria, and greater emphasis on clear analysis and synthesis.

The standards to which IRIS assessments are held, including the rigorous independent external peer review of every draft IRIS assessment, are among the best in the federal government and the scientific community. Over the coming months, the IRIS program will fully implement the NAS recommendations and continue to improve the IRIS process to reflect the highest standards of scientific integrity and credibility. Strengthening and streamlining the IRIS process is a continuing and ongoing priority for EPA. Thank you for the invitation to share my thoughts on this important topic. I will gladly answer any

questions you have.

Chairman Broun. Thank you, Dr. Anastas.

I now recognize our next witness, Mr. Trimble.

TESTIMONY OF DAVID TRIMBLE,

DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT,

U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. Trimble. Chairman Broun, Ranking Member Edwards, and Members of the Subcommittee, I am pleased to be here today to discuss our prior work and recommendations on EPA's Integrated Risk Information System. As you know, the IRIS database contains EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals in the environment. IRIS assessments are a critical component of EPA's capacity to support scientifically-sound risk management decisions, policies, and regulations.

In March 2008, we reported that the IRIS Program was at serious risk of becoming obsolete because the Agency has not been able to complete timely, credible chemical assessments or decrease its backlog of 70 ongoing assessments. We found that the timeframes for completing assessments were unacceptably long, often taking over a decade. In many cases assessments became obsolete before they could be finalized and were stuck in an endless loop of assessment and reassessment.

In April 2008, EPA revised the IRIS process, but the changes made were not responsive to our recommendations. The new process was actually worse than the one it replaced, institutionalizing a process that resulted in frequent delays by enabling OMB to determine when an IRIS assessment could move forward. Further, this process effectively excluded the content of OMB's comments to EPA and those from the other interested federal agencies from the public record.

Concerned with these problems and the agency's lack of responsiveness, we added EPA's process for assessing and controlling toxic chemicals to our January, 2009, report on government-wide high-risk areas in need of increased attention by executive agencies and Congress.

In May 2009, the EPA made significant changes to the IRIS process. In June of that year we testified before this Subcommittee that these changes, if implemented and managed effectively, would be largely responsive to the recommendations we made in our March 2008 report. Let me highlight three of these key changes.

First, the IRIS process would be managed by EPA rather than OMB as the former process was, restoring independence to EPA. Second, it required that all written comments provided by OMB and other federal agencies on draft IRIS assessments be part of the public record, adding transparency and credibility to the process. Third, the new process consolidated and eliminated steps, streamlining the process.

Notably, the new process eliminated the step under which other federal agencies could have IRIS assessments suspended indefinitely to conduct additional research. As we have reported, we understand that there may be exceptional circumstances under which it may be appropriate to wait for the results of an important ongoing study. However, as a general rule, we believe the IRIS assessments that are based on the best available science is a standard that would best support the goal of completing assessments within reasonable time periods and minimizing the need to conduct wasteful rework.

While the May, 2009 IRIS process changes reflect a

significant improvement that can help EPA restore the integrity and productivity of the IRIS Program, EPA still faces significant management challenges as it seeks to complete timely, credible IRIS assessments.

First, the EPA must continue to balance the need for using the best available science with completing IRIS assessments in a timely manner. As we have reported, even one delay can have a domino affect, requiring the process to essentially be repeated to incorporate changing science.

Second, EPA faces long-standing difficulties in completing assessments of chemicals of key concerns; those that are both widespread and likely to cause significant health issues. We believe that EPA must continue to focus on the best available science, attaining credible expert review and finalizing IRIS assessments.

Third, EPA must be disciplined in keeping to timelines, even in the absence of statutory deadlines for completing IRIS assessments.

Lastly, we believe that to produce timely, credible IRIS assessments over a sustained period of time, it will be imperative for EPA to maintain a stable consistent process going forward.

We are currently reviewing EPA's implementation of its revised 2009 IRIS assessment process and its response to our previous recommendations. As part of this review, we will be examining EPA's response to NAS's recommendations for improvements to the IRIS process. We plan to issue a report later this year.

That concludes the summary of my statement. I will be happy to answer any questions that you or the Members of the committee may have.

[The prepared statement of Mr. Trimble follows:]

Prepared Statement of Mr. David Trimble, Director, Natural Resources and Environment, U.S. Government Accountability Office

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Chairman Broun. Thank you, Mr. Trimble.

I know recognize for five minutes our next witness, Dr. Samet.

TESTIMONY OF JONATHAN M. SAMET, MD, MS,

PROFESSOR AND FLORA L. THORNTON CHAIR,

DEPARTMENT OF PREVENTATIVE MEDICINE,

KECK SCHOOL OF MEDICINE, UNIVERSITY OF SOUTHERN

CALIFORNIA, AND CHAIR, COMMITTEE TO REVIEW

EPA'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE,

NATIONAL RESEARCH COUNCIL, THE NATIONAL ACADEMIES.

Dr. Samet. Good morning, Mr. Chairman and Members of the Subcommittee. I am Jonathan Samet from the University of Southern California. As noted, I chaired the National Research Council committee that reviewed the EPA's draft IRIS formaldehyde assessment. I also currently chair the Clean Air Scientific Advisory Committee of the Agency.

The draft, our review of the draft assessment was written by a 15-member committee that had a wide range of scientific expertise needed for the task. Our charge focused primarily on specific questions related to the Agency's approach to the IRIS

assessment. But beyond these charge questions, the committee assessed the processes underlying the development of the draft and made suggestions about the process generally followed by EPA in developing the IRIS assessments. We were not charged or constituted to carry out an independent review of the evidence on formaldehyde.

To do its job we reviewed the 1,000 page, approximately, draft assessment and key literature and determined whether EPA's conclusions were supported on the basis of that assessment and the literature reviewed. Much of our report is directed at providing constructive comments and recommendations on improving this draft specifically following our charge.

That said, we felt that we could not address our charge without considering the methods and structure of the document as a whole and in responding to its charge questions, the committee found some recurring methodological problems that are cut across components of its charge.

Consequently, we commented on the general methodology of the assessment in our second chapter and offered general suggestions in chapter seven with regard to the processes used by EPA. The general problems that we identified were not unique and have been reported by other committees. I think those problems have already received some comment. We found relatively little documentation of methods and insufficient clarity and transparency in how the evidence reviewed in the report was related back to the weight of evidence guidelines.

We offered six specific recommendations with regard to how the present draft could be completed and moved forward satisfactorily. I will not go through these. They are listed in chapter seven of our report. They are straightforward and could be followed to bring the report to completion.

I will turn to our general comments and suggestions on IRIS. As noted, we found general problems that we thought had been persistent in looking at NRC reviews of other IRIS reports. On the basis of lessons learned from the formaldehyde assessment, we offered our suggestions for changes in the IRIS development process that might help EPA improve its approach. We recognized that EPA had already implemented the plan discussed, released, and covered in the memorandum of 2009 from Administrator Jackson.

We put together our own view of the underlying development process and offered a several-page roadmap for changes in the development process. The term roadmap was used because the topics that need to be addressed are set out, but we did not give detailed guidance. Each topic, in fact, would speak--would need to be developed in further detail.

For each of the critical steps in the roadmaps there are underlying processes that would need to be examined and reconsidered. Our report provides further detail. We think that change in the IRIS development process, the process by which the drafts are developed, is feasible. We note as one example of the largely-successful overhaul of the process used for the National Ambient Air Quality Standards as an example. I have personally watched the revision of that process and noted its benefits.

In conclusion, thank you for the opportunity to speak with you today, and I look forward to answering your questions.

[The prepared statement of Dr. Samet follows:]

Prepared Statement of Dr. Jonathan M. Samet, MD, MS, Professor and Flora L. Thornton Chair, Department of Preventive Medicine, Keck School of Medicine, University of Southern California; and Chair, Committee to Review EPA's Draft IRIS Assessment of Formaldehyde, National Research Council, The National Academies

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Chairman Broun. I want to thank the panel, all of you.

Reminding Members the committee rules limit questioning to five minutes each. The chair at this point will open the round of questions.

The chair recognizes himself for five minutes.

EPA announced changes to the IRIS process 2 days ago. In that announcement EPA indicated that it signed an MOU with the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment to--in order to cooperate in the development of health assessments to encourage data sharing, avoid duplication of effort.

Dr. Anastas, as a Georgian why should I be subject to California's risk assessments? If states are doing this work, why do we need IRIS? If IRIS assessments are better than state assessment, why have California do assessments for EPA? If IRIS isn't sufficient, why not rely on one own state assessment. Why just rely on one own state assessment? Please explain this to me why this isn't a backdoor attempt to implement California's risk assessment policies on the rest of the Nation.

Dr. Anastas.

Dr. Anastas. Thank you very much, Mr. Chairman. I am very happy that you asked that question because it gives the opportunity to explain some misconceptions about what IRIS is.

IRIS assessments are not risk assessments. They are not risk management actions. They are not regulations. They are scientific assessments to understand the hazard, the underlying toxicity of substances. So the information that would be being shared between California and EPA is simply the underlying scientific basis, the assessments that are done by using the open scientific literature that is the basis of the science, but in no way would these assessments be risk assessments, California risk assessments, California regulations. These are only the underlying scientific bases that would be shared and the basis of these health hazard assessments.

Chairman Broun. Well, I have got some follow-up questions to that that I will give you in writing to go forward, but just in the sake of time, Dr. Samet, as chair of the National Research Council committee that reviewed the EPA's draft IRIS assessment on formaldehyde, the committee decided to devote an entire chapter entitled, ``Roadmap for Revision.'' That highlighted specific changes to improve the formaldehyde IRIS assessment but also went a step further and offered recommendation for improving the IRIS process in general.

Why did the committee decide to offer additional recommendations to improve the IRIS process? What letter grade would you give EPA for its formaldehyde assessment, A being excellent and F being a failure? And how about for the four other assessments that NAS has reviewed since 2005?

Dr. Samet. The committee in its chapter seven wanted to give very specific guidance to the Agency on how to bring the formaldehyde assessment to completion. That was the six recommendations. The document, the draft assessment involves a number of underlying processes that have a generality to them, pulling together all the evidence, reviewing it, and evaluating it. And as we looked at the assessment, we found weaknesses which we documented in how those processes had been put into place and carried out.

We felt that it was important to give the specific suggestions but also to provide general guidance on what needed to be done to help improve not only this IRIS assessment but hopefully future ones. As you noted, the National Research Council has reviewed other major IRIS assessments in the last decade and have found deficiencies in those documents.

Now, I will say the committee was not asked to give a

letter grade. I certainly couldn't give an A. I probably would be, Paul, sorry, a little pressed to give a B, and let us say we would certainly give--we will give a passing grade here, and I am not sure, and if I give a too-low grade, I know they will come back and ask me to revise it.

Chairman Broun. Okay. Thank you, Dr. Samet.

My time has just about expired, so I will recognize Ms. Edwards for five minutes.

Ms. Edwards. Thank you, Mr. Chairman, and thank you to our witnesses this morning.

Dr. Samet, your panel laid out certain challenges for EPA to take up to make the formaldehyde assessment stronger. Your panel did not recommend, however, that EPA bring that revised assessment back to the Academy for another round of review but to finish it and finalize it.

Do you have confidence that EPA can successfully address the issues raised by your panel regarding how to strengthen and clarify the formaldehyde assessment?

Dr. Samet. As a first comment, of course, an Academy panel can't recommend that something be brought back to the Academy, and I think however the document is revised I suspect that EPA will undertake further review. I think we were careful in chapter seven to say specifically what should be done. These changes as I noted in my testimony should be feasible, and they are changes that--and revisions that the agency should be able to make successfully.

Ms. Edwards. And Dr. Anastas, do you have confidence that you will be able to make that assessment given the analysis by the Academy?

Dr. Anastas. Yes. I think the important thing is we seek out the type of input that we received from the National Academy, we seek out from scientific experts, and we are very confident that getting the kind of input, the kind of recommendations, that we are able to follow through and incorporate those suggestions.

Ms. Edwards. Thank you, and to follow on then, Dr. Samet, the Subcommittee has received some testimony for this hearing that suggests that the Academy should review every IRIS assessment, then review every revised assessment after changes are made following the NAS report. Would this be a difficult thing for the Academy to take on, and what effort would it require to review 20 IRIS assessments a year?

Dr. Samet. Well, I, you know, certainly I am now speaking as chair of the committee and not in general with the Academy, which I can't do. I think there are many ways to have successful peer review. The Science Advisory Board of the EPA, which I serve on, being one. The Academy being another. I will say that now speaking individually, the effort involved in completing this review was substantial as I have mentioned. A 15-member committee of volunteers working in four meetings in 8 months and producing a, you know, a report over 100 pages.

So substantial effort would be involved, and I think if the full load of peer review were somehow placed before the Academy, I am certain that that would stress the community of scientists who carry out such reviews.

Ms. Edwards. Yes. I suspect that would be pretty impracticable.

I wonder, Dr. Samet, you also provided a roadmap for EPA on how you think the IRIS process could be improved, and your panel apparently believed that EPA is actually capable of implementing those changes that the agency decides make sense.

As chair of the Clean Air Science Advisory Committee at EPA you have had such changes take place and then I will just use the acronym, in the NAAQS process, and also as chair of CASAC and those assessment processes, are there lessons that might be

learned here for IRIS?

Dr. Samet. Well, I think if you look at chapter seven of our report we provided a case study of the revisions that were made, and having participated in reviews of NAAQS standards now for several decades and I think the process has become much clearer, must more transparent, and much more efficient, and I think it has worked. It took some time on the part of the Agency and some interactions with CASAC, but I think an improved process resulted.

Ms. Edwards. And I just want to be clear. Your report contained examples of where your panel felt that the EPA got the science wrong or failed to adequately communicate how they evaluated studies and came to conclusions, but I couldn't find anyplace where you imply that EPA purposely distorted the science or their findings. Did you find any evidence at all of purposeful deception or intentional manipulation on the part of EPA?

Dr. Samet. Well, certainly as we addressed our charge, we look carefully at how studies were selected and reviewed. I think we certainly found many examples where we felt that EPA had not communicated well or we could not follow their methodology but nothing that I would regard as purposeful to use your words.

Ms. Edwards. Thank you, and then lastly, we will hear testimony today that argues that the Science Advisory Board lacks independence because it depends on EPA staff. Doesn't the CASAC also depend on EPA staff for its work?

Dr. Samet. Well, EPA, I am sorry, CASAC certainly is supported by EPA staff. Our deliberations and discussions are fully public, and I certainly don't see them as influenced by EPA staff as we carry them out in the complete open.

Ms. Edwards. Does either CASAC or the Science Advisory Board have, do you have any reason to believe that they lack any kind of independence because they rely somewhat on EPA staff?

Dr. Samet. Not in my experience. No.

Ms. Edwards. Thank you very much, and with that I yield.

Mr. Hultgren. [Presiding] I am going to yield myself five minutes for some questions as well. So, Mr. Trimble, if I could start with you, what would it take to remove the IRIS Program from GAO's high-risk series?

