

TESTIMONY OF  
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ON BEHALF OF:  
NATURAL RESOURCES DEFENSE COUNCIL

BEFORE THE U.S. HOUSE  
COMMITTEE ON ENERGY AND COMMERCE  
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS<sup>1</sup>

AT HEARING ENTITLED:  
*SCIENCE UNDER SIEGE: SCIENTIFIC INTEGRITY AT THE  
ENVIRONMENTAL PROTECTION AGENCY*

September 18, 2008

## One-Page Summary

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Testimony of Jennifer Sass, Natural Resources Defense Council, before the US House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, at hearings entitled: *Science under Siege: Scientific Integrity at the U.S. EPA*

Throughout the eight years of the Bush Administration, NRDC has documented the science under siege at the EPA, to expose the chemical industry's campaign to destroy EPA's technical infrastructure and policy framework.

Not content to simply undermine health standards for a host of toxic chemicals one-by-one, Administration officials have also attacked the foundational process for assessing the risks of toxic chemicals, the EPA Integrated Risk Information System (IRIS) program that assesses hazardous substances. The new 2008 IRIS process introduces three new opportunities for the White House Office of Management and Budget (OMB) and other non-health agencies to weigh in on EPA's health assessments, where previously there was only one. Importantly, interagency comments and OMB comments for all three of the new intervention points are shielded from public view. Thus, whereas the pre-2004 IRIS process provided the agencies and OMB with the draft assessment at the same time as it was provided to the public, the new process invites polluting agencies such as the Department of Defense (DOD) and the Department of Energy (DOE) into the assessment process at an earlier stage, and forces the IRIS staff to address the queries of the agencies and OMB, whether or not they are consistent with health-protective policies; these exchanges are not publicly accessible. Following this negotiation, the draft review is publicly noticed. But then there is a final intervention point provided to OMB and the other agencies that require that the IRIS staff to resolve any outstanding concerns by OMB and the other agencies, including polluting agencies, before the assessment can be finalized. While the 2008 process boils down to 'death by a thousand cuts,' this ability to have the last word – and to potentially to axe an assessment at the bitter end -- may be the deepest cut of all. Although current EPA management argues that the new process was developed in order to provide 'greater transparency, objectivity, balance, rigor and predictability' to the IRIS assessments, this new process gives the polluting agencies more access and more influence to what has historically been a reasonably objective scientific evaluation process.

Another example of politics trumping science is the recent dismissal by EPA of one of their most respected and credible scientific reviewers, Dr. Rice, in direct response to a written request from the Brominated Flame Retardant Industry Panel (BFRIP) of the American Chemistry Council.

Good morning and thank you for this opportunity to testify on science under siege at the Environmental Protection Agency. I am Jennifer Sass, PhD., a Senior Scientist at the Natural Resources Defense Council (NRDC). I work in the Health and Environment Program, which reviews the federal regulation of industrial chemicals and pesticides. Over my eight years with NRDC, I have published over two dozen articles in scientific journals, provided written and oral testimony to Congress, to the Environmental Protection Agency and to the National Academies, as well as served on Federal scientific and stakeholder committees. I completed post-doctoral studies in toxicology at the University of Maryland, doctoral studies in developmental biology, and a master's thesis in neurobiology at the University of Saskatchewan.

The Natural Resources Defense Council (NRDC) is a national, nonprofit organization of scientists, lawyers and environmental specialists dedicated to protecting public health and the environment. Founded in 1970, NRDC has 1.2 million members and online activists, served from offices in New York, Washington, Chicago, Los Angeles, San Francisco and Beijing.

NRDC's Health program focuses on toxic chemical pollutants in air, water, food, and shelter. Over the years, we have focused our particular attention on the "biggest pollutants" in these media, the ones disproportionately responsible for the biggest threats to human health. This has led to successful efforts to substantially reduce diesel air emissions from trucks and buses, for example, and to take a number of dangerous and outdated pesticides off the market. There are more than 70,000 chemicals in commerce,

but some are much more toxic than others, and we can make great progress in environmental health protection if we focus on the chemicals pollutants that pose the greatest threat to human and ecological health.

