



NATURAL RESOURCES DEFENSE COUNCIL  
THE EARTH'S BEST DEFENSE

**Comments from NRDC to the  
SAB Chemical Assessment Advisory Committee (CAAC)  
on the IRIS program and the development of  
IRIS toxicological reviews  
April, 2013**

The purpose of the CAAC meeting is to: 1) acquaint committee members with the work of the IRIS Program; 2) orient them to the process it uses to develop chemical assessments, also known as Toxicological Reviews; and 3) to discuss the role of the CAAC in this process.

More information is on the EPA SAB website here:

<http://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/1363eb27571284ed85257b0f0062f32b!OpenDocument&Date=2013-04-02>

These comments are submitted on behalf of NRDC (Natural Resources Defense Council), a nonprofit environmental policy organization with 1.2 million members

## GETTING THE SCIENCE RIGHT – National Academies recommendations

The National Academy of Sciences released three reports in 2007-09, each recommending modernization of chemical health evaluations in the United States.<sup>1 2 3</sup> Chemical evaluations, including chemical testing and risk assessment, are important because they are used to set allowable levels of human exposure. If the testing or assessments are not done right, or are done too slowly, people can become ill because legally allowable levels of chemical exposures may be unsafe based on outdated or inaccurate science or no data at all.

The NAS recommended that, in order to properly focus and avoid getting bogged down, the agency should first identify the decision that needs to be made, and then focus the assessment on answering the specific questions that would most significantly inform the decision. Specifically, the NAS committee recommended identification of options to reduce identified hazards or exposures at the earliest stages of decision-making and using risk assessment to evaluate the merits of the various options, with public involvement at all stages.<sup>4</sup> Furthermore, the NAS recommended that simplified guidelines and methods be developed to allow risk assessments to be done in a timely fashion, and to facilitate community participation.

The NAS reports recommended four main areas of reform:

*1) Identify and incorporate variability in human exposure and vulnerability into health assessments, so that all people are better protected.*<sup>3</sup>

In the 2009 report, Science and Decisions: Advancing Risk Assessment, the NAS recommended that in addition to providing a more robust characterization of the population at risk, special attention should be directed to vulnerable individuals and populations that may be particularly susceptible and/or more highly exposed.

Agencies should develop clear guidance to help individual risk analysts determine the appropriate level of detail (and resources) to spend on uncertainty and vulnerability analyses, depending on the importance and nature of the decision to be made.

For cancer assessments, the NAS committee recommended that EPA add a factor of 25 to account for differences in median versus higher end response to carcinogens.<sup>5</sup> The NAS pointed

---

<sup>1</sup> Toxicity Testing in the Twenty-first Century: A Vision and a Strategy. Committee on Toxicity and Assessment of Environmental Agents, National Research Council (2007). National Academies Press, Washington D.C. ISBN: 0-309-10989-2.

<sup>2</sup> Phthalates and Cumulative Risk Assessment: The Tasks Ahead. Committee on the Health Risks of Phthalates, National Research Council (2008). National Academies Press, Washington D.C. ISBN: 0-309-12841-2.

<sup>3</sup> Science and Decisions: Advancing Risk Assessment. Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, National Research Council (2009). National Academies Press, Washington D.C. ISBN: 0-309-12047-0.

<sup>4</sup> Science and Decisions, pp. 10-12.

<sup>5</sup> Science and Decisions, p. 168.

out that variability (differences in exposure or vulnerability) is distinct from uncertainty (data gaps), and each of these important issues should be addressed separately.

2) *When information is missing or unreliable, use scientifically-based default assumptions that will protect health, rather than waiting for more data, in order to improve the timeliness of the chemical assessment and decision-making process. There should be a clear set of criteria for when to depart from default assumptions.*<sup>3</sup>

In Science and Decisions, the NAS committee concluded that “established defaults need to be maintained for the steps in the risk assessment that require inferences”.<sup>6</sup> Most default factors are based on data, including extensive data sets in some cases, across many chemicals; they are not purely policy, as is sometimes alleged. EPA and other agencies could update the default factors and assumptions based on the best current science, identify where unstated or implicit assumptions are used, and replace these with explicitly stated ones.