Mr. Trimble. That is a challenging question. We are in the process of working with the agency and OMB to discuss what sort of steps we would like to see along that process. I think there is no simple answer that is X and Y and Z. I think that we have got a little bit more work to figure out all the steps.

Clearly from our prior work some of the steps they have taken has moved the ball along in terms of restoring independence, adding some transparency to the process, but clearly a lot of work needs to be done in terms of being able to address the large backlog that still remains, as well as to be able to move ongoing assessments forward in a timely manner.

I think there is also the issue that is still lurking out there regarding sort of the pent-up backlog of IRIS assessments that the Office of Water and other parts of the EPA have not put in requests because they know there is such a logjam currently. So there are a lot of other hidden issues that we haven't addressed yet, but we are in the process of planning work.

Mr. Hultgren. Do you have any estimate on the timeline on that?

Mr. Trimble. Well, we have meetings scheduled I believe this fall with the Agency and OMB to sort of do a status report, and you know, I am not, I don't have a timeline at this stage.

Mr. Hultgren. Dr. Anastas, let me read one part of Dr. Samet's testimony where he says, ``In the roughly 1,000 page formaldehyde draft reviewed by the present committee, little beyond a brief two-page introductory chapter could be found on the methods for conducting the assessment. In fact, the introductory chapter of formaldehyde is nearly identical to that used in the IRIS assessments. Numerous EPA guidelines are cited, but their role in the preparation of the assessment is not clear. In general, the committee found that the draft was not prepared in a consistent fashion. It lacked clear links to an underlying conceptual framework, and it does not contain sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies for critically evaluating individual studies for assessing the weight of evidence and for selecting studies for derivation of the RFCs and unit risk estimates. The critical summary sections that synthesized the evidence are variable and too often brief or not present, and strength of evidence is not characterized with standardized descriptors.''

How do you respond to that?

Dr. Anastas. The reason that the Environmental Protection Agency seeks out the type of peer review, expert peer review from whether it is our Science Advisory Board or the National Academies is to get that exact type of review, that exact type of input. We take those recommendations extremely seriously. We think that those improvements are absolutely essential to improving and finalizing this draft assessment. That is why we seek it out. That is why we fully accept them. That is why we are integrating them into our revision of the formaldehyde assessment.

Mr. Hultgren. So what is your intention, I guess, with, I mean, this is pretty significant what they have said, you know, that it sounds like there was a pretty significant failure here in the processes. What will happen to address those recognized failures?

Dr. Anastas. I guess I look at it a little bit differently. I view that as a success in the process. We seek out this exact type of peer review in order to continuously improve this draft document. When we write a draft document, we want that type of input so that the final version that gets posted and is available to the American public and beyond is of the highest quality. That is why we accept those recommendations, and that is why we will build them into our revision.

Mr. Hultgren. Okay. Dr. Samet, with my last remaining minute here, in her testimony Ms. Steinzor takes exception to your scolding of EPA staff in the April formaldehyde report by saying, ``I wish that the NRC Committee had not adopted such a haughty tone in scolding EPA staff.''

In responding to her observation can you provide us with some context of how many reviews the Academy has done of other IRIS assessments and how often you or other chairs repeated the suggestions and recommendations that ultimately led to chapter seven of the formaldehyde report?

Dr. Samet. Well, I guess I had not read the testimony or seen the term, scolding. I think that our comments in chapter seven are provided as recommendations and as positive help to the Agency in trying to improve the process as Dr. Anastas mentioned. I think probably, and I can look to my left and get a little help, but this is probably the fifth review in the last decade by a National Research Council committee of an IRIS assessment. These have been the larger, more complicated assessments, and I think in all of them there have been one or more general comments about methodology and some specific chapters on aspects of methodology with concerns expressed.

Mr. Hultgren. Thank you. My time is up.

I yield five minutes to Mr. McNerney.

Mr. McNerney. Thank you, Mr. Chairman. I thank the panel for stepping forward this morning. I appreciate, Dr. Anastas, the attitude that you have about looking for input from independent sources. That is very important. As a scientist I appreciate that, and I understand that the Office of Research and Development relies on a board of scientific counselors to help provide an independent evaluation of your programs. That board did an assessment in 2008, and then again in 2010.

Later this morning we are going to hear that the IRIS assessments are considered irrelevant and the department weak in science. Can you tell us a little bit about the board and what sort of people serve on it, their independence, and summarize their observations for us, please?

Dr. Anastas. Yes. A number of years ago we sought to establish the Board of Scientific Counselors to give us independent reviews of our general performance, how we are performing on the wide range of activities that the Office of Research and Development undertakes. Specifically we asked them to review the IRIS process, and these Members who are of the highest quality from industry, academia, a broad spectrum of people, looked at the IRIS Program and gave us tremendous feedback, both constructive recommendations, as well as recognizing the strengths.

Some of the quotes from the Board of Scientific Counselors include, ``Internationally IRIS assessments are considered to be of the highest quality and reliability.'' Another quote is, ``IRIS assessments are among the most heavily-peer-reviewed documents produced by scientists anywhere.''

So there are tremendous strengths to the IRIS Program, but we also need to recognize that even strong programs can and must improve. I come from Boston where the Boston Red Sox happen to be in first place right now, but they are always seeking to improve. We will always engage in continuous improvement because that is what scientists do.

Mr. McNerney. Was the Board's recommendations or are their recommendations aligned more or less with the recommendations from the National Academy?

Dr. Anastas. Yes.

Mr. McNerney. Thank you. Dr. Samet, why did the National Academy undertake the assessment in the first place, and who paid for that effort?

Dr. Samet. Well, the National Research Council was asked by the Agency to carry out this review. I think there is a somewhat long and complicated history about that request that you are likely aware of, but the support for the review to the Academies came from the Environmental Protection Agency.

Mr. McNerney. Did the National Academy feel that their recommendations or that your recommendations should be mandatory and enacted by the end of this year? Was that the intent?

Dr. Samet. Well, the Academy, of course, makes--our report provides its recommendations. These have no binding requirements for the Agency. They are really peer review and suggestions and comments that we make in the spirit that we hope they will prove to be useful to the Agency as it revises the document or if it chooses to undertake revisions to the IRIS process itself.

Mr. McNerney. So, I mean, they weren't initially given as, hey, you need to do this by the end of this year, or this is a big problem. That wasn't the intent then, was it?

Dr. Samet. Well, an Academy committee would not make recommendations in that spirit. I mean, again, the Academy is an advisory to the government.

Mr. McNerney. Thank you. Mr. Trimble, you reported this

morning that the assessment, the IRIS assessment was unresponsive. I think that is the word I heard a number of times. What do you believe is the underlying cause for that assessment for your unresponsive assessment?

Mr. Trimble. I believe the unresponsiveness I was referring to was in response to our 2008 report where we made recommendations to improve the process and then later in 2008, they made changes formalizing the process which was essentially no change. They institutionalized the things we had identified as problematic. That process was then changed in 2009.

So the lack of responsiveness is to our prior recommendations and one of the reasons we put the area on our high-risk list.

Mr. McNerney. I mean, you didn't answer my question. What do you think the underlying causes of that unresponsiveness?

Mr. Trimble. Well, at that time I believe OMB and the EPA were committed to the procedures they had in place, and they were--their position was that the OMB's comments and other agencies' comments were deliberative and should not be put in the public domain.

Mr. McNerney. Okay. My time has expired, but you never really answered the question. Thank you.

Mr. Hultgren. I recognize Dr. Benishek for five minutes.

Dr. Benishek. Thank you, Mr. Chairman. Distinguished Members of the panel, thank you for your time today. I know we are here to talk about chemicals, and as a physician I have a bit of experience with chemicals.

I would like to talk today about a chemical called acrylonitrile or AN. It kind of has a funny name, and you probably never heard of it, but we all come in contact with it. As a physician I really haven't been aware that I was using the compound, but it is around in medicine a lot. It is found in everything from dialysis tubing to cell phones to computers and golf clubs.

Recently the EPA released an IRIS assessment for AN with a 60-day comment period, and based on initial review of the draft it doesn't seem to have a comprehensive objective review of the science. The draft completely ignores many of the articles published in reputable peer review journals, many with opposing views.

I am concerned that the assessment will lead to burdensome regulations in a variety of industries, you know, especially in my district, plastics and boating industry, medical equipment. I find it troubling that the Agency seems to spend a lot of time and money accusing us in Congress to not--to ignoring science but fails to follow some of its own advice.

Is the EPA's objective to review all critical published scientific information when preparing these assessments, whether or not the Agency agrees with the position? Dr. Anastas.

Dr. Anastas. Thank you very much for the question. The short answer to your question is yes. We--an essential part of all of our analyses, speaking generally across all of the IRIS assessments, is understanding the relevant, credible scientific information and composing its assessments. Those assessments, and I am speaking specifically to acrylonitrile right now, go into an external peer review process where we get the reaction to this draft assessment.

So if there are concerns about particular studies that may not have been identified, considered, that those are caught during this period in the peer review process.

Dr. Benishek. Well, the reason I am asking this is, you know, apparently what this is, acrylonitrile review, there is no mention of several other publications. I am looking at one here. The International Agency for Research on Cancer, part of

the World Health Organization published a review that wasn't cited. There is a review on AN in North Carolina Scientific Advisory Board that wasn't cited. There was a review by an independent peer review panel organized by TERA, the Toxicology for Excellence and Risk Assessment. There are several conflicting sources of information that aren't cited in the review and I just want to understand how the committee decides which studies to include in the review and which studies not to include.

I mean----

Dr. Anastas. That is an excellent question. The process by which studies are selected based on their relevance, their credibility is something that as we have spoken about, is always something that we are seeking to make clear, transparent with these public meetings, with this public external peer review. All of these comments are considered. That is why this draft is going out for this public peer review.

I do want to clarify one thing that I mentioned earlier. These assessments are not regulations. These assessments are not risk assessments. These are the underlying scientific characterization of the hazard.

Dr. Benishek. Well, it doesn't seem to me to, you know, I have read the papers where you may have like 100 citations, and just not having all the citations that are available doesn't seem to make any sense to me. You know what I mean? Why some are not listed I just don't get it, because, I mean, you just put another citation in there. It makes sense to have comments on both sides of the issue.

Dr. Anastas. Absolutely and that is why we have these public sessions to consider all scientifically-sound, credible information be part of these assessments.

Dr. Benishek. And yet these things that I cited weren't included. So I just don't understand why not.

Dr. Anastas. If there were any scientific, credible, independent studies that were not included, then this is the process to ensure that all of them are included. This is why we go to the external public peer review.

Dr. Benishek. So then are we going to include these studies that I had mentioned to you in the future or reevaluate the situation or what?

Dr. Anastas. Any literature, any study that is relevant, sound, independent, scientifically credible. Anything that is-- that meets those criteria would certainly be included.

Dr. Benishek. Well, great. Then we will have the committee forward these studies to you, but maybe they can be included in your evaluation.

Dr. Anastas. And the timing is excellent, because this is the external peer review and public assessment comment.

Dr. Benishek. All right. Thanks.

I yield back my time.

Chairman Broun. The gentleman's time is expired.

Now I recognize Mr. Miller for five minutes.

Mr. Miller. Thank you. This is an issue, the IRIS System, that this Subcommittee considered when I was chair of the Subcommittee. We have thousands of chemicals that are in widespread use. We really do not know what the public health consequences are of exposure to those chemicals. We have about 700 new chemicals entering the marketplace every year. We have no idea what most of those do to anybody. We have got cancer clusters and clusters of birth defects all over the country we know have got to be the result of exposure to something, and we don't know what, and the IRIS System is supposed to be how we assess the risk of exposure to chemicals.

But despite all that because of the system that was in place there are only about three new or revised assessments

being issued a year, and there was ample evidence of political interference and a great deal of influence by the industries that made those chemicals or use those chemicals.

I have three charts I would like to show, and I believe somebody is, yes, standing by, and I hope the witnesses can see these.

[Chart]

This is actually a schematic of the process that the Bush Administration inherited from the Clinton Administration. Well, I believe it was in effect for most of the Bush Administration, and then a step or supposedly this was streamlined.

Can we show the second?

[Chart]

Yeah. That is the streamlined version. Now, at the time I said that I was reminded of Chico Marx quote, ``Who are you going to believe, me or your own eyes,'' that that was a streamlined version of the process that had existed before. What that did, however, was put OIRA in the middle of the whole process.

Now, Dr. Anastas, when Chairman Broun scolded you for not getting your testimony in on time, he said you had completed it, but you had to get it reviewed. Was that a review by OMB?

Dr. Anastas. All testimony is reviewed by OMB.

Mr. Miller. Okay, and that is where the holdup was? Well, I know you don't want to criticize OMB. Is OIRA a part of OMB?

Dr. Anastas. Yes.

Mr. Miller. Okay. Thank you, and that is the system that slowed it, that appeared to slowed it down greatly. Now, Mr. Trimble, the GAO has been in--very involved in all this in reviewing the IRIS System, and you were not suggesting--well, let us now go to the third slide.

[Slide]

And that is the slide that supposedly is streamlined, and actually it appears that you could believe your own eyes that that is streamlined. You are not suggesting we go from that back to the previous system, are you?

Mr. Trimble. No, sir. The opposite.

Mr. Miller. Okay. The opposite. All right.

Dr. Samet, you reviewed a lot of OIRA's assessments. You looked at, let us see, formaldehyde, perchlorate, dioxin, trichloroethylene. I am not on of the committee's doctors. And tetrachloroethylene.

Which of those systems were those assessments done under?

Dr. Samet. I would, I can't exactly answer that. I mean, I would have to look at the timing of each of those and when they were done. They were mostly done over the last 5 or six years, so I guess that would be back with your 2004, 2008 slide.

Mr. Miller. Well, Dr. Anastas, can you answer that question? Were any of these assessments that the academies have found fault with been performed under that system?

Dr. Anastas. No.

Mr. Miller. They were all under the previous systems?

Dr. Anastas. Correct.

Mr. Miller. The streamlined previous systems?

Dr. Anastas. Correct.

Mr. Miller. All right, and, again, although Susan Dudley, who headed OIRA at the time, sat right there, raised her hand, right hand, took the same oath that you all had, and said that there was never any--they never really substituted their judgment on science for EPA. There was a huge amount of evidence that that happened routinely.

The impression from that period and from our hearings before is that the work EPA was doing to get a risk assessment through this streamlined process was one performed under fire, under hostile fire from the industries that produced the

chemicals and from the industries and the agencies of government that used the chemicals. Is that correct?

Dr. Anastas. Was that the characterization?

Mr. Miller. Yes, sir.

Dr. Anastas. That was the characterization.

Mr. Miller. Okay, and is it possible that some of the fault that the academies have found with EPA's work in this is the result of the fact that the people performing the work felt they were under fire and were trying to anticipate every possible criticism?

Dr. Anastas. There are those who have characterized that that way. Yes.

Mr. Miller. Okay. Would you be one of those who characterizes it that way?

Dr. Anastas. I think the excellent scientists who dedicate their professional lives to this have felt under a tremendous amount of pressure from different sources. Correct.