Throughout the eight years of the Bush Administration, NRDC has documented the science under siege at the EPA, to expose the chemical industry's campaign to destroy EPA's technical infrastructure and policy framework.<sup>2</sup> Evidence of industry's efforts include attempts to weaken EPA assessments of vinyl chloride carcinogenicity,<sup>3</sup> the effects of low levels of the rocket fuel perchlorate,<sup>4 5</sup> and environmental impacts of the pesticide atrazine<sup>6</sup>, as well as actions taken by the Office of Management Budget (OMB) on formaldehyde, which ultimately led to an EPA assessment that was several thousand times weaker than EPA staff recommended.<sup>7</sup>

We are very pleased to testify today on scientific integrity issues at the Environmental Protection Agency (EPA), particularly as these issues relate to the scientific assessment of health risks posed by exposure to hazardous chemicals. Efforts of the chemical manufacturing industry to bias the scientific reporting on the hazards of their products have long been documented.<sup>8 9 10</sup> Over the past eight years, the industry has broadened its attack on EPA science with the assistance of EPA's political appointees:

- blocking, delaying or weakening individual health standards,

- undermining the fundamental program that establishes the level of risk posed by toxic chemicals, and
- attacking the objectivity and credibility of independent and government scientists, while shamelessly promoting the supposed objectivity of industry scientists and consultants, many with direct financial conflicts in the matters they are reviewing.

These efforts to interfere with good science at EPA are the focus of our testimony to the Committee today.

#### OMB-IMPOSED ALTERATIONS TO IRIS PROCESS OF HAZARDOUS CHEMICAL EVALUATIONS UNDERMINE A PROGRAM CRITICAL FOR PROTECTING PUBLIC HEALTH

Not content to simply undermine health standards for a host of toxic chemicals one-by-one, Administration officials have also attacked the foundational process for assessing the risks of toxic chemicals, the IRIS program. The recent changes to the IRIS process that are the subject of today's hearing should properly be viewed as one part of a much broader agenda to sacrifice public health protections and limit public understanding of the risk of toxic chemicals, in a manner that benefits a host of polluting industries and federal agencies. Indeed, by attempting to weaken the IRIS process, the Administration has zeroed in on one of the earliest and most fundamental steps in the process of protecting public health, that in which EPA's scientists identify the health risks posed by exposure to certain chemicals. The committee's hearings should preface Congressional action to reverse the recent changes to the IRIS process and ensure the integrity and effectiveness of the program is restored.

### *The importance of the IRIS database*

The IRIS database is a publicly available database which contains EPA's evaluation of potential human health effects from exposure to more than 540 chemicals, including highly hazardous chemicals such as PBDE's (polybrominated diphenyl ethers, a class of flame retardants), vinyl chloride, butadiene, benzene, lead, mercury, and asbestos.<sup>11</sup> While these evaluations are not regulations *per se*, they are used by both state and federal regulators and by the international community for a range of environmental health regulation and management purposes. For example, the information can be used in combination with exposure data to set cleanup levels at hazardous waste sites, or to set exposure standards for air, water, soil, and food. Thus, the accuracy, credibility, and timeliness of IRIS assessments have real world consequences for human health.

The global importance of this database cannot be overstated. For example, last month (August, 2008), the IRIS website received over 27,000 visits (an average of over 885 per day), from over 3,000 distinct computer sources over 60 countries around the world.<sup>12</sup>

### *IRIS conducts scientific assessments, not policy documents*

Risk assessments involve the integration of hazard identification, dose-response assessment, and exposure assessment to estimate the probability (likelihood) of harm.

Rather than conducting entire risk assessments, the IRIS program is limited to conducting hazard identification and assessing dose-response relationships for environmental chemicals; EPA factors in exposure scenarios and risks under its regulatory programs.

Hazard identification, the first step in a risk analysis, determines whether or not the substance of concern is likely to have adverse health effects. This step requires a thorough review of relevant toxicologic data and may include human epidemiology, whole animal studies, non-animal data, and field data. The result is a scientific determination of whether or not a substance causes adverse health outcomes such as cancer, neurological disease, birth defects, or death. Since reliable human data is often not available, hazard evaluations generally rely heavily on identifying whether the substance is toxic in animals or other test systems.