With these recommendations the committee is pushing EPA to “continue and expand use of the best, most current science to support or revise its default assumptions”<sup>7</sup> – making them stronger, rather than reducing reliance on them. In fact, the committee specifically recommended that EPA develop “clear standards for departures from defaults”.<sup>8</sup> The committee notes that establishing, “clear criteria for departure from defaults can provide incentives for third parties to produce research” that can support alternative assumptions and over time drive more accurate assessments. Importantly, by using the established defaults more often, EPA avoids “the paralysis of having to re-examine generic information with every new risk assessment”.<sup>9</sup> The agency should also evaluate and quantify, where possible, the impact of the uncertainty associated with the use of a default assumption, including a description of how use of the default versus the chosen alternative assumption impacts the decisions that protect the environment and public health.

CAAC should support the use of established defaults by IRIS to protect human health and the environment, in accordance with EPA’s guidelines.

3) *In assessing the risk of chemicals, incorporate information about the potential impacts of exposure to multiple chemicals. In addition, consider other factors, such as exposure to biological and radiological agents and social conditions.*<sup>2,3</sup>

In the 2009 report, Science and Decisions, the NAS underscored the key recommendations of the NAS Phthalates and Cumulative Risk Assessment report (2008), and added: “There is a need for cumulative risk assessments (CRA) ...—assessments that include combined risks posed by aggregate exposure to multiple agents or stressors; aggregate exposure includes all routes,

---

<sup>6</sup> Science and Decisions, p. 7.

<sup>7</sup> Science and Decisions, p. 207.

<sup>8</sup> Science and Decisions, p. 199.

<sup>9</sup> Science and Decisions, p. 191.

pathways, and sources of exposure to a given agent or stressor.”<sup>10</sup> The NAS definition of “agent or stressor” includes not only chemicals, but also biological agents, radiologic agents, physical agents, and psychosocial stressors.<sup>11</sup> The committee recognized that a broad variety of factors, including nutritional factors, health status, and psychosocial stress, can increase individual vulnerability to toxic chemicals, and these factors – and the variability in them across a population – need to be considered in risk assessment in order to protect public health. The NAS recommended that EPA should develop databases and scientifically based default approaches to allow the incorporation of key non-chemical stressors in the absence of population-specific data to make the process more efficient.<sup>12</sup>

*4) Because the population is exposed to multiple chemicals and there is a wide range of susceptibility to chemical exposures, it cannot be presumed that exposures - even low ones - are risk free. It should therefore be assumed that low levels of exposures are associated with some level of risk, unless there are sufficient data to reject this assumption.<sup>3</sup>*

According to the NAS, “small chemical exposures in the presence of existing disease processes and other endogenous and exogenous exposures can have linear dose response relationships at low doses”.<sup>13</sup> In other words, there may be no “safe” threshold in the human population for many chemicals. The NAS committee recommended that agencies use the same approach for addressing risks from both cancer and non-cancer health effects (such as developmental or reproductive effects). The committee concluded that “scientific and risk management considerations both support unification of cancer and non-cancer dose response assessment approaches.”<sup>14</sup> They called for a “unified-dose response framework” that includes a systematic evaluation of factors such as background exposures, disease processes and inherent vulnerabilities. This evaluation will inform the choice of the appropriate dose-response model. The NAS also pointed out that there are multiple differences in the population due to age, disease status, nutrition, and other factors. Due to these differences, and the fact that people are exposed to multiple chemicals, the science supports using a model that does not have an assumption of a “threshold” below which exposures cause zero risk in the population. The NAS recommended that a conceptual model be developed that is “from linear conceptual models unless data are sufficient to reject low-dose linearity; and nonlinear conceptual models otherwise.”<sup>15</sup> In essence, the new NAS recommended approach is to assume that all exposures, even low ones, are associated with some level of risk, unless there is sufficient data to reject this assumption, after accounting for background chemical exposures, biological additivity, and population variability.

CAAC should support the use of default health-protective assumption of low-dose linearity in IRIS assessments, and require substantial evidence to depart from protective assumptions.

---

<sup>10</sup> Phthalates and Cumulative Risk Assessment, p. 9-10.

<sup>11</sup> Phthalates and Cumulative Risk Assessment, pp. 224-229.

<sup>12</sup> Phthalates and Cumulative Risk Assessment, p. 236.