Mr. Miller. Okay. My time has expired, Mr. Chairman.

Chairman Broun. Thank you, Mr. Miller. Nice seeing you stay within five minutes. No, I said that in all sincerity.

Now the Chairman recognizes Mr. Rohrabacher for five minutes.

Mr. Rohrabacher. Thank you very much, Mr. Chairman.

Yeah. I guess we have seen lots of examples where scientists have been put under pressure, especially during this investigation of global warming and such issues where our scientists were denied grants because they did not believe in global warming's theory, which we heard reports of across the board for years in this committee.

So we know that there are certain advocacy elements within the scientific community that are willing to pressure other people within the scientific community. It is sort of like tenure in college for the college professors, of course, would never think about trying to control what type of people are hired onto their departments, but we all know that happens, don't we?

I would like to ask in terms of how this affects the scientific questions that we are dealing with today, is--and I certainly would--I will take you, I will address you, you are the head man. Are the scientists who are involved with this risk assessment program, are they--are steps taken to make sure that they have not been part of advocacy groups prior to their involvement with this program?

Dr. Anastas. I can't say that I do not investigate the backgrounds of scientists.

Mr. Rohrabacher. Okay. So there is no background check to see if a scientist has been involved with an advocacy program or actually been hired, perhaps, by an advocacy organization prior to him getting involved and his decision making being trusted by your organization?

Dr. Anastas. The only background check that would be done is for the scientific excellence.

Mr. Rohrabacher. Okay. So you could have someone who is very etiological, very, very etiological and even being hired by groups that are just adamant about what they believe, and that person could still be someone who you are relying on for their judgment not to be impaired.

Dr. Anastas. I can only say that we hire people for their excellence in science, that demonstrated excellence in science.

Mr. Rohrabacher. Uh-huh, and you don't take into consideration if that person had been involved in an organization that perhaps that organization is so committed to a position that it reflects anyone who could associate. You know, there are certain groups that have a position, whether they are against what you believe or for what you believe, but

they are so adamant that we know that that might indicate the person doesn't have an open mind towards certain issues.

But that is not taken into consideration for hiring someone?

Dr. Anastas. You raise an excellent point, Congressman, because at the essence of scientific excellence is objectivity.

Mr. Rohrabacher. Correct.

Dr. Anastas. And so when I use the words, scientific excellence, embedded in that definition would be objectivity.

Mr. Rohrabacher. Okay, and however, someone's affiliation with certain advocacy groups is not something that you would look at to determine their objectivity?

Dr. Anastas. If a person skewed their science in order to meet ideological ends, that would be antithetical to scientific excellence.

Mr. Rohrabacher. And there is no organizations that you believe that just an association with that organization would say, well, maybe that person is just too much involved with advocating a position to be able to come on board?

Dr. Anastas. I would only say that we need to evaluate the scientific excellence and the objectivity and other litmus tests, background checks----

Mr. Rohrabacher. Right.

Dr. Anastas. --or----

Mr. Rohrabacher. Now, what we have seen too much of is scientific excellence is dependent on whether someone agrees with me or not, and that is what we have seen over and over and over again by the liberal establishment here in this city in dealing with scientific issues. And I certainly would think that if we have certain people that are committed to a position and they are involved with organizations that are committed, that that should be taken into consideration when giving them responsibility to assess whether or not something is scientifically viable or not.

Let me ask you another thing.

Chairman Broun. The Chairman's time has expired.

Mr. Rohrabacher. Oh. Pardon me.

Chairman Broun. Thank you, Mr. Rohrabacher.

I now recognize Mr. Clarke for five minutes.

Mr. Clarke. Thank you, Mr. Chairman. My question is more than likely for Dr. Anastas abut anyone else could feel free to answer. It is really a basic one.

I just wanted to get clarification again between the difference between an IRIS scientific assessment and a complete risk assessment, if there are certain elements in a risk assessment that the IRIS assessment does not address. And then ultimately how you would compare the IRIS assessment in time development and in substance to the ultimate regulatory proposal that is issue?

Dr. Anastas. Certainly and thank you very much for the question.

The information that is provided in an IRIS assessment is an essential and key part that feeds into a risk assessment. However, there is the hazard characterization. In order to come up with the risk assessment, the risk probability, you need exposure data. So the exposure of an individual to the substance through a variety of roots, whether it is children, it is breathing in air, it is ingested in the water, that-- those components coming together are part of the risk assessment process, which then feeds into the risk management alternatives. Those are the regulatory determinations that are carried out by our program offices, our Office of Water, our Office of Air, to take into account a wide variety of other factors, including everything from socio, economic, other considerations, technological feasibility of various risk

management options.

And so while the IRIS assessments and the information they provide is a critical piece, it is significantly removed from the regulatory process.

Chairman Broun. Thank you, Mr. Clarke.

Now recognize the full committee Chairman, Mr. Hall, for five minutes.

Chairman Hall. Thank you, Mr. Chairman. Inasmuch as I don't know what questions have been asked or answers elicited and as much as I probably wouldn't believe anything any of the three of you say, I will yield back my time.

Chairman Broun. I can't believe it. Okay.

Mr. Sarbanes is still down there. I yield Mr. Sarbanes five minutes.

Mr. Sarbanes. Thank you, Mr. Chairman. I appreciate it. Thank your for your testimony.

I always start these hearings, these hearings being ones that are about chemicals and the risks that chemicals pose out there and our efforts to try to get a handle on that and get more information by observing it, if the average member of the public understood how little information and knowledge we have about the chemicals that are being put out there in the stream of commerce, in the natural streams, and so forth, they would be amazed and appalled. I think they have the expectation that our level of knowledge is much, much higher than it is, and a lot of the delay that we see in the kind of regulation and oversight and assessment is something they wouldn't imagine would be happening in the United States of America in the 21st century. So I don't know who is watching this hearing out there in the public, but I hope they spread the word on this.

I was looking at this silver book, as it is so called, and on the back it talks about how risk assessment has become a dominant public policy tool for making choices based on limited resources to protect public health and the environment. So we talked a lot about that.

However, risk assessment is at a crossroads, it says. Despite advances in the field risk assessment faces a number of significant challenges including lengthy delays in completing complex risk assessments, lack of data leading to significant uncertainty in risk assessments, and many chemicals in the marketplace that have not been evaluated, and emerging agents requiring assessment, which is a pretty good encapsulation of the testimony and exchange that we have been having here this morning.

I think you all recognize that, and I see the three of you working in concert to try to improve the process, improve the reliability of the risk assessment process, and Dr. Anastas, I appreciate your lack of defensiveness with respect to the assessments and evaluations that have been done that you invite in terms of the IRIS process, and you are getting some good constructive input.

Then commenting on the silver book, this--the back flap here says, ``Science and decisions,'' which is the name of the silver book, ``makes practical scientific and technical recommendations to address these challenges,'' i.e., the ones just referred to.

Can you speak to the value of this? This is a follow up on an earlier framework known as the red book, as I understand it it complements it, but can you speak to the value of this, and then Dr. Samet, I would like to get your perspective on it as well. Thank you.

Dr. Anastas. Thank you very much, Congressman, for the question because the so-called silver book was carried out by the National Research Council and chaired by a very well-respected professor at Johns Hopkins University named Tom Burke

and provided some excellent framework for how we need to continuously improve our risk assessment processes, how we need to think more broadly if we are going to ensure that the risk framework is as strong as it needs to be.

As Science Advisor of the Agency, I have the honor of chairing the Science Technology and Policy Council. Adopting the recommendations in the science book is something that is going on in real time, moving ahead so that across the Agency the findings of the silver book are able to be incorporated.

Mr. Sarbanes. Thank you. Dr. Samet.

Dr. Samet. I think the silver book was an important updating and broadening of the concepts that were in the so-called red book.

I would also bring your attention to one other report that came out from the National Research Council around the same time, Toxicity Testing for the 21st Century, which laid out, I am sorry to use the word again, but a roadmap or a blueprint for how to address the problem highlighted in the comments on the back of the silver book. We need to have a way to test with validity the many chemicals coming into the marketplace. And the proposal in that document is how do we use our new science to try and address this question with some certainty, dealing with the hundreds of chemicals whose risks we are uncertain about as they come into the marketplace, using the best science possible.

So I think that together those two reports do set out a, hopefully a new approach for the future.

Mr. Sarbanes. Thank you. I yield back.

Chairman Broun. The gentleman's time has expired. Thank you so much, Mr. Sarbanes.

I want to thank the panel for you all's testimony and your answering questions, particularly in an expeditious manner, and I want to thank the committee Members for also asking their questions in an expeditious manner.

You will be excused. Members may desire to submit written questions, and I trust that we will get replies in a timely manner from you all, so you all are excused, and thank you for your testimony today.

And if the second panel will expeditiously also take their seats.

At this time I would like to welcome and introduce our final panel of witnesses. First is the Honorable Calvin Dooley. He is President and CEO of the American Chemistry Council. Congressman Dooley previously represented the 20th Congressional District in California. We have Ms. Rena Steinzor, who is Professor at the University of Maryland School of Law and Founder and President of the Center for Progressive Reform. We have Dr. Gail Charnley, is Principal at HealthRisk Strategies. Dr. Charnley is an internationally-recognized scientist who has served on several advisory committees, including peer review panels for the EPA and FDA, the Presidential Congressional Commission on Risk Assessment and Risk Management, and is currently on the National Academy of Sciences Board on Environmental Studies in Toxicology. The Honorable Chris Bollwage is Mayor for the City of Elizabeth, New Jersey, a position he has held for the past 18 years. I am sorry. You have got one of the hardest jobs in politics. Mayor Bollwage also serves as Chair of the Conference of Mayors Brownfields Task Force.

As our witnesses should know, spoken testimony is limited to five minutes each, and please try to maintain that five minutes. After which Members of the committee will have five minutes to ask each questions. I ask the committee Members to please be mindful of the time. Your written testimony will be included in the record of the hearing. It is the practice of

the Subcommittee on Investigations and Oversight to receive testimony under oath. Do any of you have objections to taking an oath?

Let the record reflect that all witnesses are willing to take an oath.

You also may be represented by counsel. Do any of you have counsel here today?

Let the record reflect that none of the witnesses have counsel. I think Congressman Dooley, you indicated you do not. Okay. That is great. If all of you would please now stand and raise your right hand. Do you solemnly swear or affirm to tell the whole truth and nothing but the truth, so help you God?

Thank you, and you may be seated. Let the record reflect that all the witnesses participating have taken the oath.

I now recognize our first witness, Congressman Dooley, for five minutes.

TESTIMONY OF CALVIN DOOLEY,

PRESIDENT AND CHIEF EXECUTIVE OFFICER,

AMERICAN CHEMISTRY COUNCIL

Mr. Dooley. Good morning Mr. Chairman and Members of the committee. I appreciate the opportunity to be here today to speak to the pressing need to fix the Environmental Protection Agency's Integrated Risk Information System or IRIS.

IRIS is one of the most important programs that EPA uses to assess the safety of chemicals. But in recent years, IRIS frequently has been criticized for failing to meet high standards of scientific inquiry, transparency, and quality.

I have outlined several examples of flawed IRIS assessments in my written testimony, but the recent peer review of formaldehyde is perhaps the most telling. After EPA's draft IRIS review of formaldehyde was scrutinized, EPA asked the independent experts at the National Academy of Sciences, NAS, to review its findings.

The NAS review questioned the evidence IRIS used to support its conclusions that a link exists between the exposure to formaldehyde and certain types of leukemia, stating, ``Conclusions appear to be based on a subjective view of the overall data, and the absence of a causal framework for these cancers is particularly problematic given the inconsistencies in the epidemiologic data, the weak animal data, and the lack of mechanistic data.''

The NAS report also devoted an entire chapter to needed program improvements. NAS summed it up by saying, ``The committee is concerned about the persistence of problems encountered with IRIS assessments over the years, especially given the multiple groups that have highlighted them. If the methodologic issues are not addressed, future assessments may still have the same general and avoidable problems that they highlighted in their report.''

While IRIS is a complex program that examines complex issues, the problems can be boiled down to two things. First, IRIS does not reflect modern scientific methods or 21st century knowledge about how chemicals interact in the body at different levels of exposure. Rather, IRIS continues to rely too heavily on outdated assumptions that were formulated in the 1970s.

Second, there is little independence in the program's peer review process. EPA controls each step of the review process and ultimately decides which recommendations from peer review groups to act upon and which to ignore.

IRIS needs a comprehensive overhaul to ensure that assessments are based on proven scientific data and modern

scientific understanding. The peer review process must be enhanced so there is an honest broker to ensure that IRIS assessments are reviewed independently and recommendations from peer reviews and public comments are adequately incorporated.

While EPA announced some process changes earlier this week and we are pleased that EPA has done so and that they recognize the program must be reformed, we remain concerned about the lack of a truly independent peer review process. ACC continues to believe that NAS should review all pending IRIS assessments to ensure their quality until the systematic problems with the program are fixed. And I will stress that. Until we have the confidence that the systematic problems are fixed.

If the improvements announced this week are effective, that will validate--be validated by NAS reviews. Anyone who looks at the evidence, whether you are a state regulator, a public health official, or a furniture maker can see that the IRIS Program is broken. Getting it right is in the interest of us all. The current deficiencies and the lack of confidence in the program cause delays and unnecessary costs. Flawed assessments create public confusion, unwarranted alarm, unnecessary product de-selection, and litigation, all of which can put jobs and innovation at risk without a sound scientific basis.

By making needed changes to IRIS we can minimize delays and provide answers to the public, public health professionals, and industry in a far-more credible and timely way.

Thank you very much for the opportunity to testify, and I look forward to taking your questions.

[The prepared statement of Mr. Dooley follows:]

Prepared Statement of The Honorable Calvin Dooley, President and Chief Executive Officer, American Chemistry Council

Mr. Chairman and Members of the Committee. I am Cal Dooley, president and CEO of the American Chemistry Council. I appreciate the opportunity to be here today to speak to the pressing need to fix the Environmental Protection Agency's (EPA) Integrated Risk Information System, or IRIS.

Shortly after taking office, President Obama committed that science and the scientific process would guide decisions of his Administration. We at the American Chemistry Council (ACC) welcomed this pledge, because we agree that credible, accurate, modern science must form the foundation of regulatory decisions.

Three years later, though, our confidence in the Administration's commitment to scientific integrity in the regulatory process has eroded. This is in large part due to troubling inconsistencies, inefficiencies and lack of transparency in the federal system for assessing the safety of chemicals.

IRIS is one of the most important programs EPA uses to assess chemical safety. It serves as a leading source of health risk information for other federal, state, and international regulatory bodies. But over the years, the program has been repeatedly criticized for failing to consistently meet high standards of scientific inquiry, transparency and quality.

It is time to fix the IRIS program to protect health, safety and the environment and preserve the ability of American industry to innovate, compete and create jobs.