The dose-response assessment follows hazard identification and is designed to identify safe levels of exposure for chemicals that pose harm. This assessment consists of scientifically characterizing the relationship between the amount of exposure (dose) and the incidence of an adverse health endpoint. Methodologies for dose-response assessment often differ between cancer and non-cancer effects and between acute and chronic exposure scenarios. They are often scientifically controversial, because they must extrapolate from high experimental doses to more typical ambient exposure levels.

Ideally, epidemiological data would be available that clearly illuminate the hazards and the dose-response relationships for chemicals of concern in human

populations. Unfortunately, this is nearly never the case. Most chemicals lack key studies of effects in humans as well as studies of effects in animals at ambient levels. As a result, IRIS assessors are called upon to make informed judgments regarding the relevance of the animal data to humans, and to select the most appropriate extrapolation method. Further, the IRIS assessments require independent expert judgment to decide whether various safety factors should be applied to assessment data to ensure public health protection. For example, EPA often decides to include margins of safety to protect vulnerable populations, relevant genetic variations, vulnerable life stages, disease states, concomitant exposure to complex mixtures, and other relevant factors that may influence the probability of an effect caused by exposure to the substance of concern.

Importantly, decisions made in the IRIS program are informed by various EPA guidance documents that are publicly-available and publicly-documented, and have been publicly-vetted. Reliance on these important guidance documents is crucial to ensure that evaluations are consistent across substances and as objective as possible.

The new process established by the White House turns this process on its head: it invites the injection of non-scientific considerations into the IRIS assessments, and further, it shields from public scrutiny the input from other parts of the government with a potential financial or political interest in the outcome of a particular assessment. When political appointees, perhaps acting on behalf of regulated industries, and polluting agencies are able to interfere in a non-transparent and inappropriate manner, the whole process is severely compromised.

### *Summary of the new process*

The new 2008 IRIS process introduces three new opportunities for OMB and other non-health agencies to weigh in on EPA's health assessments, where previously there was only one. Importantly, interagency comments and OMB comments for all three of the new intervention points are shielded from public view: the first two bites at the apple, and the last one. Thus, whereas the pre-2004 IRIS process provided the agencies and OMB with the draft assessment at the same time as it was provided to the public, the new process injects polluting agencies such as DOD and DOE into the assessment process at an earlier stage, and forces the IRIS staff to address the interests of the agencies and OMB, whether they are consistent with health-protective policies or not. These exchanges take place out of the public eye. Following this negotiation, the draft review is publicly noticed. But then there is a final intervention point provided to OMB and the other agencies that require that the IRIS staff to resolve any outstanding concerns by OMB and the other agencies, including polluting agencies, before the assessment can be finalized. While the 2008 process boils down to 'death by a thousand cuts,' this ability to have the last word – and to axe an assessment at the bitter end -- may be the deepest cut of all.

The U.S. Government Accountability Office (GAO) recently released its review of the new process, in a report entitled: *Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information*

*System.*<sup>13</sup> This report provided a detailed and highly critical assessment of the failures of the IRIS program to meet its deadlines and requirements, blaming in large part the interference by polluting agencies and political appointees. The GAO report predicts that the new process will produce IRIS assessments that lack credibility, and will worsen what is already a critical backlog of new and updated assessments. NRDC agrees with the GAO evaluation, whose many findings validate our years of work to right this cornerstone program for public health protection.

For many years, IRIS assessments were developed by EPA scientists. Drafts were released simultaneously for public comment and external (independent expert) peer review. OMB and government agencies such as DOD or DOE, who sometimes had a stake in the outcome of the evaluation because of their obligations to address contamination at federal facilities, had an opportunity to review and comment on the draft when it was released for public review and comment.

Table 1: A comparison of the new and previous (pre-2004) process to conduct and review chemical assessments for the IRIS program

NEW PROCESS	COMPARISON WITH PREVIOUS PROCESS
Scientific literature review (60-90 days)	No significant change
Data call-in (45-60 days)	New
IRIS staff develops a Draft Qualitative Assessment (without any quantitation)	New. In the past, qualitative and quantitative assessments had been presented together; the new process adds an extra assessment to the review cycle
Draft Qualitative Assessment must pass ORD clearance	New