<sup>13</sup> Science and Decisions, p. 158.

<sup>14</sup> Science and Decisions, p. 9.

<sup>15</sup> Science and Decisions, p. 144.

## *Conclusion*

Each of these recommendations incorporates the best scientific understanding of environmental chemical risks to better protect people from toxic chemicals. The EPA IRIS program should move forward quickly to incorporate these new scientific approaches into their guidelines and procedures.

At this time, the policies that determine how industrial chemicals are regulated presume that the chemicals are safe in the absence of an assessment. This can be reversed by setting default interim health-protective standards and restrictions pending completion of a risk assessment. Such a 'default' would stimulate more research, reward a chemical manufacturer for producing data instead of avoiding it, and remove many of the incentives that chemical manufacturers now have to delay final assessments. This could be done right away, while the Agencies further plan how to implement many of the recommendations of the NAS reports.

SAB should recommend that IRIS assessments incorporate the recommendations of Science and Decisions as summarized above, and be finalized in a timely manner according to the best available science at the time, without undue delay.

### **PRIMARY PREVENTION – Place the burden of proof on chemicals and agents, rather than on the public**

Cancer is still mainly a lethal disease, despite billions of research dollars spent on understanding, detecting, and treating it.<sup>16 17</sup> Because cancer and other diseases are complicated, the scientific understanding of *how* a chemical leads to a disease outcome often comes much later than the evidence that it does so. But when there is scientific evidence showing a statistically significant causal link between an exposure and an adverse effect, science accepts that evidence even without a full mechanistic explanation. For example, science still cannot fully explain exactly how lead damages kids' brains, but we know it does and we banned lead from house paint in 1978 and from gasoline in 1986. Congress banned PCB's long before scientists understood how they caused cancer. Since then we've learned more about the mechanism, but if we'd waited then many more kids would have had permanent lead-induced brain damage and more people would have had PCB-related cancer. Science is still exploring the mechanism of how smoking causes cancer, but we no longer allow smoking in most public places. In fact, we now know that the tobacco industry hid evidence for decades that cigarette

---

<sup>16</sup> Tomatis L, Melnick RL, Haseman J, Barrett JC, Huff J. Alleged 'misconceptions' distort perceptions of environmental cancer risks. *FASEB J.* 2001;15:195–203

<sup>17</sup> Melnick RL, Huff J. Lorenzo Tomatis and primary prevention of environmental cancer. *Environ Health.* 2011 Apr 5;10 Suppl 1:S14.

smoking caused premature death, that tobacco was addictive, and that its own health research was a sham.<sup>18 19</sup>

EPA must set timely health-protective policies based on available well-conducted animal studies and other predictive toxicological approaches. The alternative, waiting for human cases from epidemiologic studies means assessing the potential hazards of chemicals *a posteriori*, after the harm has been done. Even worse would be holding up health protective policies until scientific understanding of the mechanism of harm has been established.

Some have argued that even with scientific evidence of harm from epidemiologic studies, that workplace exposures are not relevant to environmental exposures. This is not true. Dr. Tomatis, former Director of the International Agency for Research on Cancer and founder of the IARC Monographs program, said that, “The differences between cancers that occur as a consequence of occupational exposure and other cancers are not only their preventability but, more importantly their social unacceptability”<sup>20</sup> Even more importantly, environmental exposure levels that may seem low enough to be without appreciable harm may not actually be safe in the context of concomitant exposures to other chemicals, to developmental stage or age, and to factors such as health status, nutritional status, or stress level.<sup>21</sup>

### *Conclusion*

The proposition that no conclusion can be reached about a chemical’s hazard and no regulation should take place until we fully understand the mechanism of action is based upon the precedent of the tobacco industry’s historic efforts to disregard evidence, to delay regulations, and to deny harm. The EPA is a public health agency charged with protecting human health and the environment. Dr. Tomatis said, “Primary prevention remains the most relevant approach to reduce mortality through a reduction in incidence”.<sup>22</sup> In fact, anything else is a failure of public health.