Several examples illustrate the shortcomings of the IRIS program:

Formaldehyde

Perhaps the most telling example can be found in the recent case of formaldehyde. Formaldehyde has been the subject of scientific study for years. Numerous organizations including the World Health Organization have concluded that a large body of evidence shows that the levels of formaldehyde most people encounter do not cause adverse health effects. Despite this, EPA completed its IRIS review of formaldehyde in 2010,

asserting that a link exists between exposure to formaldehyde and certain types of leukemia. EPA's conclusions quickly came under scrutiny. To provide clarity, EPA asked the National Academies of Science (NAS) to convene an expert Committee to review its findings.

The NAS Committee issued its report earlier this spring and in it, they questioned the evidence EPA used to support its conclusion. In the report NAS stated:

> ``Conclusions appear to be based on a subjective view of the overall data, and the absence of a causal framework for these cancers is particularly problematic given the inconsistencies in the epidemiologic data, the weak animal data and the lack of mechanistic data.''

In the report, the NAS Committee also offered a harsh critique of the IRIS program in general. In fact, the expert committee felt so strongly that they included an entire chapter devoted to the program improvements that they saw as ``critical for the development of a scientifically sound IRIS assessment.'' The NAS report stated:

> ``The committee is concerned about the persistence of problems encountered with IRIS assessments over the years, especially given the multiple groups that have highlighted them. If the methodologic issues are not addressed, future assessments may still have the same general and avoidable problems that are highlighted here.''

Hexavalent Chromium

In 2009, industry undertook a multi-million dollar mode-of-action research program to develop new data that EPA could use to assess the risk that Cr6 poses from low-level, environmentally-relevant exposure through drinking water. The research was directly responsive to the data needs of the Agency, and EPA staff was consulted during the process of developing the research plan.

Despite the pending research, due later this year, the agency significantly accelerated its timetable for the hexavalent chromium IRIS assessment, publishing a draft in late 2010. EPA's independent peer review group expressed significant concerns about the scientific quality of the draft assessment, citing knowledge gaps, including those that could be filled by the industry research. EPA still intends to finalize the IRIS assessment by the end of September, about the same time that the new research should be completed.

With this intensive schedule, we are concerned that EPA will not fully incorporate the extensive comments from EPA's peer review group. Failure to address the peer review comments and include the new research findings will result in a risk assessment that will be out-dated and inaccurate as soon as it is released.

Dioxin

The IRIS program first published its draft assessment of dioxin in the mid nineteen-eighties, but it remains a point of contention today. Specifically, both EPA's own Science Advisory Board (SAB) and the NAS criticized the model that EPA used in the IRIS assessment to evaluate cancer risk.

In 1995, the Scientific Advisory Board told the IRIS program that it was inappropriate to extrapolate using a linear low dose method to estimate cancer risk to humans. EPA revised the assessment, but failed to follow the SAB directive.

In 2006, after reviewing EPA's 2003 reassessment of dioxin, the NAS concluded--unanimously--that a non-linear method (as opposed to a linear dose-response model) should be used to extrapolate for estimating cancer risk to humans.

Despite the National Academy's 2006 recommendation, EPA's reanalysis of key issues in the dioxin assessment again used a linear

dose-response model.

Sixteen years after EPA was given a clear recommendation by the SAB peer review to use a model that reflects knowledge of mode of action in the dioxin IRIS assessment, IRIS continues to push an out-dated risk assessment model for dioxin. Based on the expert review in 1995 and 2006, IRIS has no scientific justification for doing so.

Inorganic Arsenic

In a case similar to dioxin, EPA defaulted to a linear no-threshold model in its draft IRIS assessment of inorganic arsenic, disregarding the 2005 EPA peer review panel recommendation to consider a threshold model. This is critical because applying the proposed model would result in naturally occurring levels in many soil and water supplies around the country being considered ``unacceptable'' by EPA guidelines.

If this draft IRIS assessment stands, it could lead to confusion, undue concern and unnecessary costly modifications to water treatment systems, the abandonment of water sources, and the forced identification of alternative water supplies. And it could create the impression that typical arsenic levels in foodstuffs such as rice, fish, grapes, and other common foods could be cancer-causing.

These examples clearly demonstrate that IRIS has failed to evolve with the significant progress that has been made in the science and technology of chemical risk assessment.

Over the years, researchers and health professionals have gained a greater scientific understanding of the human body; the ways chemicals can interact with the body at different levels of exposures; and how that knowledge applies to determine the safety of chemical uses. However, IRIS risk assessments lag behind these advances and rely too heavily on outdated assumptions formulated in the 1970s.

For example, IRIS assessments of carcinogenic responses in high-dose animal studies typically take the most conservative default approach, rather than applying relevant mode of action and real world exposure information to more accurately show the risk to humans.

In effect, IRIS has clung to risk assessment approaches that assume that there is no safe dose or threshold--even when experts tell the program otherwise--as was the case with dioxin and inorganic arsenic. IRIS's failure to integrate this information into program decisions undermines the development of new science-based risk assessment practices, wastes investments in research and undercuts effective public health science policy.

Not only has IRIS failed to keep pace with modern science, the program lacks the scientific accountability needed to be considered objective and credible.

There is little independence in the IRIS program's standard peer review process: the IRIS office controls the development of the assessment, the design of the peer review charge questions, and the evaluation of the peer review findings. Ultimately, the IRIS program itself decides which recommendations from peer review groups to act upon and which to ignore. As we have seen in the case of dioxin, the IRIS office has exhibited steadfast reluctance to upgrade the assessments in response to the demands of independent peer reviewers.

To restore credibility to the program, there must be an honest broker to ensure that EPA adequately considers and incorporates changes from peer reviews and public comments. That is why ACC has called for the NAS to review all pending IRIS assessments. Unfortunately, EPA dismissed this suggestion saying, ``IRIS is a model for openness, transparency, scientific integrity and scientific quality.''

Anyone who looks at the evidence, whether you are a state regulator, a public health official or a furniture maker, can see that the IRIS program is broken and fails to effectively support EPA's mission to protect public health and the environment.

EPA's refusal to fully acknowledge and rectify the many problems

with the IRIS program calls for Congress to step in.

EPA must be required to take immediate steps that will ensure pending IRIS assessments meet the highest standards of accuracy and scientific integrity:

IRIS assessments in progress should incorporate the recommendations described in Chapter 7 of the NAS panel formaldehyde scientific peer review report where they are applicable;

IRIS assessments that are currently in draft form (or that will be issued as draft for public comment and peer review in 2011 and 2012) should be submitted to the NAS for independent scientific peer review; and,

Revised IRIS assessments developed by the Agency must be evaluated (preferably by the same NAS panel that conducted the initial peer review) to ensure that the peer review panel's findings and recommendations have been adequately and transparently addressed.

While NAS review of pending assessments will help improve the program in the interim, EPA must also initiate a comprehensive overhaul of the program to make IRIS effective and efficient in the future:

Assessments must rely on proven scientific data instead of outdated assumptions;

EPA must establish consistent data evaluation methods;

EPA must adopt a consistent weight of evidence framework, based on transparent, rigorous evaluation methods, so that all available data can be taken into account, with the best and most relevant science given the greatest weight;

Assessments should be based on 21st century knowledge of how chemicals interact with the human body;

EPA must adopt proven approaches for evaluating cause, effect and uncertainty as part of IRIS assessments; and,

EPA must enhance public comment and independent scientific peer review processes.

The IRIS program is a critical part of our chemical regulatory system, and it must be improved. The current deficiencies and lack of confidence in the program are resulting in delays and unnecessary costs as the frequent shortcomings in draft assessments are addressed. Flawed assessments have significant consequences in and of themselves. They create public confusion, unwarranted alarm, unnecessary product de-selection and litigation, all of which ultimately can put jobs at risk without sound scientific basis.

To be clear, ACC is not suggesting that IRIS assessments be suspended or delayed. We are proposing concrete ways to make pending and future reviews more accurate and more credible. Making the necessary changes will ensure that the program completes assessments more efficiently and provides answers to the public, public health professionals and industry in a far more timely way. Thank you very much for the opportunity to testify. I look forward to taking your questions.

Chairman Broun. Thank you, Congressman.

Now I now recognize our next witness, Ms. Steinzor. You are recognized for five minutes.

TESTIMONY OF RENA STEINZOR,

PROFESSOR, UNIVERSITY OF MARYLAND SCHOOL

OF LAW AND PRESIDENT, CENTER FOR PROGRESSIVE REFORM

Ms. Steinzor. I appreciate the opportunity to testify on one of EPA's most important and foundational programs. These days the more important a public health program, the more likely it is to be the subject of relentless, intemperate, and unjustified attacks. IRIS is no exception. The program is a serious, well-informed, and carefully-conducted scientific effort to synthesize existing research in order to set reference doses for the worst toxic chemicals. But industry lobbyists have mischaracterized it as an anti-scientific effort to demonize such ostensibly benign substances as arsenic, formaldehyde, and dioxin. Arsenic, formaldehyde, dioxin. Really?

Without IRIS EPA would be hard pressed to develop standards for the control of emissions of toxic chemicals that cause brain damage, cardiovascular illness, reproductive dysfunction, cancer, and a range of other diseases. Delaying IRIS profiles has and will endanger public health, an intolerable outcome that this committee must not allow to happen.

The simple fact is that everyone attending this hearing would be hard pressed to come up with more than a handful of toxic chemicals that were exonerated by additional research. The overwhelmingly powerful historical trend moves in the opposite direction. As the research accumulates, chemicals prove to be more toxic than we first imagined, often by several orders of magnitude.

From the American public's perspective the central and urgent problem with IRIS is not that it rushes to judgment on toxic chemicals. Far from it. The problem is that repeated rounds of redundant peer review and interagency comment allow, in fact, invite chemical manufacturers to slow the program to a crawl. Because of these delays IRIS is woefully incomplete.

Profiles are missing for at least 255 high-priority chemicals. The 2008 GAO report warned that the Bush Administration's approach to IRIS left the database at risk of becoming obsolete. To its credit, the Obama Administration reviewed IRIS in an effort to speed the production of assessments. Although these changes are a definite improvement, the rate of production is still slow enough that EPA will not catch up with its existing backlog for another 55 years.

Chemical manufacturers and their allies, most notably federal agencies like the Department of Defense and NASA, have targeted IRIS as a chokepoint for regulation. Anyone who has followed the IRIS Program closely for many years cannot help but find their recent denunciations of the program disingenuous and surreal. They have been in the thick of the action since IRIS began, making their case to IRIS staff, more senior EPA officials, sympathetic federal agencies and departments, and the White House Office of Information and Regulatory Affairs. In fact, the reason why IRIS profiles have ballooned into unmanageable length is the reaction of EPA staff to constant harassment by industry participants.

The remedies proposed by the chemical industry will make these problems worse, not better. One of the most intemperate proposals is that OIRA increase its oversight of the program. OIRA is staffed almost exclusively by economists who have no better idea of what constitutes a good RfD than any other layperson.

A second demand is that the NRDC be brought in to review--NRD be brought in to review all IRIS assessments. The academic scientists who serve on NRC review committees receive compensation that does not nearly pay for their time. Instead,

they are motivated by a commitment to public service and the prestige of serving on a panel to consider cutting-edge scientific issues. Using NRC to run around double-checking routine government work would disrupt this delicate balance, damaging the National Academies as well as EPA.

The final example of overreaction is the rider proposed for EPA's appropriations bill that would bar EPA from moving forward with future assessments until all existing assessments had been revised to conform to the NRC's advice about the formaldehyde assessment. This proposal would paralyze the IRIS Program for the foreseeable future by forcing its staff to engage in a massive round of paper shuffling.

The chemicals we are talking about here are the worst of the worst, produced in amounts of millions of pounds annually. The victims of further IRIS delays are neither the companies that makes these chemicals, nor the scientists engaged in the endless research, but rather Americans and their health.

Thank you.

[The prepared statement of Ms. Steinzor follows:]

Prepared Statement of Ms. Rena Steinzor, Professor, University of Maryland School of Law, and President, Center for Progressive Reform

Mr. Chairman, Ranking Member Edwards, and Members of the Subcommittee, I appreciate the opportunity to testify before you today on one of the Environmental Protection Agency's (EPA) most important and foundational programs, the Integrated Risk Information System (IRIS). Let me get straight to the point. These days, the more important a public health program, the more likely it is to be the subject of relentless, intemperate, and unjustified attacks. IRIS is no exception. What is in fact a sober, well-informed, and carefully conducted scientific effort to synthesize existing research in order to set reference doses for the most toxic chemicals is portrayed by industry lobbyists as an anti-scientific effort to ``demonize'' such ostensibly benign substances as arsenic, formaldehyde, and dioxin. This deliberate misreading of the science by industry lobbyists is intended to prolong Americans' exposure to dangerous substances in the service of corporate profit, while at the same time immobilizing the federal agency best qualified to protect public health, the EPA.

The truth is that everyone attending this hearing would be hard-pressed to come up with more than a dozen examples of toxic chemicals that have been found to be significantly less harmful than we originally thought when additional research was done. The powerful historic trend moves strongly in the opposite direction: as the research has accumulated, chemicals like dioxin, arsenic, formaldehyde, cadmium, mercury, and lead prove to be more toxic than we first imagined. Endless efforts to deconstruct individual studies should not obscure this trend, as the chemical industry was well aware until the current backlash against regulation offered it new opportunities to defeat safeguards that protect public health by distorting EPA's track record.

IRIS started as an internal EPA database used to develop toxicological profiles for common chemicals. These profiles set the reference dose, or RfD, for a given chemical on the basis of existing scientific literature. An RfD is the amount below which human exposure is deemed unlikely to cause adverse health effects. Over time, IRIS has become an invaluable resource: It receives some 2,000 internet visits a day, testament to its importance as among the best, most comprehensive databases for this kind of baseline information. And, although IRIS itself most definitely is not a regulatory program, it provides a strong scientific foundation for much of the rest of the agency's work. Without the scientific determinations IRIS contains, EPA would be hard-pressed to develop standards for the control of emissions of toxic chemicals that cause brain damage, cardiovascular illness, reproductive dysfunction, cancer, and a range of other diseases. Delaying the production of IRIS profiles costs lives and endangers public health, an intolerable outcome that this Committee must not allow to happen.

My testimony today makes four points about the future of the IRIS program:

From the American public's perspective, the central and urgent problem with IRIS is not that it rushes to judgment on toxic chemicals. Far from it. The problem is that repeated rounds of redundant ``peer review'' and interagency comment allow--in fact, invite -chemical manufacturers, the Department of Defense, and other self-interested parties to slow the program to a crawl. Because these delays help to ensure that dangerous chemicals are left in commerce for years longer than necessary, people suffer avoidable diseases and irrevocable neurological and reproductive damage. The Government Accountability Office (GAO) has repeatedly warned Congress about the negative implications of these delays. See, e.g., GAO-08-6743T, EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals (April 29, 2008) and GAO-09-271, HIGH-RISK SERIES, An Update (January 2009). GAO has placed the EPA chemicals program in the ``high risk'' category reserved for a small number of the most troubled programs in government. It made this important decision in part because IRIS updates are so slow that the data base risks becoming obsolete. It did not make any reference to the distorted critique of EPA science that the chemical industry has developed.