Draft Qualitative Assessment must undergo Inter-Agency review and comments. Comments are deliberative.	New. Note that neither the draft nor the agency comments are publicly accessible and that Inter-Agency review is not restricted to health agencies.
Public release of Draft Qualitative Assessment for public and interagency review and comment (45-60 days)	New
Federal Agencies identify mission critical chemicals	New
Interagency evaluation to close data gaps for mission critical chemical: Agencies can submit a research plan for 'closing data gaps' for mission critical chemicals (90 days)	New
Proposed research and peer review conducted for mission critical chemical; development of new studies (up to 540 days)	New
IRIS staff completes Draft IRIS Toxicological Review (both qualitative and quantitative chapters), addressing public and interagency comments (120-270 days)	No significant change
Interagency review (45-105 days) For mission critical chemicals, EPA cooperates with other agencies to determine peer review process (eg, NAS, SAB); OMB/Interagency review of peer review charge	New
External (independent expert) peer review and public comment (120-280 days)	No significant change
IRIS staff address peer review and public comments, revises IRIS Tox Review and develops IRIS Summary (120-150 days)	No significant change
IRIS staff initiates final OMB/ interagency review and approval of IRIS Tox Review and IRIS Summary (30-45 days)	New to include OMB and interagency approval at this point.
IRIS staff addresses and resolves OMB/interagency remaining issues in consultation with OMB and other agencies. EPA makes final decision.	New to include OMB consultation and approval at this point. Used to be Agency review and clearance only.
EPA completes IRIS Tox Review and IRIS Summary (60 days)	No significant change

The new IRIS process introduces significant new steps that are both time-consuming and undermine the objectivity and transparency necessary for credible and valid assessments (see Table 1). Significant aspects of the new process are as follows:

1. In the 2008 process, IRIS staff is now required to develop a qualitative draft assessment, prior to the quantitative assessment, which must undergo both public and interagency review. This qualitative draft serves as a summary of the scientific literature that the staff intends to rely on to support its assessment. Although this procedure sounds benign, it seriously compromises the timeliness and transparency of the IRIS program. First, it allows other government agencies to delay an assessment for nearly two years to do additional research on any chemicals that an agency deems to be "mission critical," thereby significantly stalling the start of the formal IRIS evaluation. Even more alarming, the comments and submissions of the other agencies to the qualitative draft are considered 'deliberative' which, if unchallenged or upheld by the courts, would shield the comments from public scrutiny.
2. In the new 2008 process, agencies outside of EPA are invited to designate chemicals as 'mission critical' and to intervene in the IRIS assessment of these chemicals. Mission critical chemicals are defined as those that are, "an integral component to the successful and safe conduct of an Agency's mission in any or all phases of its operations. Impacts on use of mission critical chemicals include cessation or degradation of the conduct of the mission and/or unacceptable resource constraints." [emphasis added] In other words, "mission critical" chemicals includes not only those that are vital and have no viable substitute, but also those where the potential cost to an agency of cleaning up a pollution mess it (or its contractors) have created is "unacceptable" or where potential future

limitations on use (such as stricter exposure standards) are deemed too expensive by the agency. These are exactly the kinds of policy considerations that should *not* be allowed to intrude on the IRIS assessment process.

3. Following the quantitative draft, the IRIS staff develops the draft quantitative assessment (the Toxicological Review). This is subjected to public and interagency review, followed by external (independent expert) peer review. The important difference is that prior to 2004, this represented the first and simultaneous opportunity for both the public and the other agencies to comment, with all comments publicly accessible. By contrast, with the 2008 process this is now the second public comment opportunity, and the third OMB/interagency intervention point, but the first where the OMB/interagency comments would be publicly accessible.
  
4. Finally, before the IRIS assessment can be finalized and publicly released, the 2008 process requires OMB and interagency approval. The pre-2004 process had only required internal agency review. This 2008 process invites the fourth and final opportunity for OMB/interagency interference with the evaluation. Although the new process says that EPA has the power to make the final decision, it is clear that the other agencies and OMB will have significant access and influence over the final editing choices.

Although current EPA leadership argues that the new process was developed in order to provide “greater transparency, objectivity, balance, rigor and predictability”<sup>14</sup> to the IRIS assessments, we strongly disagree. In fact, the administration’s claims are Orwellian. This new process is designed precisely to give the polluting agencies more access and more influence to what has historically been an objective scientific evaluation process -- and to add at least two or more years to the review of mission critical chemicals.