SAB should recommend that IRIS assessments be finalized in a timely manner according to the best available science at the time, without awaiting further science. This would increase the output of the IRIS program, thereby providing the public with critical timely information about

---

<sup>18</sup> Cummings MK, Brown A, O’Connor R. The cigarette controversy. *Cancer Epidemiol Biomarkers Prev.* 2007 June;16:1070

<sup>19</sup> Glantz SA, Barnes DE, Bero LA, Hanauer P, Slade J. Looking through a keyhole at the tobacco industry: the Brown and Williamson documents. *JAMA* 1995;274:219–24

Glantz SA, Slade J, Bero LA, Hanauer P, Barnes DE. *The cigarette papers.* Berkeley (CA): University of California Press; 1996.

<sup>20</sup> Tomatis L. The contribution of the IARC monographs program to the identification of cancer risk factors. *Ann NY Acad Sci.* 1988;534:31–38

<sup>21</sup> Melnick RL, Huff J. Lorenzo Tomatis and primary prevention of environmental cancer. *Environ Health.* 2011 Apr 5;10 Suppl 1:S14.

<sup>22</sup> Tomatis L, Melnick RL, Haseman J, Barrett JC, Huff J. Alleged ‘misconceptions’ distort perceptions of environmental cancer risks. *FASEB J.* 2001;15:195–203

the potential harm of chemicals so that primary prevention measures can be taken to avoid harmful exposures.

### **POLITICAL INTERFERENCE –Review of IRIS process and chemical assessments by the CAAC SAB and the NRC**

The scrutiny of the IRIS program process and specific chemical assessments is the direct result of an aggressive campaign by the chemical industry to “protect” formaldehyde and styrene from a growing body of scientific evidence that they cause cancer in humans is now more than a decade old.<sup>23 24</sup> The condensed recent political history of the IRIS formaldehyde review is summarized below.

EPA began an effort to update its initial health assessment of formaldehyde in 1998. In 2003, studies from the National Cancer Institute (NCI) and the National Institute of Occupational Safety and Health (NIOSH) reported evidence of an association between workplace exposure to formaldehyde and leukemia.<sup>25</sup> In 2004, U.S. Senator James Inhofe demanded that EPA postpone its revisions to the formaldehyde assessment until the agency could take into account industry data developed in response to the workplace studies. The Bush administration agreed, and EPA complied.

In 2009, after updating the science, making its earlier conclusions of carcinogenicity even stronger, EPA again prepared to issue its revised assessment of formaldehyde. In response, the industry trade group “The Formaldehyde Council” enlisted U.S. Senator David Vitter of Louisiana to place a hold on the Obama Administration’s nominee to be the head of EPA’s Office of Research and Development (which is where the IRIS program that did the formaldehyde assessment is located) until EPA Administrator Lisa Jackson agreed to send EPA’s draft assessment of formaldehyde to the National Academy of Sciences (NAS) for review.<sup>26</sup> The EPA Administrator ultimately agreed to make the referral, which further delayed the agency from moving forward on the assessment – already underway for a decade - for an additional two years.<sup>27</sup>

---

<sup>23</sup> <http://blogs.edf.org/nanotechnology/2011/06/13/acc-resorts-to-smear-tactics-to-defend-its-cash-cows-formaldehyde-and-styrene/>

<sup>24</sup> [http://switchboard.nrdc.org/blogs/drosenberg/cancer-causing\\_chemicals\\_have.html](http://switchboard.nrdc.org/blogs/drosenberg/cancer-causing_chemicals_have.html)

<sup>25</sup> NCI. National Toxicology Program. Bioassay of Styrene for Possible Carcinogenicity (CAS No.100-42-5). Natl Toxicol Program Tech Rep Ser. 1979;185:1-107.

<sup>26</sup> Sapien J. How Senator Vitter Battled the EPA Over Formaldehyde's Link to Cancer. Why is formaldehyde still listed by the EPA as a probable rather than a known carcinogen, despite major scientific research linking it to leukemia and other forms of cancer? Scientific American, April 16, 2010. Available at <http://www.scientificamerican.com/article.cfm?id=vitter-formaldehyde-epa>

<sup>27</sup> Sass JB, Rosenberg DR. The Delay Game: How the Chemical Industry Ducks. Regulation of the Most Toxic Substances. A report of the Natural Resources Defense Council (NRDC). October 2011. Available at <http://www.nrdc.org/health/thedelaygame.asp>

Senate confirms deputy administrator, research chief. Sara Goodman, E&E reporter. Published: Monday, January 4, 2010

In April 2011, the NAS released its report on EPA's IRIS assessment of formaldehyde. Although the report was critical of some aspects of EPA's draft assessment, including its length, organization, and clarity, it did not dispute the central findings of EPA that there is strong evidence to support formaldehyde being a cause of nasopharyngeal cancer and some evidence, including from studies of people exposed in workplace settings, for formaldehyde being a cause of myeloid leukemia. The NAS was clear in calling for EPA to move forward with completing the formaldehyde and other IRIS assessments, and not wait until all its recommendations have been addressed.