Given that IRIS is constantly struggling to avoid capture by the chemical industry and, if anything, gives manufacturers far too many opportunities to befuddle final assessments, the chemical industry's sudden discovery of its flaws is as opportunistic as it is incredible.

The National Research Council's (NRC) report on formaldehyde does not justify the radical changes sought by the industry. In fact, the NRC explicitly endorsed the program's continuation and improvement. Its critique of the formaldehyde assessment constitutes robust peer review, not an outright condemnation of the program and EPA science as industry witnesses would have you believe. I wish that the NRC committee had not adopted such a haughty tone in scolding EPA staff. But that tone was the product of political naivet regarding how its report would be exploited in the existing political climate. It cannot fairly be characterized as a recommendation that IRIS stop-or even slow-its critical work.

The remedies sought by the American Chemistry Council (ACC) are designed to run IRIS off the road, further undermining EPA's mission to protect public health. I urge the Committee to side with the public, not the manufacturers of toxic chemicals long overdue for assessment and control.

I am a law professor at the University of Maryland School of Law and the President of the Center for Progressive Reform (CPR) (http://www.progressivereform.org/). Founded in 2002, CPR is a 501(c)(3) nonprofit research and educational organization comprising a network of sixty scholars across the nation who are dedicated to protecting health, safety, and the environment through analysis and commentary. I joined academia mid-career, after seven years as an attorney at the Federal Trade Commission, five years as staff counsel to the House Energy and Commerce Committee, and seven years representing small and mid-sized electric utilities. My work on environmental regulation includes four books, and over twenty-seven articles (as author or co-author). My most recent book, published by the University of Chicago Press, is The People's Agents and the Battle to Protect the American Public: Special Interests, Government, and Threats to Health, Safety, and the Environment, which I co-authored with Professor Sidney Shapiro of Wake Forest University's School of Law, analyzes the state of the regulatory system that protects public health, worker and consumer

safety, and natural resources, concluding that these agencies are under-funded, lack adequate legal authority, and are undermined by political pressure motivated by special interests. I have served as a consultant to EPA and have testified previously before Congress on regulatory subjects on numerous occasions.

Saving IRIS

Since 2005, Member Scholars at the Center for Progressive Reform (CPR) have researched and written five white papers regarding IRIS and the need to streamline the process for developing toxicological profiles and several letters to decision makers concerned about the program's future. They are available here: http://www.progressivereform.org/IRIS.cfm, and I have attached the two most recent reports, Corrective Lenses for IRIS and Setting Priorities for IRIS to this testimony. Our key findings include:

1. IRIS is woefully incomplete. EPA is many years behind in completing profiles of at least 255 chemicals. Some 109 chemical profiles that EPA was required by the Clean Air Act Amendments of 1990 to have completed by 2008 are either included in IRIS but missing critical elements, or entirely absent from the database. A similarly sad situation afflicts the agency's efforts to carry out the statutory mandates of the Safe Drinking Water Act. Every five years, EPA generates a new Contaminant Candidate List (CCL). The lists contain recommendations both for chemicals and microbiological contaminants. Since 1996, EPA has published three CCLs that contain 156 distinct chemical substances. IRIS profiles are missing for 64 (41 percent) of these substances.

2. So severe are the delays in the IRIS process that a 2008 GAO report warned that the Bush Administration's approach to IRIS, which resulted in just two completed profiles per year, left the database at risk of becoming obsolete. (The report is available at http://www.gao.gov/new.items/d08743t.pdf.) To its credit, the Obama Administration revised the IRIS process in an effort to speed the production of assessments, and has managed to increase the number of completed profiles to nine annually. But although this performance is a definite improvement, the rate of production is still slow enough that, if nothing else is done to improve the pace of IRIS, EPA will not catch up with its existing backlog for another 55 years.

3. One area of particular concern is that the Obama Administration's new IRIS process left in place many of the roadblocks GAO had previously identified, including interagency review of individual assessments, multiple reviews by outside science panels, and prioritization of a few high-profile assessments at the expense of faster assessments. Potentially regulated parties, including other federal agencies like the Department of Defense and National Aeronautics and Space Administration, have targeted IRIS as a choke point for regulation. The labyrinthine process they have demanded, diagrammed on page 9 of the Corrective Lenses report, contains multiple rounds of peer review, public comment, and interagency review that are as redundant as they are time-consuming. In effect, the program suffers from the problem of ``information capture''-a phenomenon where potentially regulated industries and their federal agency clients submit so much irrelevant data to EPA, and do so with such frequency, that new assessments become mired in never-ending controversy.

4. To close data gaps and reestablish IRIS's credibility as a cutting-edge database, EPA needs to make four changes. First, EPA should reduce the procedural burdens that were formalized during the Bush administration. Second, EPA must articulate clear, statute-driven priorities about which assessments to complete to ensure that data gaps in statutory mandates would be more quickly addressed. Third, the IRIS

process must be restructured to allow for timely assessments to be written on the basis of the weight of available evidence at the time an assessment is undertaken. Fourth, EPA must have adequate resources-and use those resources efficiently--to complete a much larger number of assessments.

One additional point is worth making. The chemicals we are talking about here are the worst of the worst, produced in amounts of millions of pounds annually. As just one example, chromium compounds, which are categorized in the worst ten percent of all toxic chemicals and are among the hazardous air pollutants missing from IRIS, are emitted in amounts exceeding 58 million pounds annually. Unsafe exposure to chromium compounds causes cancer, suppresses immune systems, and harms kidney and respiratory functions. Over the last several years, industry has sponsored several studies of chromium. When a study documents adverse effects at common levels of exposure, the sponsors commission a second study designed to rip apart the first. Unfortunately, the victims of this endless treadmill are neither the sponsors, nor the scientists engaged in chasing each other's tails, but rather the public's health.

Industry Influence over IRIS

Anyone who has observed IRIS for many years cannot help but find the chemical industry's recent denunciations of the program disingenuous, even surreal. Far from being helpless bystanders in the process, industry Members have been in the thick of the action since the database was initiated, submitting the research they think most important and repeatedly advocating their view of the research to IRIS staff, more senior EPA officials, sympathetic federal agencies and departments, and the White House Office of Information and Regulatory Affairs (OIRA). To whatever extent that IRIS science is flawed, the people complaining about those flaws are full partners in its development. In fact, one reason why IRIS profiles have ballooned into unmanageable length is the reaction of EPA staff to constant harassment by industry participants.

The Formaldehyde Review

The NRC conducted a robust peer review of the draft IRIS formaldehyde assessment. The report is written in the detailed language of one group of scientists giving another group of scientists an unvarnished assessment of how a scientific finding could be revised and bolstered. Its work will undoubtedly improve the IRIS process, and EPA is already taking its recommendations to heart.

Unfortunately, the NRC reviewers also succumbed to the fatal attraction of reiterating their professional superiority, using tough, even haughty language to critique EPA's work, and exhibiting a remarkable level of insensitivity to how their comments would be interpreted in the over-heated political atmosphere that afflicts the nation's Capitol these days. Clearly, the NRC committee was trying to help IRIS staff to do better, not to immobilize the program. Consider the following direct quotes from the NRC report:

> The draft IRIS assessment correctly concludes that formaldehyde is a genotoxic (DNA-reactive) chemical that causes cytogenetic effects, such as mutations. (emphasis added) (p. 4)

> The committee recognizes that revision of the approach will involve an extensive effort by EPA staff and others, and it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach. However, models for conducting IRIS assessments more effectively and efficiently are available, and the committee provides several examples in the present report. Thus, EPA might be able to make changes in its process relatively quickly by

selecting and adapting existing approaches. (emphasis added) (p. 11)

As a person who teaches for a living, I would urge future NRC panels to keep in mind how much self-important scolding can interfere with a student's learning process-we all know that truth in our academic lives but may forget it when we enter the policymaking world. Regardless, Congress would make a grave error if, at the behest of self-interested chemical manufacturers, it ignored the stated goals of the NRC's review.

Excessive Remedies

The remedies proposed by the chemical industry representatives here today confuse and distort the core purposes of IRIS. For example, one of the most intemperate proposals advanced by the American Chemistry Council is that the OIRA increase its oversight of the program. OIRA is the division within the White House that checks agency cost-benefit analyses. It is staffed almost exclusively by economists who have no better idea of what constitutes a good RfD than any other lay person. Two scientists work at OIRA, in comparison to the dozens of well-qualified scientists representing multiple disciplines who work at EPA. The recommendation that OIRA be put in charge of IRIS is not designed to improve the program's scientific validity, but rather is intended to give chemical manufacturers a sympathetic forum where they can tie IRIS in knots more easily.

A second industry demand voiced by ACC is that NRC be brought in to review all IRIS assessments. NRC is the gold standard for peer review and, as I mentioned earlier, its critiques are always interesting. On the other hand, the academic scientists who serve on NRC review committees receive compensation that does not nearly pay for their time. Instead, they are motivated by a commitment to public service, the pleasure of engaging with bright and sophisticated colleagues, and the prestige of serving by invitation on a panel convened by the finest scientific institution in the nation. Using NRC to run around double-checking government work would corrode this delicate balance, ultimately rendering it unworkable. Not incidentally, it would also add unreasonable delay to an already dangerously slow process. I hope that the NRC recognizes the insidious implications of this recommendation and strongly opposes it.

The invocation of NRC, and the National Academies as a whole, has become a common practice for potentially regulated parties who hope to slow down EPA decision making. The little-recognized hypocrisy of this practice is that when NRC ratifies EPA's judgments without qualification, aggrieved industry participants simply ignore its findings and proceed with their campaign against the agency. So, for example, NRC issued a report on mercury that was fully supportive of the RfD that EPA had set for the substance. (The NRC report is available at http://www.nap.edu/openbook.php?isbn=0309071402.) The electric utilities fighting EPA's regulatory efforts simply ignored the NRC report as if it had never been completed, continuing their attacks on the research underlying the agency's decision. Far from serving as an umpire in heated disputes, NRC was exploited as a tool to delay final action and then promptly cast aside.

The final, penultimate example of overreaction that will endanger public health is the rider now pending in the House Appropriations Committee. It would bar EPA from moving forward with future assessments until all existing assessments had been revised to conform to the NRC's advice about the formaldehyde assessment. This proposal would paralyze the IRIS program for the foreseeable future by forcing its staff to engage in a massive round of paper shuffling.

In a surprisingly successful effort to obscure the real motivations behind these radical suggestions, regulated industries have portrayed them as essential to job creation, and therefore of direct benefit to the average American. Fundamental to this set of claims is the notion that regulatory excesses in these times of economic recession have hit

industry so hard that its Members cannot afford to expand their businesses and put people back to work. But some quick research on the percentage increase in profits from 2009 to 2010 for some of the ACC's largest Members yielded surprising results.

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Rules to protect public health and the environment most definitely do not have the effect of sweeping money into a pile and setting it on fire. Rather, they save the lives of millions of people, prevent many more millions from getting sick or becoming sicker, and preserve the irreplaceable natural resources without which human life would be impossible.

For example, Clean Air Act regulations are uniformly recognized as a wonderful economic bargain by honest experts from all points on the political spectrum. According to EPA's very conservative numbers, which dramatically understate benefits and overstate costs, clean air rules saved 164,300 adult lives in 2010, and will save 237,000 lives annually by 2020. EPA estimates that the economic value of Clean Air Act regulatory controls will be $2 trillion annually by 2020; costs of compliance in that year will be $65 billion. Air pollution controls saved 13 million days of work loss and 3.2 million days of school loss in 2010. By 2020, they will save 17 million work loss days and 5.4 million school loss days. I emphasize that EPA's cost estimates are based on extraordinarily conservative assumptions regarding regulatory benefits. For example, EPA says that a non-fatal heart attack in a person 0-24 years old is worth only $84,000 and that an emergency room visit to treat an asthma attack is worth only $363 per incident-hospitals don't give you a plastic ID bracelet for that little.

And according to OIRA, which houses the staff of economists so embraced by ACC, ``the estimated annual benefits of major federal regulations are in the aggregate between $132 billion and $655 billion, while the estimated annual costs are in the aggregate between $44 billion and $62 billion.'' (See http://www.whitehouse.gov/sites/default/files/omb/inforeg/2011--cb/2011--cba--report.pdf.)

Thank you, Mr. Chairman and Ranking Member Edwards. I would be happy to answer any questions you may have.

Attachments:
1. CPR Report, Corrective Lenses for IRIS
2. CPR Report, Setting Priorities for IRIS

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Chairman Broun. Thank you, Ms. Steinzor.

I now recognize our next witness, Dr. Charnley, for five minutes. Dr. Charnley.

TESTIMONY OF GAIL CHARNLEY, PRINCIPAL, HEALTHRISK STRATEGIES

Dr. Charnley. Thank you, and good morning. I am a toxicologist, a human health risk analyst, and a toxicology consultant who has relied for many years on the information contained in the IRIS database for my work. I am speaking on the basis of my 30-year career as a scientist evaluating the relationship between chemical exposures and human health effects, and I am not representing any organization today.

The role and purpose of IRIS are good and well-intentioned, but over the years IRIS has lost its way, straying from science and veering towards advocacy. As a result it no longer has much scientific credibility outside the agency or, importantly, within the agency itself.

IRIS started out as a good idea, an advisory group of scientists that assessed chemical toxicity for the rest of EPA. The reach of IRIS goes way beyond EPA, however, as other

federal agencies, state and local governments, both within the United States and in other countries, lacking their own resources to generate toxicity values, chemical toxicity values, have come to rely on those generated by IRIS. Because the influence of IRIS is so broad, the scientific quality and integrity of its reviews are critically important.

The problem is that IRIS toxicity evaluations do not follow a rigorous, objective, transparent, scientific weight of evidence process, instead, relying on what--in the absence of such a process--appears to be cherry-picking data in support of policy preferences as needed.

A true weight of evidence analysis should explicitly present the criteria for inclusion and exclusion of studies so that all relevant information is included and so that biases towards the inclusion of certain outcomes are avoided.

IRIS assessments fail to use a weight of evidence process despite the explicit direction to do so provided by EPA's own risk assessment guidance and repeatedly by various National Academy of Sciences committees. My written statement details some of the large body of EPA documentation stating that it is EPA policy to perform balanced weight of evidence analysis as part of chemical risk assessment, a policy that is clearly being ignored by IRIS.

I think the solution is not to try once more to tweak or revamp the existing process but to start over. Public health is not served by a broken, cumbersome, controversial process that lacks a rigorous scientific foundation and a transparent, replicable weight of evidence framework. Setting up a more effective process should follow the recommendations of a National Academy of Sciences committee convened for that purpose and should follow a weight of evidence procedure recommended by the Academy.

Chapter seven of the Academy's formaldehyde report provides helpful but general guidance toward that end, and, no, I am not advocating that NAS review all IRIS reviews.

EPA's recently proposed IRIS redesign relies on EPA's Science Advisory Board for, ``independent review and oversight,'' instead of the Academy. However, the SAB is not independent. EPA officials select SAB Members, formulate charge questions, provide staff support for the review process, and oversee SAB deliberations and report drafting.