To put it plainly, in this new proposal the Administration is attempting to provide those agencies with the most at stake in the degree of protection established for a particular chemical multiple opportunities to weigh-in and influence the outcome of EPA’s decisions, while hiding the exercise of that influence from the public. The Administration’s claim that, for example, providing the Department of Defense multiple opportunities to weaken or delay setting a health standard for trichloroethylene (TCE) -- a chemical for which DOD is responsible of widespread contamination of drinking water -- completely outside of public view, will result in a more balanced and objective result, doesn’t pass the laugh test.

The EPA leadership further claims that the outcome of the new process is expected to ‘streamline’ the IRIS process and make it more ‘transparent’. Again, we strongly disagree. The new process allows public review at only one stage, which is review of the qualitative draft. All other evaluation steps occur behind closed doors,

shielded from accountability to the public or other more objective, outside scientific experts.

It is indicative of the Administration's disregard for public input on its changes to the IRIS process, and its eagerness to put them in place, that OMB admonished GAO for being so critical of a draft proposal, and assured the GAO that "[i]ndeed, the process will not be complete until EPA circulates its draft to the public for comments and then releases a final product that is responsive to those comments." Assurances notwithstanding, some six weeks later the Administration finalized this deeply flawed proposal without any opportunity for public review or comment. This short-circuiting of the public comment process does not square with the principles of public right-to-know, or EPA's lip service in support of an open and transparent process.

*Backlog at IRIS: Timeliness is already a terrible problem that cannot bear to be compounded by further delay*

In the U.S., there are about 8,000 chemicals in commerce deemed "economically significant" (i.e., produced or imported at a rate greater than 10,000 pounds per site annually). Unfortunately, only about 550 chemicals in total have been evaluated in the IRIS program. Even when compared just to the universe of chemicals regulated by EPA, IRIS is obviously failing to adequately serve the public's needs. For instance, the EPA is responsible for regulating the emissions of 188 hazardous air pollutants (HAPs) under the Clean Air Act, but only 129 of them appear in the IRIS database. In other words, in

almost 20 years since IRIS was created, the EPA has been unable to complete Toxicological Reviews for nearly one-third of these dangerous pollutants.

Furthermore, even when important chemicals are in the IRIS database, the risk assessments available for many of these chemicals are outdated: the average assessment on IRIS is over 13 years old, with the oldest having not been significantly revised since the mid-1980s. Considerable new evidence of toxicity has emerged for many of these chemicals since their last assessment, which renders the conclusions potentially obsolete and limits their usefulness and credibility with regulatory agencies.

According to the IRIS website, the program has finalized only thirteen assessments since 2004. As GAO notes “[t]he IRIS database is at serious risk of becoming obsolete because EPA has not been able to routinely complete timely, credible assessments or decrease its backlog of 70 ongoing assessments.”<sup>15</sup>

Consider for example *Trichloroethylene* (TCE), a solvent used as a degreasing agent. TCE is one of the most common contaminants of Superfund sites across the nation, primarily from military uses, and is linked to cancer, including childhood cancer, and birth defects.<sup>16</sup> The IRIS draft was initiated a decade ago, in 1998. In 2001, EPA concluded that TCE was “highly likely” to cause cancer and specifically noted the added health risks when exposures took place during childhood. Finalization of that assessment has been held up after repeated objections from military contractors and the Department of Defense. Finally it was reviewed by the National Academies, which issued their report

in July 2006, finding that the data linking TCE with cancer was even stronger than EPA IRIS staff had determined, and recommending that the IRIS assessment be finalized as soon as possible. Nonetheless, the Defense Department continued to insist that it not be finalized until more data was available, and today the assessment has still not been finalized and no target date for its completion has been set.<sup>17</sup>

Clearly, constructive reform for the IRIS program would focus on increasing resources available to undertake IRIS reviews as well as policy changes that would streamline the difficult decision-making inherent in the process. The new procedures run completely counter to these goals and will only exacerbate this backlog.