In response to the NAS review of formaldehyde, Assistant Administrator Paul Anastas (whose nomination was held up by Senator Vitter) announced EPA's intent to follow the recommendations made by the NAS, both for the formaldehyde assessment itself, as well as future chemical assessments. Dr. Anastas proposed additional changes including the formation of a new standing peer-review panel of its Science Advisory Board, to review IRIS assessments.

Nevertheless, the chemical industry and its Congressional allies have seized upon the NAS formaldehyde report and used it ever since to support its claim that the IRIS program lacks credibility and cannot be trusted to competently assess the health effects of chemicals.<sup>28,29</sup>

When the House Appropriations Committee finalized its appropriations bill for EPA in July 2011 a rider was included that required EPA to send three of its IRIS assessments to the NAS for review. However, although the bill was briefly debated on the floor of the House, it was pulled by House leaders before the IRIS rider could be debated or an amendment to strike it from the legislation could be put to a vote. The Senate never considered or debated an IRIS provision. A modified version of the House rider was ultimately included in the Omnibus Spending bill in December 2011, requiring EPA to send three IRIS assessments to the NAS for review.<sup>30</sup> After the rider was enacted, the scope of the NAS review was further revised to instead be a panel conducting a broad overview of the IRIS program, and a panel to review the IRIS program's draft assessment of inorganic arsenic.<sup>31</sup>

In October 2012 the chemical industry and its Congressional allies launched another attack on science with a proposed Bill (HR6564) targeting the structure and function of the EPA Science Advisory Board (SAB) that would favor participation by industry scientists (for example, by stating that people with direct financial conflicts should not be excluded), while excluding independent scientists (for example, by limiting participation of scientists with government funding). The bill was strongly opposed in letters to Congress by public interest groups and

---

<sup>28</sup> EPA Faulted Over IRIS, Peer Review Reforms. Inside EPA. Posted: February 21, 2013

<sup>29</sup> Letter from Senators Vitter, Crapo, and Inhofe to EPA Acting Administrator Perciasepe and Dr. Olden. February 20, 2013

<sup>30</sup> Democrats pleased with EPA provisions in omnibus. Jeremy P. Jacobs, E&E reporter. Published: Friday, December 16, 2011

<sup>31</sup> Guidance for and Review of EPA's IRIS Toxicological Assessment of Inorganic Arsenic. DELS-BEST-12-01

prominent scientists including Deans of several Schools of Public Health, and the Executive Director of the American Public Health Association (attached).<sup>32</sup>

### *Conclusion*

Politically-motivated interference in IRIS chemical assessments favor the manufacturers of toxic chemicals while imposing delays of health protections for air, drinking water, and contaminated soil. In instances when they are ordered by Congress at the behest of the regulated industry, without any public notice or opportunity for discussion or debate as a tactic to delay or reverse unwanted negative conclusions by non-industry scientists, than they are a misuse of public funds.

### **BIAS AND CONFLICT – Members of the SAB CAAC should be evaluated for conflicts**

The SAB's decision to evaluate the impartiality of CAAC members *only* in relation to their committee work on specific chemicals is not appropriate and contrary to the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 2, *et seq.* The CAAC will address broad issues, having a significant and lasting impact on future IRIS assessments. These overarching issues are of great interest to the chemical industry as a whole, including to the American Chemistry Council (ACC), the trade organization representing most corporate chemical manufacturers. By declining to consider financial and other conflicts of committee members at the outset of the CAAC's work, SAB greatly undermines its credibility.