In contrast, the NAS process for selecting scientific panel Members and conducting reviews assures independence and objectivity along with appropriate expertise for which they are not compensated in any way.

Truly independent peer review is the only way to give stakeholders confidence in the credibility of the outcome. Stakeholders are likely to accept the outcome of an independent Academy committee and unlikely to accept the outcome of an EPA-administered committee.

In conclusion, the IRIS process is dysfunctional and attempts to tweak it have not resulted in meaningful improvements. Changes proposed this week are promising, but I believe that implementing those changes and implementing an improved, scientifically-based, transparent IRIS process would benefit greatly from National Academy of Science's guidance. The NAS is in a unique position to provide unbiased, credible, expert advise that, sadly, is so critically needed at this point if we are to move IRIS into a 21st century approach to assessing chemical toxicity effectively.

Thank you.

[The prepared statement of Ms. Charnley follows:]

Prepared Statement of Dr. Gail Charnley, Principal, HealthRisk Strategies

Good morning. I am speaking today as a toxicologist with a Ph.D.

from MIT, as a human health risk analyst, and as a toxicology consultant to private clients who has relied for many years on the information contained in the IRIS database for my work. I am speaking on the basis of my 30-year career studying the relationship between chemical exposures and human health effects, as executive director of the bipartisan Presidential/Congressional Commission on Risk Assessment and Risk Management, as a member of the National Toxicology Program's Report on Carcinogens Committee, as a former senior program officer in the National Academy of Sciences' Toxicology and Risk Program, as a member of National Academy of Sciences committees, and as a member of the National Academy of Sciences Board on Environmental Studies and Toxicology. I am not representing any organization today, however, or being paid for my testimony.

The role and purpose of IRIS are good and well-intentioned, but over the years IRIS has lost its way. IRIS started out as a good idea-a scientific advisory group that assesses chemical toxicity for the rest of EPA so as to avoid every office having to do it themselves and generating potentially conflicting toxicity values. The reach of IRIS goes far beyond EPA, however, as other federal agencies and state and local governments in the U.S. and other countries lacking their own resources for generating chemical toxicity values have come to rely on those generated by IRIS. IRIS assessment can thus become a de facto component of regulatory decision-making without benefit of appropriate administrative process. Because the influence of IRIS is so broad, the scientific quality and integrity of its reviews are critically important.

Unfortunately, over time the IRIS process has become politicized and, as a result, it no longer has much scientific credibility outside the agency or, importantly, even within the agency. The process has strayed from science and veered towards advocacy. As you have heard from other speakers this morning, IRIS toxicity evaluations do not follow a rigorous, objective, transparent, scientific weight-of-evidence process, instead relying on cherry-picking data as needed to support policy preferences. Indeed, many of IRIS' recent conclusions appear to be based on what my colleagues and I refer to as ``magical modes of action'', that is, highly speculative biological explanations for toxicity.

IRIS assessments fail to evaluate potential human cancer and noncancer effects of chemical exposures using a weight-of-evidence analysis despite the direction to do so provided by EPA's own risk assessment guidance documents and, repeatedly, by various National Academy of Sciences committees. For example, EPA's Information Quality Guidelines state that when EPA develops ``influential'' scientific risk assessments, it intends to use all relevant information and reach a position based on careful consideration of all such information, a process typically referred to as the ``weight-of-evidence'' approach. \2\ EPA's Assessment Factors Handbook \3\ states that a weight-of-evidence approach generally considers all relevant information in an integrative assessment and explains how the various types of evidence fit together. EPA's Risk Assessment Principles & Practices documentation asserts that risk assessment involves consideration of the weight of evidence provided by all available scientific data. \4\ My point is that there is a large body of EPA documentation stating that it is EPA policy to perform balanced weight-of-evidence analysis as part of chemical risk assessment that is clearly being ignored-a glaring omission in light of EPA's own guidelines, policies, and NAS recommendations.

\1\ EPA (2002) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency. EPA/260R-02-008. Office of Environmental Information, Washington, DC

\3\ EPA (2003) A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information. EPA 100/B-03/001. Science Policy Council, Washington, DC

\4\ EPA (2004) Risk Assessment Principles and Practices. EPA/100/B-04/001. Office of the Science Advisor, Washington, DC

A weight-of-evidence analysis for any potential health effects, whether cancer or noncancer, should be more than a matter of describing a set of available studies with an array of results and then announcing one's overall subjective judgment. Because judgments made about potential risk will usually not be definitive, it is important to present the strengths and weaknesses of alternative judgments that could be made, giving the reader a picture of how strongly one or another interpretation is supported vis- . . . -vis alternative possible explanations. Instead, IRIS assessments preclude a weight-of-evidence analysis by selecting almost solely for studies that demonstrate a positive result and a dose-response relationship, typically excluding studies that demonstrate no effect and thereby effectively preventing a balanced consideration of available evidence supporting or refuting the biological plausibility and likelihood of effects.

A true weight-of-evidence analysis should explicitly present the criteria for inclusion and exclusion of studies so that all relevant information is included and so that biases toward inclusion of certain outcomes-such as only positive outcomes-are avoided. The goal should be to interpret possible reasons for disagreement, not to select the ``best'' study and rely on it even if it is contradicted by other study results. Omitting endpoints or studies that do not show a dose-response relationship in the direction EPA favors discounts valuable information, particularly information that could inform mode of action as well as dose-response.

I think the solution is not to try once more to tweak or revamp the existing process but to get rid of it entirely and start over. Public health is not served by a broken, cumbersome, controversial process that lacks a rigorous scientific foundation and a transparent, replicable weight-of-evidence framework. Setting up a more effective process should follow the recommendations of a National Academy of Sciences committee convened for that purpose and should follow a weight-of-evidence procedure recommended by the Academy. Chapter 7 of the Academy's formaldehyde report provides helpful guidance to that end. \5\

\5\ National Academy of Sciences/National Research Council. 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. National Academy Press. Washington, DC

Some have proposed that IRIS rely on EPA's Science Advisory Board for independent external review and oversight instead of the Academy. However, the SAB review process is not independent. EPA officials select SAB Members, formulate the charge questions, provide staff support for the review process, and observe SAB deliberations and report drafting. According to the SAB web site, ``The Staff Office manages EPA requests for scientific and technical advice and peer review. The Staff Office also provides policy, technical and administrative assistance to advisory committees in conducting meetings and preparing reports. The SAB Staff Office oversees the formation of advisory committees and panels . . .'' and so forth. In contrast, the NAS process for selecting scientific panel Members and conducting reviews assures independence and objectivity along with appropriate expertise. Truly independent peer review is the only way to give stakeholders confidence in the credibility of the outcome. Stakeholders are likely to accept the outcome of an independent Academy peer review and unlikely to accept the outcome of an EPA-administered peer review. Then there's the problem of delay. Most of the recent controversial IRIS assessments reviewed by the NAS had already been reviewed by the SAB, but ended up at the Academy anyway.

In conclusion, the IRIS process is dysfunctional and attempts to tweak it have not resulted in meaningful improvements. Developing an

improved, scientifically based, transparent IRIS process would benefit greatly from National Academy of Sciences guidance. The NAS is in a unique position to provide unbiased, expert advice that, sadly, is so critically needed at this point if we are to move IRIS to a 21st century approach to assessing chemical toxicity effectively.

Chairman Broun. Exactly five minutes. Exactly.

Mayor Bollwage, you are now recognized for five minutes.

TESTIMONY OF J. CHRISTIAN BOLLWAGE, MAYOR, CITY OF ELIZABETH, NEW JERSEY

Mr. Bollwage. Thank you very much, Mr. Chairman and Members of the committee. I just want to say upfront that I am a mayor. I am not a scientist, so I talk about trying to create jobs, economic development. We work with our city councils, our department managers. We make decisions on the ground every day, but risk management is one of those areas where local elected officials must make decisions, and we always like to have the best available tools.

The IRIS System is a mix of scientific measure, expert guesswork, and surrounded by a high level of uncertainty with what might happen to humans if they are exposed to chemical substances. In the end from my position it is a tool, and we have learned through the experience of governing city that when you use a tool to guide decision making, you want to use the right tool, applied to the right problem, and use the tool in the right way. And the IRIS method has to yield the result that makes commonsense.

I have worked closely with the Conference of Mayors for 15 years in convincing the EPA and the Congress that not all contaminated sites in communities are the same. There are grossly contaminated sites called Superfund, but there are hundreds of thousands throughout our country less contaminated brownfield sites. I am very concerned with the public health in my community, and if that health threat can be dealt with and brownfield sites properly redeveloped, then it is a win-win for the community. Brownfield legislation has helped us remove that public health threat. We put these lands back to productive use creating jobs, urban redevelopment, new sources of revenues that are used to support public safety, public health, and maintain our physical infrastructure.

One of the greatest impediments to this type of progress was the way that the EPA and the press have over-characterized the risk to the public. This attached an unpardonable stigma to any site whether the contamination was serious or negligible. Generally the risk has been overplayed, and it has become difficult from my position to educate the public about the difference between a brownfield site and a Superfund site.

This was the case even after the EPA Administrator Browner released over 30,000 sites that were on the CERCLIS list, and these were not contaminated enough to warrant any further EPA action.

I have a Superfund site in the City of Elizabeth. It is severely contaminated and way too costly to ever clean up. I also have brownfield sites. I am proud to report we developed many of those, IKEA Super Center, Jersey Gardens on a 166-acre former landfill. Has four hotels as well as 2 million square feet of retail space. They are thriving, and they have created hundreds of jobs, promoted redevelopment, and has been an enormous success for our community.

I have submitted to the committee a report prepared by the Conference of Mayors that shows brownfield redevelopment in cities across the Nation have had the same positive impact because of local government's decisions.

EPA's dioxin reassessment will converge with the IRIS System, and this combination will impact a wide range of policy decisions. The Conference of Mayors believes this tool as applied to brownfield sites could bring back the stigma of a Superfund site. And as a tool the IRIS System relies on toxicity values that are established with a very wide margin of error that is intended to allow for uncertainty.

So when the IRIS System is used to inform risk management decisions, it must be noted that the compound effect of overly-conservative toxicity values with overly-conservative exposure scenarios can yield a very distorted characterization of risk.

For example, when EPA proposed to lower the dioxin soil concentration for a contaminated site remediation, they proposed to lower the existing guideline from one point--one part per billion to 76 parts per trillion or even 3.7 parts per trillion.

So not only is the exposure scenario unrealistic, but at 3.7 parts per trillion of dioxin, the soil in every urban center in this country would pose an unacceptable risk because background levels are normally two to four times higher than that.

So here is what troubles the mayors. People get 95 percent of dioxin from the foods they eat, not from a contaminated brownfield site. EPA continues to rely on a worst-case exposure scenario. So I have doubts about how this IRIS tool can be applied with any certainty.

So I would like to make some following suggestions. The EPA can continue to improve the IRIS and the information based on toxicity and exposure assessment. The exposure assessment is something that should be evaluated by the National Academies of Science to determine if more realistic assumptions are appropriate.

For example, it would be helpful to have actual measurements of a most-likely-case scenario in addition to a worst-case scenario.

IRIS should be a tool to advise decisions, not mandate them. Mayors need the best tools available to help us make sound decisions. Our goals for our cities are to protect the public health and the environment while encouraging economic vitality.

I want to thank you, Mr. Chairman, for this time, and thank Members of the committee as well.

[The prepared statement of Mr. Bollwage follows:]

Prepared Statement of The Honorable J. Christian Bollwage, Mayor, City of Elizabeth, New Jersey

My name is J. Christian Bollwage, and I am Mayor of the City of Elizabeth, New Jersey and Chair of the Conference of Mayors Brownfields Task Force for the past 15 years. I appreciate this opportunity to provide comments to the House Science Committee and I thank the Chairman for extending the invitation to participate in this panel.

I am here representing The United States Conference of Mayors which is the non-partisan organization that represents cities with populations of 30,000 or more through their chief elected official, the Mayor. There are over 1,200 cities throughout the United States.

I want to emphasize that I am a Mayor, not a scientist and therefore I am not accustomed to participating in scientific and technical discussions. However, I was asked to come before you today to provide comments on the real-world impacts of applying scientific assessment tools at the community level, and this I have done since becoming a locally-elected official.

I am certainly not an expert on the IRIS system, but for want of a better tool, my staff are users of the IRIS system approach to hazard and human exposure assessment.

Mayors, with their City Councils and Department Managers, have to make decisions on the ground every day to run a city. While many of

these decisions require the careful application of common sense, some are more complicated, and these types of decisions require the use of more sophisticated decision-making tools.

Risk management is one of those areas where local elected officials must make decisions, and we like to have the best tools available to assist us with our efforts.

The IRIS system is not some sort of ``sacred tool'' that should never be questioned or evaluated. It does seem, however, that it is shrouded in a mix of scientific measurement, expert guesswork, and deals with a high level of uncertainty.

I have been told that the IRIS method is one that combines measurement precision and a lot of guesswork about what might happen in humans if they are exposed to chemical substances. But, in the end, it is just a tool used by decision-makers.

I have learned through the experience of governing a city for nearly 2 decades that when you use a tool to guide decision-making, you want the right tool, applied to the right problem. And you want to use that tool the right way.

So, even though the IRIS method has some valid scientific components, it still has to yield a result that makes sense, even to the laypeople in the community.

That is what I want to comment on here today.

I worked closely with the Conference of Mayors starting 15 years ago to convince the EPA and Congress that not all contaminated sites in communities are the same.

There are grossly contaminated sites that are Superfund sites with New Jersey having more than its fair share. But there are hundreds of thousands of less contaminated sites, known as brownfields that could be a potential public health threat but could also be cleaned up and turned into property that contributes to the well-being of that community. As a Mayor, the public health in my community is a paramount consideration. I am seriously concerned about the health of our children, our pregnant women, our average citizens and our city employees. However, I also don't want to unnecessarily cordon off pieces of property that should be properly evaluated, cleaned up, and reclaimed.

That is why I worked so hard with the Conference of Mayors to get Congress and the Administration to establish Brownfield redevelopment policies.

Brownfield legislation has helped us remove the public health threat, and we have put these lands back into productive use creating jobs, urban redevelopment and new sources of revenues that are used to support public safety, public health and maintain our physical infrastructure.

One of the greatest impediments to this type of progress was the way EPA and the popular press characterized contaminated land in the 1980s. EPA was, in our opinion, `less than careful' about how they originally characterized the risk to the public. In public hearings in many communities across the nation there was an unpardonable stigma attached to any site with contamination whether the contamination was serious or negligible. The popular press played an important role in fanning the flames of fear among the public. This made it virtually impossible to redevelop these properties. Developers wouldn't touch them, banks wouldn't lend money, and instead we had the abandonment of previously developed sites in favor of greenfields which contributed to urban sprawl.

Generally, the risk was so over-played that it became a burdensome task to educate Congress and the public about the difference between a brownfield site and a Superfund site. This was the case even after EPA Administrator Carol Browner released over 30,000 sites that were on the CERCLIS list and said that these were not contaminated enough to warrant any further EPA action.