*Delays to IRIS assessments result in continued unsafe exposures to humans and wildlife*

Setting a health assessment standard under IRIS is only the first step in a long regulatory process. For example, for the EPA to establish a national drinking water standard, the Agency would typically reach out to stakeholders for input and perhaps even convene a Federal Advisory Committee, which could take over a year. Additionally, the docket for a proposed rule could remain open for at least a few months to collect comments from the public. Depending on the extent of the comments received, the Agency could again take up to a year or more to address and respond to those comments. In the end, it could take the Agency years, even decades, to finalize a drinking water regulation.

As new or updated IRIS assessments continue to languish, or get weakened to satisfy the demands of OMB and federal agencies including the Department of Defense and Department of Energy, the process of setting health standards becomes unspeakably prolonged. And the public continues to suffer due to lack of adequate public health protections.

For example, the administration has successfully blocked a much needed update of the IRIS assessment for formaldehyde. An updated assessment reflecting recent science that shows greater health hazards posed by formaldehyde could ultimately be the basis of establishing stricter emissions or exposure limits from building materials and other sources. Meanwhile, people living in temporary trailers provided by FEMA after hurricane Katrina have complained of a host of illnesses they believe are related to the high levels of formaldehyde which they have been exposed to in those trailers. At this time, the IRIS program estimates that it will finalize its assessment by the end of 2009.<sup>18</sup>

Similarly, delays with IRIS assessments has contributed to an inexcusable failure to develop a national health-protective standard for perchlorate, a component of rocket fuel and other explosives, in drinking water. Scientific evidence is overwhelming that exposure to perchlorate, an iodine uptake inhibitor in the thyroid gland, can cause significant development problems for developing infants. Subtle alterations of thyroid hormones during pregnancy – even within the normal range – have been associated with decreased intellectual and learning capacity in childhood.

Approximately 350 public water systems serving over 41 million have reported perchlorate detections.<sup>19</sup> The source of the contamination at many of these sites is defense and aerospace facilities and military installations.<sup>20</sup> The Defense Department mounted a years-long battle, and elicited White House support, against IRIS draft assessments in 1998 and in 2002 (both assessments were subject to public comment and external peer review) that had determined that even low doses of perchlorate may be harmful to early development of the human brain.<sup>21</sup> The final IRIS assessment was not completed until 2005.<sup>22</sup> Due to the year's-long delay in assessing and quantifying the harm posed by perchlorate in the IRIS program, the public remains years away from a national drinking water standard that will protect their health.

*Objectivity and transparency of IRIS review is paramount*

IRIS assessments must be shielded from political interference and be open to public scrutiny to ensure their scientific rigor and adherence to public health protective policies.

Under the new IRIS process, polluting federal agencies are provided excessive and redundant opportunities to intervene in the development of the IRIS assessments, shielded from scrutiny by the scientific community and the public. This is indefensible. The IRIS assessments and the comments provided by federal agencies, academics, industry, public interest groups, the general public, and others regarding drafts are supposed to be about science. The Administration has no reason for insisting upon

secrecy other than to shield injection of politics and policy into the scientific debate, and avoid public airing of scientific arguments that won't stand up to public scrutiny.

*Political appointees in the EPA undermine EPA's mandate to protect human health and the environment*

The director of the IRIS program, George Gray, is clearly subverting the mission of the EPA in the development of the new IRIS process, essentially carrying out the mission of the OMB instead. Gray, who is EPA Assistant Administrator for the Office of Research and Development was previously the Director of the Harvard Center for Risk Analysis, a seemingly prestigious academic center but one quite notorious for its extensive support from corporate money and its tendency to promote industry perspectives in environmental health policy deliberations. With Gray holding direct management power over the IRIS program the Administration has ensured that EPA resistance to the agenda of undermining public health protections will be minimal, and, more often, will be aided by its political appointee.

A documented example of Gray's role in blocking the work of his own IRIS staff is the case of the Toxicological Review of tetrachloroethylene also known as perchloroethylene (perc), a dry cleaning and degreasing chemical and widespread groundwater contaminant. The IRIS assessment was initiated in 1998. In 2006 *Risk Policy Report* revealed that George Gray was insisting that his staff reanalyze the cancer risks of the chemical to try to fit the data to a model that would have assumed (without

scientific evidence) that low doses were safe, whereas the staff's careful review of all available data did not support this assumption.<sup>23</sup> In addition, Gray's directive contradicts EPA's established, peer-reviewed cancer guidelines. Had the IRIS staff complied with Gray's directive, it would have resulted in a less-protective assessment. This assessment has still not been updated.<sup>24</sup>

In short, the political appointee currently in charge of the IRIS program, and defending the Administration's new reforms to Congress and the public, has blocked an updated assessment of a chemical polluting groundwater across the nation, and is insisting EPA scientists use unsupported and inadequately protective assumptions in a model intended to downplay the potential harm posed to the public by the chemical.