The composition of the CAAC, moreover, is contrary to the requirements of FACA.<sup>33</sup> The CAAC must comply with FACA's mandate that the committee be "fairly balanced in terms of the points of view represented and the functions to be performed" and protected from "inappropriate[] influence[] by the appointing authority or by any special interest." 5 U.S.C. app. 2 § 5(b)(2)-(3). SAB, however, has not vetted CAAC members for financial and other conflicts, notwithstanding its own concession that such an evaluation is required. See SAB PANEL/COMMITTEE FORMATION and the Chemical Assessment Advisory Committee (Apr. 2, 2013 at 15 ("SAB Staff Office conducts a review...in the context of each advisory activity to ensure there is no conflict of interest and no appearance of loss of impartiality.")).

As a result of SAB's failure to properly evaluate CAAC members, the committee will be "inappropriately influenced" by its members with financial conflicts, including those who are directly employed by the chemical industry. If industry representatives have specific knowledge or expertise of value to the deliberations of a committee, then invitations to address the

---

<sup>32</sup> [http://switchboard.nrdc.org/blogs/jsass/hr6564\\_-\\_the\\_house\\_republican.html](http://switchboard.nrdc.org/blogs/jsass/hr6564_-_the_house_republican.html)

<http://blogs.edf.org/nanotechnology/2012/12/07/scientists-push-back-against-a-bill-that-would-pervert-the-whole-concept-of-conflict-of-interest/>

<sup>33</sup> EPA has acknowledged that FACA applies to the CAAC. 76 Fed. Reg 71561 (Nov. 18, 2011) ("The SAB conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations.")

committee during public meetings are appropriate. However, individuals with financial conflicts should not serve as members of an SAB committee convened pursuant to FACA.

While we do not impugn the integrity or qualifications of any of the proposed panel members, we are deeply concerned about certain members' potential biases and conflicts of interest. We have specific concerns that the following nominees whose employers have financial or competing interests that should prevent them from service on this CAAC. We have provided details in the comments below.

#### Summit Toxicology (Sean Hays, President and Founder)

Dr. Hays is the President and Founder of Summit Toxicology, a small consulting firm with four principle employees, including Dr. Hays. Summit's website says, "We work with private industry, law firms and government agencies to help solve complex problems related to public, occupational and environmental health."<sup>34</sup> It lists its services to clients as including: regulatory toxicology, litigation support, and expert witness testimony.<sup>35</sup> One of Summit's ongoing clients appears to be the American Chemistry Council, which is the trade organization representing the manufacturing corporations of the toxic chemicals that are the subject of IRIS reviews. For example, in October 2010 members of Summit Toxicology provided technical comments to the EPA SAB on behalf of the ACC related to derivation of the reference dose (RfD) for dioxin (TCDD).<sup>36 37</sup> More recently, researchers from Summit and ToxStrategies, another consulting firm, collaborated on a presentation for the 2013 Annual Society of Toxicology meeting and research funded by the Cr6 (hexavalent chromium) panel of the ACC.<sup>38</sup> Hexavalent chromium is a drinking water contaminant currently being assessed by the IRIS program.

Summit Toxicology employees have corporate clients whose toxic chemical products are the subject of IRIS reviews. Putting Summit employees on the SAB represents both a bias and a conflict.

#### Exponent (Abby Li)

Dr. Li is employed full-time by Exponent, a scientific consulting firm. Exponent is paid by its clients to influence policy. As Dr. David Michaels, now Secretary of OSHA, states in his book, *Doubt is Their Product* (2008), writing about Exponent, ChemRisk, the Weinberg Group, and other consulting firms started by scientists that "cut their teeth manufacturing uncertainty for

---

<sup>34</sup> <http://www.summittoxicology.com/index.html>

<sup>35</sup> <http://www.summittoxicology.com/index.html>

<sup>36</sup>

[http://yosemite.epa.gov/sab/sabproduct.nsf/2A832F8D9A2587CE852577C200438FB5/\\$File/Presentation+by+Lesa+Aylward,+Summit+Tox+on+behalf+of+the+American+Chem+Council.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/2A832F8D9A2587CE852577C200438FB5/$File/Presentation+by+Lesa+Aylward,+Summit+Tox+on+behalf+of+the+American+Chem+Council.pdf)