I have a Superfund site in Elizabeth New Jersey. It is severely contaminated, and would pose a public health problem if it were not cordoned off properly- which it is. This site will likely plague the

city for the next century because it was determined that it will cost too much money to clean it up.

I also have quite a few brownfield sites in Elizabeth. I am proud to report that we have redeveloped many of them including the IKEA Super Center and the Jersey Gardens, an economically thriving shopping center that has created hundreds of jobs, promoted redevelopment and has been an enormous help to the city's economy.

I am submitting to the Committee a report prepared by the Conference of Mayors that shows that brownfield redevelopment in cities across the nation have had the same positive impact because local government made the decision to clean these sites up, remove the potential public health threat and returned the land to productive use.

But once again I am in Washington on the topic of not stigmatizing the redevelopment of brownfields unnecessarily. EPA's dioxin reassessment will converge with the IRIS system, and this combination will impact a wide range of policy decisions, including Preliminary Remediation Goals (PRGs) for dioxin levels in soil. The Conference of Mayors' believes this could have a severe impact on brownfields and other urban and suburban development.

The U.S. Conference of Mayors is concerned that EPA's toxicity and exposure assumptions would drive dioxin PRG values down to levels that are below average concentrations in U.S. cities, and perhaps below current background levels in urban and suburban soils.

As a tool, the IRIS system relies on toxicity values that established with a very wide margin of error built in that is intended to allow for uncertainty. The system also relies on exposure assessment calculations that rely on substantial exaggeration on risk.

When the IRIS system is used to inform risk management decisions it must be noted that the compound effect of overly conservative toxicity values with overly conservative exposure scenarios yield a very distorted characterization of risk.

This type of calibration of the different parts of the tool leaves local decision-makers with a risk analysis that is not realistic.

For example, when EPA proposed to lower the dioxin soil concentrations for contaminated site remediation they intended to lower the existing guideline from 1 part per billion to 76 parts per trillion or even 3.7 parts per trillion. These lower standards were based on EPA's overly conservative approach to estimating dioxin toxicity in combination with assumptions about exposed children wallowing in the contaminated site soils.

Not only is the exposure scenario unrealistic, but at 3.7 parts per trillion of dioxin, the soil in every urban and suburban area would pose an unacceptable risk because background levels are normally two to four times higher than 3.7 parts per trillion.

Even lowering the dioxin standard in soil to 76 parts per trillion is lowering the so-called danger point to where the public will question their safety.

What is troubling about those proposals for a Mayor is two important facts:

1. All of our citizens are getting 95 percent of their dioxin from the foods they eat, not from a contaminated brownfield site, and,

2. Rather than rely on worst-case exposure scenarios, the University of Michigan published a study that looks at actual dioxin levels in people reports:

> People who live on contaminated soil and have contaminated household dust do not have higher levels of dioxins in their blood. A study involving direct human measurement included 21 people who lived on soil contaminated at 1,000 to 11,200 ppt TEQ of dioxins.
>
> The study authors stated that they believe their results apply to populations whose soil is contaminated in this range.

EPA exposure assumptions are predominantly determined by policy judgments that are so overwhelmingly reliant on worst-case scenarios that they do not at all reflect the realities of potential human exposure

So, I have doubts about how this IRIS tool can be applied with any certainty. And I am very concerned that it is the wrong tool for making local decisions.

Our August 2010 Policy Paper highlights that these dioxin standards ``at or below background levels and if implemented will have an immediate chilling effect on the successes achieved over the last two decades to clean-up [brownfields] sites and return these properties to productive use.''

So using this tool with its distortion of risk does not pass the reasonable-sense test at the local level.

On the other hand, I understand the need for the EPA to develop assessment tools to help local decision-makers, so I would like to make the following suggestions.

1. The EPA should continue to improve IRIS and the information base on toxicity and exposure assessment

2. The exposure assessment assumptions should be evaluated by the National Academies of Science

I think we are too smart in today's world to rely on one-size-fits-all assumptions in risk management when the stakes are so high

Instead of EPA focusing on ``worst case scenarios'', they should also look at the ``most likely case''. This would be more useful to decision-makers to better understand the true risk of their decisions.

3. The EPA should not force local officials to rely on the IRIS system to make local decisions until the Agency improves the toxicity and exposure assessment methods to better reflect reality

In particular, EPA should not force state regulators to base brownfield site clean-up decisions on the IRIS system

Mayors need the best tools available to help us make sound decisions. Our goals for our cities are to protect the public health and the environment while encouraging the economic vitality. We need tools that are based in reality and common sense.

I want to thank the Chairman and this Committee for the opportunity to give a Mayor's perspective on this important issue.

Chairman Broun. Thank you, Mr. Mayor. I thank you all for your testimony today.

Reminding Members that committee rules limit questioning to five minutes. The chair will at this point open the round of questions.

The chair recognizes himself for five minutes.

Dr. Charnley, to your knowledge does the IRIS Program reflect the framework outlined in the report, ``Risk Assessment and Risk Management in Regulatory Decision Making,'' developed by the Presidential Congressional Commission on risk assessment and risk management?

Can you briefly outline the key aspects of the framework that should be reflected in IRIS risk assessments, and what does it mean to understand the context of a risk problem as discussed in the framework?

Dr. Charnley. Well, what the risk commission framework does is emphasizes the importance of figuring out what the problem

is you are trying to address before you address it, to clarify what your risk management goals are, and use those as a guide to risk assessment. As Dr. Anastas pointed out, however, the IRIS Program does not perform risk assessments. It generates safety values. It generates toxicity values that then a risk assessment would take, would use and compare to exposure values to come up with some understanding of what a human health risk might actually be.

So what the IRIS Program does is provide some of the information that could be used in risk management but doesn't, it doesn't have the same context.

Chairman Broun. Okay. Congressman Dooley, 2 days ago Dr. Anastas participated in a press conference and offered some insight on a new and improved IRIS process that will allegedly incorporate the Academy's recommendations from April, while building upon the 2009 revisions proffered by Administrator Jackson.

Can you comment on the Agency's announcement?

Mr. Dooley. Yes.

Chairman Broun. Congressman, press the button so we can hear you, please, sir.

Mr. Dooley. Yeah. We commend the EPA and Dr. Anastas on some of their recent actions. I think that whatever stakeholder you might be here, whether you are a member of Congress, a mayor, whether you are representing consumer interest groups or environmental groups or if you are part of the industry, we want to have an IRIS Process that meets a gold standard. We heard Dr. Samet say today that he would barely give it a passing grade on the formaldehyde IRIS assessment. I don't think any of us think that that is adequate.

And so what we have been suggesting is that we are looking forward to the reforms that EPA is administering or enacting now to improve their program. I think we would all have a greater confidence that they were getting it right if for the next period of time that the next IRIS assessments that are coming out under these new reforms, that we would submit them to NAS just to make sure that we would have a double check on it to understand: did they enact the best processes, to ensure that we are using the best scientific process, that standards that ensure that the weight of evidence on the scientific research was adequate, that we had a peer review process that provided appropriate levels of transparency and independence.

That is what we are suggesting when the industry, as we were characterized, is asking for NAS to play a major role in reviewing the IRIS assessments that could be issued in the next few months under the new and improved guidelines. We would all benefit and have greater confidence if we had NAS, you know, taking a review, making sure they got it right.

Chairman Broun. Thank you, Congressman.

Mayor Bollwage, I have got 1 minute left, so please answer quickly. Can you give us an idea of what sort of actions that you would need to consider as mayor if EPA proceeds with its proposed dioxin PRG, which as you note is at or below background levels, and what would it mean to your city, your constituents, your economy, your jobs, et cetera? What would be the positive outcomes of such a low dioxin PRG? That is, how would it affect safety?

Mr. Bollwage. Thank you. Mr. Chairman, I can only explain it real quickly with we had an outdated plastics facility, and we wanted to convert it to Little League fields. We scraped away 3 inches of dirt and we mediated that and converted it into two healthy Little League fields.

If the levels are lowered, we are going to wind up scraping away, what, 8 inches, 10 inches, 12 inches, a lot more of the dirt in order to make that area safe for Little League.

You make the cost of a municipality increase substantially, and I don't know of any kids who are rolling around in the brownfields who have caught dioxin.

Chairman Broun. My time has expired.

Now I recognize Ms. Edwards for five minutes.

Ms. Edwards. Thank you, Mr. Chairman, and thank you to our witnesses today.

I just want to start out by noting that I do share Mr. Rohrabacher's view that it is important for us to know who is before us and who is influencing a process but merely working in an industry or working at an organization that advocates for a certain position is not a reason to exclude either that testimony or information.

Nonetheless, I think it is also important that we have the same kind of transparency and accountability that we are demanding of the EPA and other agencies and their process is the same kind of transparency and accountability that we want in those who seek to influence or advocate in the process because it could otherwise operate to the detriment of the public health.

Dr. Charnley, I have looked at your resume. It is very impressive, and I note that you are currently serving on the National Academy of Sciences Board of Environmental Science and Toxicology. Your appointment began in 2009. Is that correct?

Dr. Charnley. Yes.

Ms. Edwards. Thank you, and when you joined the--I also note in your testimony you indicated that you participated on numerous peer review panels convened by the EPA. You say that in your participation you acted independently. Isn't that correct?

Dr. Charnley. Correct.

Ms. Edwards. Thank you, and when you joined the National Academy of Science Board on Environmental Science and Toxicology, we have been told that you would occasionally maybe once or some number of times recuse yourself from board discussions of formaldehyde. Is that right?

Dr. Charnley. That is correct.

Ms. Edwards. And why did you feel a need to or were you required to recuse yourself, and in addition, who was paying you at the time, and what were you being paid to do that required your recusal?

Dr. Charnley. Nobody was paying me at the time but before I joined the board I had given some advice to the Formaldehyde Council on how the National Academy of Sciences process works, and so when I served on the board, although the Academy does not believe that previous employment counts as a conflict, I felt that from an optics point of view, from a perception point of view that it would make sense to recuse myself from any discussions on formaldehyde just so that----

Ms. Edwards. Thank you.

Dr. Charnley. Yeah.

Ms. Edwards. Well, let us not talk about optics. Let me just ask were you specifically in your--previous to your--prior to your appointment, were you paid to advise the Formaldehyde Council about ways in which they could use the NAS process to, you know, to thwart the assessment process through IRIS?

Dr. Charnley. Of course not.

Ms. Edwards. And so I am just curious, were you paid by them to advise you on how to get an Academy study on the EPA's IRIS draft assessment for formaldehyde?

Dr. Charnley. I was not.

Ms. Edwards. Okay. So what we will do is perhaps ask you some questions, specific questions on the record and also the Academy about the recusal process and about your work for the Formaldehyde Council and whether that had any impact on its

work.

Mr. Dooley, when we go to the Formaldehyde Council's webpage right now, and I have it, we are directed to a page that has the ACC logo on it. And then both organizations are shown to reside at the same address in Arlington, Virginia. What do you say about that?

Mr. Dooley. The Formaldehyde Council, just earlier this year, I guess about 6 months ago, moved from being an independent agency to become one of among 50 different specific product panels that we have under ACC. So they are a self-funded group that is operated under the umbrella of the American Chemistry Council.

Ms. Edwards. So I am--maybe I am confused, but--so what we have here today is we have an organization that has taken on the work of the Formaldehyde Council, an expert who advised the Formaldehyde Council, in my view, I think, to just use its power to get the NAS study started. And then we are also aware, I know I am, that Dr. Anastas's appointment was held up in the Senate by Senator Vitter until EPA would agree to fund the NAS formaldehyde review. And then we have one of the people who was advising the Formaldehyde Council on how to get a report requested of the Academy, I believe, and that report is now being misused to excuse or cripple EPA's assessment process.

And so, as far as I am aware, none of that is--and--or those relationships have been disclosed to the committee, but it certainly puts your testimony in an informative light. Thank you very much, and I yield.

Chairman Broun. Thank you, Ms. Edwards. The Chairman now recognizes Dr. Benishek for five minutes.

Dr. Benishek. Thank you, Mr. Chairman. I find this all kind of scary because we have limited resources to deal with these risks, and when you hear conflicting testimony as to the accuracy and broadness of the investigation concerning a chemical risk, you want to spend your resources toward the chemical that has the most risk. And to not have that risk be politicized so you are wasting your resources on something that is not where you should be spending your resources.

Dr. Charnley, do you have these same concerns that I do about this process? I am concerned about the Scientific Advisory Board for the EPA being open and not being biased. I find in different areas of the EPA the Scientific Advisory Boards don't have the experts on the panel that they should have, that have enough knowledge of the thing that they are actually judging the scientific validity of the people there, and not the experts in the field. Do you have any information about that that you can relate to us here?

Dr. Charnley. Well, I think that is probably correct. I think that the difference with the Academy process is that a committee is convened of scientists to specifically address the substance or subject under consideration so that their expertise does directly inform whatever the subject matter is. And I do agree with you that putting resources towards substances that do not pose big public health impacts directs us away from issues and substances that do, and I don't think that is appropriate.

Dr. Benishek. I so much agree with you. Mr. Dooley, let me ask you a question. Do you think that the people in the formaldehyde business want trouble with formaldehyde?

Mr. Dooley. No, absolutely not. I mean--but this, again, comes to the essence of what this hearing is all about, how do we establish an IRIS assessment process that has the confidence of the NGO community or industry, that we are ensuring that it is using the best science and the best scientific process? When the NAS reviewed the IRIS review of formaldehyde, they found it was significantly flawed. That doesn't serve anyone's purpose.

Formaldehyde is a building block chemical. But, even this IRIS assessment, it has consequences. The EPA was proposing there was an assessment level for formaldehyde, in terms of where it could be a concern for cancer, that they set a reference dose level that was .008 parts per billion. That was the level that they said consumers should be concerned about a risk of exposure. The World Health Organization had also done an assessment and concluded that the average person's breath contains up to 8 parts per billion. So, you back up and you say, is this IRIS risk assessment providing information that is really informing public health concerns, when by their own action level--or reference is 1,000 times greater than the formaldehyde in the air that we exhale.

And that is where we think that we have got to step back and understand is how are we going to establish an IRIS process that is assessing--or considering hazard and exposure to some degree that actually can provide information that allows them there to make the responsible decision, that allows State regulators also to impose actions, and informs other Federal regulatory actions that emanate from this IRIS risk assessment. It needs to be done right. And what we are suggesting is until we have the confidence that it is right, we ought to allow NAS to review the IRIS assessment. And hopefully the reforms that Dr. Anastas spoke about this week will give us that positive outcome.

Dr. Benishek. Appreciate it. I yield back my time. Thank you.

Acting Chairman Bushon. I recognize the gentleman from North Carolina, Mr. Miller.