According to NRDC discussions with IRIS staff, additional instances of interference by George Gray to delay or weaken assessments include:

- blocking IRIS from posting acute (less than 24 hour) risk values.<sup>25</sup> Acute risk values are relevant to communities that are exposed to chemicals by burst releases of toxics (smokestacks, etc.) that may not exceed short-term (days-weeks) or long-term (months-years) regulatory standards, but may still pose a hazard to acutely exposed individuals.
- blocking IRIS from posting summaries of its assessments online, arguing that the summaries give a naïve public and regulators inaccurate impressions, contribute to misunderstandings, and are misused.

- blocking the IRIS staff recommendations to apply a 10-fold safety factor to site-specific assessments where children may be exposed to ethylene oxide, a potent human carcinogen with evidence that exposures during early life significantly increase the risk of developing cancer. Use of such a safety factor under precisely these conditions is specifically recommended in the *EPA Supplemental Cancer Guidelines on Children's Exposure*.

These examples should be alarming to any member of Congress, and any member of the public, who cares about ensuring that the best science is used by EPA to determine the risks posed by dangerous chemicals and who cares about fully informing the public about the risks posed by exposure to toxic chemicals . It also illustrates why NRDC and other environmental and public health groups, as well as the GAO, are so concerned about the changes to the IRIS process that will allow more of the decision-making to take place behind closed doors, where political appointees can make demands on career employees, without having to defend the merits of their scientific arguments (or the injection of policy and political preferences in a scientific process) before the public.

### *Conclusion*

Properly implemented, the EPA IRIS program provides a critical scientific service to the public. Like other vital EPA programs, it must be preserved and protected so that EPA's scientists can conduct their work without political interference. The EPA's authority to determine the risks posed by hazardous chemicals should not be sacrificed to

the desire of other federal agencies' or industry interests in avoiding clean-up costs or requirements for additional controls on emissions and exposures.

There are hundreds of potentially dangerous chemicals that are either already in the IRIS database but need to be updated, or that have not yet been added. Without an open, credible, effective, science-based, fully-funded program to develop these assessments without political interference from the White House or other federal agencies, EPA will continue to fall further behind in a fundamental program that serves as the foundation for fulfilling its mission: protecting the environment and public health.

As discussed above, the chemical industry has had great success, with the assistance of EPA's political appointees, in blocking, delaying or weakening individual health standards and undermining the fundamental program that establishes the level of risk posed by toxic chemicals. The third prong in industry's attack on environmental protections has been to attack the objectivity and credibility of independent and government scientists, while shamelessly promoting the supposed objectivity of industry scientists and consultants, many with direct financial conflicts in the matters they are reviewing. Sadly, EPA's political appointees have aided and abetted industry in this effort as well.

**EPA'S MISUSE OF PEER REVIEW GUIDELINES TO DISMISS DR. RICE'S PEER REVIEW OF PBDEs IS A BLOW TO GOVERNMENT EXPERTS AND A PERVERSION OF THE GUIDELINES**

When scientific experts were selected to peer review the EPA draft human health assessment for the polybrominated diphenyl ethers (PBDEs), a class of toxic flame retardants, there could be no better choice than Maine state toxicologist Dr. Deborah Rice to chair the peer review. She is an excellent scientist, respected among her peers, and even a recipient of a Level I Scientific and Technological Achievement Award (STAA) from EPA in 2004 for “exceptionally high-quality research” on lead toxicity.<sup>26</sup> Moreover, Dr. Rice is a public employee. Public servant scientists like her represent our most valuable brain trust of readily-available independent scientific expertise. Unlike experts for hire, government scientists have no financial stake in the outcome of a chemical review.

EPA opted to use an outside contractor to conduct the external peer review, which is a common practice. Deborah Rice was made chair of the peer review panel and submitted individual comments, as did the other panel members. However, a notice posted on the IRIS website states that EPA excluded Dr. Rice’s comments from the final report “*due to the perception of a potential conflict of interest.*”<sup>27</sup> (Italics added for emphasis).