Mr. Miller. Thank you, Mr. Chairman. My questions are similar to Ms. Edwards. Dr. Charnley, you testified that you were not testifying on behalf of anyone. Your disclosure statement says simply that you are not testifying on behalf of anyone. I assume that means nobody is paying you for sitting here today. I haven't asked you a question yet. But our research that our staff did shows that you have, in the past, worked for the Tobacco Institute, Phillip-Morris, Covenant and Burling, a law firm that presumably--representing industry, Chlorine Chemical Council, which is part of the American Chemistry Council, American Chemistry Council, Crop Life America, which is a pesticide manufacturer, Food Industry Dioxin Working Group, coal companies, and then a long list of groups that are funded by those industry groups. You have written papers or testified about perchlorate, dioxin, mercury. You have produced papers and editorial correspondence to learned journals, challenging the idea that children should get any extra measure of protection in regulatory science.

You spoke of optics. Do you think the optics here would not have required that you tell the--this committee some of your--the work that you have done for industry?

Dr. Charnley. Well, I think I stated clearly that I am a toxicology consultant. In my written testimony I state that work for--I consult to private entities, and it is, you know, you found who I work for, so, I mean, I--it is not like--that I am not disclosing that. I would be happy to--I have a list here of a lot of the organizations that I have worked for, and I will----

Mr. Miller. Could you provide that to the----

Dr. Charnley. Absolutely.

Mr. Miller. --and could you also provide the issues that you have worked for on them?

Dr. Charnley. Sure.

Mr. Miller. Worked on them for them.

Dr. Charnley. I would be happy to.

Mr. Miller. Okay. That would----

Dr. Charnley. Most of the work I do is pro bono, by the way.

Mr. Miller. Pro bono?

Dr. Charnley. Yes.

Mr. Miller. Okay. Well, we--actually, our able committee staff also found an invoice that you had done a couple years ago that showed your billing rate was $325 an hour. So you do--also do some work for pay?

Dr. Charnley. I do. I do----

Mr. Miller. Okay.

Dr. Charnley. --both.

Mr. Miller. Okay. You spoke earlier of recusing yourself from a peer review panel when formaldehyde came up, which is admirable. I applaud that. If you have got an apparent conflict, then you should recuse yourself. But was that before or after you wrote a letter to--what is the name of the--the Health--Environmental Health Perspectives, that did not disclose that your--the research that you referred to in the letter was funded by the chlorine industry?

Dr. Charnley. I have never failed to disclose the source of my funding in anything I have published.

Mr. Miller. Okay. Did you write a letter to the Environmental Health Perspectives?

Dr. Charnley. Yes.

Mr. Miller. Did it have to do with chlorine?

Dr. Charnley. I don't remember which one you are referring to, I am sorry----

Mr. Miller. Okay. Do you----

Dr. Charnley. --at the moment.

Mr. Miller. You don't----

Dr. Charnley. But I----

Mr. Miller. You don't recall a controversy in which--Environmental Health Perspectives I assume is a learned journal? A peer reviewed learned journal?

Dr. Charnley. It is a peer reviewed journal, yes.

Mr. Miller. Okay. You don't recall that they changed their disclosure requirements as a result of a controversy about a letter that you wrote?

Dr. Charnley. No. I recall that I said to the editor that I did not believe that I had a conflict because I no longer worked for the organization that had funded this similar work earlier. And according to the National Academy of Science's definition of conflict, which would apply to current employment, I did not have a conflict. However, I voluntarily disclosed that I had worked for such an entity in the past.

Mr. Miller. Okay. It sounds like this whole issue is coming back to you now.

Dr. Charnley. No--well, go ahead.

Mr. Miller. Sorry. No, that is all right, I--Mr. Chairman, I have no further questions, but this remains a frustration in witnesses before this committee, who simply fill out this--and I had a discussion in the committee when our rules were adopted that substantially limited the disclosure statement--disclosure requirements, in which I was assured that if a witness had substantial economic interests, those would be disclosed. And we have seen repeatedly witnesses appear before this committee and appear and testify simply as public-spirited, disinterested citizens, and it appears their entire livelihood has come from the industry whose interests are at stake in the committee hearing. I would certainly hope that we could do better in the future.

Acting Chairman Bushon. Thank you. I will take that up with the full committee Chairman. Thanks for your comments. I will now recognize myself for some questions, and assure the panel that I won't spend my entire time trying to defame all of your

character.

First I want to make a few brief comments about the--what I am hearing today. As a new member of Congress, I think the American people, if they were hearing this hearing today about EPA, and about the assessment they are making on chemicals, the American people would feel they are not getting a good bang for their buck. Just remind everyone that the budget of the EPA in 2008 was $7.6 billion. The budget was 10.3 billion in 2010. And, believe it or not, the EPA received $7.2 billion in stimulus money, and yet we are at a hearing today discussing the fact that we have the inability to properly assess chemicals at the EPA, and that is not my opinion. Let me read from--the GAO testified before the Subcommittee that--in 2009 that EPA has not been able to complete timely credible chemical assessments or decrease its backlog of 70, as of 2008, ongoing assessments, even though they received 7--well, I think 7--around 7.2 billion in stimulus money.

And it says further, because the EPA staff time was dedicated to completing assessments in the backlog, EPA's ability to both keep the more than 540 existing assessments up to date and initiate new assessments was limited. So I think, from my perspective, this calls into question a lot of the rules that the EPA is currently putting out across the economic spectrum that is hurting our economy. And it is becoming pretty clear to me we don't have solid scientific evidence to back that up. So what I want to do is direct my questions, first to Congressman Dooley, about a couple of areas. Do you see that the assessment ability of IRIS, as being adequate? And I think you have stated before that you don't think it is. And based on that, do you see that there are longstanding economic impacts of their decision-making process, based on this information, that is hurting our job creation in our country?

Mr. Dooley. First off is that the American Chemistry Council is very supportive of the suggestions that the NAS made to EPA for reforms. You know, we are encouraged that the EPA has indicated that they are going to try to enact some of those reforms. It is not mutually exclusive to have an IRIS risk assessment that is being operated in a manner that is consistent with what NAS has recommended and be a more efficient, and result in quicker IRIS assessments being done. And there shouldn't be any disagreement among any of us on that issue.

When I was in Congress, I represented a district in the central valley of California. It was the fifth lowest per capita GDP district in the nation, out of 435. And the actions that IRIS could take to establish reference doses that are below those that pose any public health safety impact at expected levels of exposure, whether it is formaldehyde or dioxin, or whether it is arsenic, and that goes below what are background levels existing naturally, is that that has not only public health impacts, but it has public welfare impacts.

If you require a lot of the low income communities in my district to comply with what is now a new arsenic standard that goes below what is naturally occurring, is that they have to allocate resources to water treatment systems that then aren't available for public health or education or, other public benefits, just as I said with dioxin. It also has an impact on private sector investments. If we have to divert revenues to achieve a higher level of remediation, or change processes that go to achieve an IRIS assessment that is below background levels, you are taking capital that could otherwise be invested in a new manufacturing capacity, creating jobs, that is going for a use that has very little benefit, and very little public health benefit.

Acting Chairman Bushon. I think the answer is yes, it is

having a significant impact, and at this time I will yield the rest of my time. And recognize the gentleman from Michigan, Mr. Clarke.

Mr. Clarke. Thank you, Mr. Chair. In addition to IRIS, which is located in the EPA, there are other programs that conduct assessments of chemical risks that are located in other agencies and departments. And this question's to anyone here. To what degree have these assessments provided conflicting guidance or conclusions, and to what degree have these different programs provided--really been duplicating work? And if you found any conflicts or duplication, what proposals do you have to better coordinate and reduce the likelihood of conflicts and reduce the cause of duplication?

Ms. Steinzor. If I could respond to that? IRIS is the premiere international source of reference dose information, which is the level below which exposure is acceptable and above which exposure is not acceptable. So it really measures whether--if we fed you dioxin on a spoon, what the level would be that would cause problems. As has been said repeatedly here, it is not a risk assessment process. It doesn't make a determination. IRIS itself is a scientific database that doesn't make a determination about what to do about the risk. It simply talks about what the reference dose is. It receives 2,000 visits a day on the Internet from all over the world. That is a pretty high number for a database that is this technical. And, if anything, it needs to be bigger, better and stronger, not abolished, not paralyzed, because without it people would really not know what a toxicological profile--what the reference dose was for chemicals. So it really is unique, and it provides a tremendous service, I would say.

Mr. Dooley. Maybe, as Ms. Steinzor mentioned, the IRIS reference dose is a standard which is not acceptable. And so I go back, and I will use the formaldehyde example, where you had the World Health Organization said the breath that you exhale has eight parts per billion. IRIS said a reference dose of .0008 parts per billion. You can also use the example of arsenic, where you have a little bit of a difference in standards internally, where you had an IRIS a risk assessment level of 1.4 parts per billion. But then you also have, in the safe drinking water standard, 10 parts per billion for drinking water. So there is some inconsistencies among various organizations there.

So I think that is where we made a suggestion from ACC that there ought to be a role for OMB to play in this whole re-evaluation of the risk assessment. And what we are driving at here is because you have got multiple agencies--you have got FDA that is involved with some chemicals, whether it is food contact notification or assisting it, you have the Agency For Toxic Substance And Disease Registry, you have the National Toxicology Program, that does the report on carcinogens, you have EPA and IRIS--is that there needs to be a quarterback. That someone should not make determinations and evaluate necessarily the risk assessment, but that there is a common scientific process being utilized that is ensuring that we are incorporating the best laboratory practices, and that we are using the best weight of evidence practices, to reach conclusions. And that ought to be consistent across all these multiple agencies. And that is where we suggest that there is an appropriate role for OMB to play, to ensure that you have that consistency so that you don't have disparity and conclusions in action levels across various organizations that are maybe addressing the same chemical.

Ms. Steinzor. Can I just add one point? My son, who is 20, is sitting behind me, and one of the most distressing things I have heard today is that he had formaldehyde in his body and

exhales it at levels that are much higher than the reference dose set by the EPA database. That didn't happen because he is walking through a natural paradise on the Chesapeake Bay, although I wish that were true. It is because the air is polluted. We live in a non-attainment area that is awash in toxics and all sorts of other problems, and that is why that has happened. I also want to just say for the record there are two scientists, two, who work at OIRA. So making them the quarterback of anything would be a strange football game indeed.

Acting Chairman Bushon. The gentleman's time has----

Mr. Clarke. If I can just respond to the formaldehyde?

Acting Chairman Bushon. The gentleman's time has expired. We will get--we will try to get back to you.

Mr. Clarke. Thanks.

Acting Chairman Bushon. I would like to recognize the gentleman from Maryland, Mr. Sarbanes.

Mr. Sarbanes. Thank you, Mr. Chairman. Thank the panel. Congressman Dooley, I wanted to--you said a lot of nice things about the National Academy of Sciences, and I guess that is the basis for your proposal that they come in and review the risk assessments that IRIS is performing for some period of time. And you have also responded positively to changes that the EPA has said they are going to make in response to the National Academy of Science recommendations and so forth. On that basis, I assume you have pretty good feelings about this silver book, because that is a product of the National Academy of Science on the very topic that we are discussing here today, so I wanted to get your reactions to whether this is a constructive resource.

Mr. Dooley. We think it is a very constructive resource. It is not that we agree with every element in it, but we think that it really does set a road map that has a lot that we can all learn from and incorporate into our government processes of assessing safety of chemicals.

Mr. Sarbanes. I haven't read it from front to back. Actually, I have just read the back, as you may have seen. But from what I understand, I am assuming it is proposing recommendations that would allow the EPA and IRIS to operate in a way that would not require a kind of constant follow up assessment by NAS with respect to each specific chemical or toxic substance that was being assessed. And I am nervous about your recommendation on that, because I am worried that you are proposing adding more steps into a process, with the potential to kind of just drag the whole thing down and further contribute to the delay that is so frustrating for so many people, particularly when it comes to the issue of the worst of the worst.

I mean, I keep hearing this phrase, I heard it in the other committee I served on in the last term, when we were looking at the Toxic Substances Control Act. I think, actually, you testified--some of those hearings. The worst, the worst. We can't seem to get even the worst of the worst--the place where we don't have to fear those substances anymore. And a lot of it has to do with this kind of, well, we need another study. We need to get the OMB in here as a quarterback, you know, OIRA and so forth and so on. We need to get moving on this stuff. And I think what this is attempting to do is propose how you can get the process and the framework that EPA uses to a place where it is working pretty well, and I am worried about that sort of getting off track.

And then, Dr. Charnley, in the time I had, you had talked about your own view, that the changes proposed this week are promising ones, and I think has--have also said that you regard the National Academy of Science recommendations as helpful and

constructive. I don't see how that jives with your suggestion that we should ``start over'' with the process that we currently have. I think that would be a mistake. Maybe you can clarify how you reconcile those two perspectives.

Dr. Charnley. Sure. I did not mean stop IRIS. I did not mean disband IRIS. I meant that past efforts to modify the process have not produced meaningful improvements, apparently, because the Academy keeps coming back and making the same recommendations they have made for years. And for that reason I think that, in order to implement the changes recommended in Chapter 7 of the formaldehyde report, that implementation would itself benefit from guidance from the National Academy of Sciences, from a group of unbiased experts who can--who have been thinking about this problem for a long time and can provide helpful guidance.

Mr. Sarbanes. Well, I think--thank you. I think that guidance is there. I think it is constructive, and I think the EPA is ready to move forward and keep this process of improving on a, you know, on a positive track. Let us not get off that track. Let us keep this process moving. With that, I yield back, Mr. Chairman.

Acting Chairman Bushon. Thank you. At this point I would like to ask unanimous consent to add a number of documents to the record that have already been shared with the minority, and I understand they wish to add the records as well. Hearing no objection, so ordered.

[The information appears in Appendix II:]

Acting Chairman Bushon. I would like to thank the witnesses for their valuable testimony and the Members for their questions. The Members of the Subcommittee may have additional questions for the witnesses, and we will ask you to respond to those in writing. The record will remain open for two weeks for additional comments from Members. The witnesses are excused, and the hearing is now adjourned.

[Whereupon, at 12:24 p.m., the Subcommittee was adjourned.]

Appendix I:

Answers to Post-Hearing Questions

Answers to Post-Hearing Questions

Responses by The Honorable Paul Anastas, Assistant Administrator, Office of Research and Development, U.S. Environmental Protection Agency

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Responses by Mr. David Trimble, Director, Natural Resources and Environment, U.S. Government Accountability Office

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Responses by Dr. Jonathan M. Samet, MD, MS, Professor and Flora L. Thornton Chair, Department of Preventive Medicine, Keck School of Medicine, University of Southern California; and Chair, Committee to Review EPA's Draft IRIS

Assessment of Formaldehyde, National Research Council, The National Academies

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Responses by The Honorable Calvin Dooley, President and Chief Executive Officer,
American Chemistry Council

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Responses by Dr. Gail Charnley, Principal, HealthRisk Strategies

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Responses by The Honorable J. Christian Bollwage,
Mayor, City of Elizabeth, New Jersey

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]

Appendix II

Additional Materials Submitted for the Record

Material Submitted by Representative Larry Bucshon

[GRAPHIC(S) NOT AVAILABLE IN TIFF FORMAT]