The actions taken by the EPA to dismiss one of their most respected and credible scientific reviewers was in direct response to a written request from the Brominated Flame Retardant Industry Panel (BFRIP) of the American Chemistry Council – the manufacturers of PBDEs -- dated May 3, 2007, one week after the peer review workshop.<sup>28</sup> George Grey, EPA’s Assistant Administrator for Research and

Development, referred directly to the letter, and a subsequent meeting with the ACC, when responding in writing to the BFRIP. Gray's letter states: "At the June 15 [2007] meeting, EPA listened to your concerns about a potential conflict of interest on the part of the Chairperson ... Since then, we have decided that the Chairperson's comments would not be considered...and that the Chairperson's comments would be removed from the Final Report of the external peer review."<sup>29</sup>

EPA has not provided a rationale for its dismissal of Dr. Rice, except the website statement quoted above.<sup>30</sup> Clearly however there was no financial conflict. Moreover, Dr. Rice meets all the criteria of a knowledgeable, respected scientific expert.

In stark contrast, as Chairman Dingell and Congressman Stupak documented in their April 2, 2008 letter to EPA on this topic, there are no fewer than nine examples of industry scientists with blatant financial conflicts of interest who were never removed from EPA panels. Some of these people had also made public statements directly on the science they were adjudicating.

Moreover, on the same peer review panel that Dr. Rice had chaired, the Agency retained Richard J. Bull of MoBull Consulting as a peer reviewer, despite his sullied reputation for having failed to disclose relevant financial conflicts of interest on a prior committee of the National Academies National Research Council (NRC). In 2004, Richard Bull was asked to resign from the NRC committee reviewing the health hazards of the rocket fuel perchlorate after he failed to disclose that he was being paid by

Lockheed Martin to serve as their scientific expert in litigation.<sup>31</sup> Although the case was still ongoing at the time, Bull failed to reveal these direct financial conflicts to the NRC staff.<sup>32 33</sup> The NRC asked Bull to resign from the committee.<sup>34</sup> The EPA leadership's hypocritical favoritism to industry consultants, while our own public servants are unfairly dismissed, rightfully makes the American public cynical about our federal agencies and their cozy relationship with polluters.

EPA made a serious error in judgment in disqualifying Dr. Rice from this panel. The EPA Peer Review Handbook recognizes that peer reviewers can hold strong opinions, noting as an example that, "as a final layer of review" the National Academies of Science "specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports."<sup>35</sup> Some scientific journal editors also do this with submitted manuscripts that could be controversial, with the goal of having the opportunity to respond to the full range of potential criticisms during the final draft stage of the document and thereby avoiding such criticisms after it is finalized.

The way George Gray has applied the peer review guidelines, an expert scientist like Deb Rice has a potential conflict – which is well-understood to mean a financial interest -- by taking a public position supporting phasing out the use of chemicals that are scientifically proven to be persistent, bioaccumulative, and toxic (PBTs) in cases where safer alternatives are readily available. This position is not in conflict with the science evidence, it is not in conflict with the scientific consensus among public health experts, and it is not in conflict with many state public health agencies where some PBDEs have

been banned or restricted, including Washington, California, and Maine.<sup>36</sup> The only potential conflict that Dr. Rice may have is with the American Chemistry Council and their member companies that manufacture PBDE's; those groups continue to defend the chemical and testify against state bans.<sup>37</sup>

## CONCLUSION

In his book, Doubt is Their Product: How Industry's Assault on Science Threatens Your Health, David Michaels emphasizes that the failures of EPA to regulate hazardous materials are not the fault of most agency scientists or career employees, "many of whom are heartsick that their work has been so undermined, to put it mildly, and that their once-proud agency has become just another enabler for the polluters and the poisoners."<sup>38</sup>

We appreciate the efforts of Congress, and this subcommittee, to investigate and oversee recent actions by the Administration including undermining the IRIS program and working in concert with industry to attack the integrity and independent of reputable government scientists. Congress needs to protect the public servants that are trying to do their jobs and serve the mission of the EPA, and prevent or overturn actions by Administration officials that weaken environmental and health protections for the public.

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