<sup>37</sup> [http://yosemite.epa.gov/sab/sabproduct.nsf/0/91BF4B5A068396048525779D006E7BF6/\\$File/10-10+Meeting+Minutes+v4.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/0/91BF4B5A068396048525779D006E7BF6/$File/10-10+Meeting+Minutes+v4.pdf)

<sup>38</sup> [http://www.toxicology.org/isot/ss/riskassess/RASSWebinar\\_010913.pdf](http://www.toxicology.org/isot/ss/riskassess/RASSWebinar_010913.pdf)

Big Tobacco...Their business model is straightforward. They profit by helping corporations minimize public health and environmental protections and fight claims of injury and illness".<sup>39</sup>

Exponent's website notes:

Exponent routinely works with clients to understand the relationship between third-party injuries and litigation risks. We have extensive experience estimating current and future liabilities for environmental and health impacts. Our approach is based on understanding the current and likely liability rules of the relevant legal environment, the technical and practical difficulties involved in proving injury and damages, and rigorous statistical analysis of the historical claims experienced in various areas of litigation. Exponent has applied its approach to quantifying litigation risks in various areas such as product liability, business interruption, and third-party damages from commercial and industrial operations.<sup>40</sup>

Exponent employees serve as litigation defense experts in cases involving toxic chemicals that are the subject of IRIS reviews. Putting Exponent employees on the SAB represents both a bias and a conflict.

#### Gradient (Lorenz Rhomberg, Principle)

Gradient is a consulting firm that advertises its services to clients as including toxic tort litigation support.<sup>41</sup> Gradient's website says that, "Gradient testified before the SAB in its review of a proposed revision to EPA's risk assessment for trichloroethylene. Gradient's testimony was submitted as part of the referral to a special committee of the National Academy of Sciences."<sup>42</sup> Gradient also provided experts for litigation defense pertaining to TCE contamination.

The Gradient website says that, "A chlorinated solvent manufacturer engaged Gradient to review a US EPA preliminary draft risk assessment"<sup>43</sup> indicating that Gradient's client services include efforts to influence the EPA's assessment of toxic chemicals.

The Gradient website says that, "Clients have retained Gradient to provide scientific comments pertaining to pending regulations or legislation involving risk-based methods, as well as issues relating to the underlying toxicology of specific chemicals."<sup>44</sup> The webpage lists projects to include comments on the IRIS naphthalene assessment, EPA's draft reference dose for perchlorate, and other activities related to the activities of IRIS.<sup>45</sup>

---

<sup>39</sup> Michaels, David. Doubt is their product: how industry's assault on science threatens your health. 2008. Page 46

<sup>40</sup> <http://www.exponent.com/Investigations-into-Litigation-Risks/>

<sup>41</sup> <http://www.gradientcorp.com/servicesandprojects/servicesandprojects.php>

<sup>42</sup> <http://www.gradientcorp.com/servicesandprojects/project.php?q=202060&sec=5&subsec=1>

<sup>43</sup> <http://www.gradientcorp.com/servicesandprojects/project.php?q=206060&sec=5&subsec=1>

<sup>44</sup> <http://www.gradientcorp.com/servicesandprojects/services.php?sec=5&subsec=2>

<sup>45</sup> <http://www.gradientcorp.com/servicesandprojects/services.php?sec=5&subsec=2>

Dr. Rhomberg has recent publications that are funded by the ACC or its member companies, including the formaldehyde and styrene industries whose products have recently been reviewed by IRIS and the NIEHS National Toxicology Program:

- The Weight of Evidence Does Not Support the Listing of Styrene as "Reasonably Anticipated to be a Human Carcinogen" in NTP's Twelfth Report on Carcinogens (2013) – funded by the styrene industry<sup>46</sup>
- Is exposure to formaldehyde in air causally associated with leukemia? – A hypothesis-based weight of evidence analysis (2011) – funded by Formaldehyde Council<sup>47</sup>
- Linear low-dose extrapolation for noncancer health effects is the exception, not the rule (2011) – funded by American Chemistry Council<sup>48</sup>

Putting Gradient employees on the SAB represents both a bias and a conflict.

### *Conclusion*

As stated earlier, we do not wish to impugn the integrity, qualifications, or technical expertise of any of the above scientists. If they have specific knowledge or expertise of value to the deliberations of this SAB, then invitations to address the committee during public meetings are appropriate.

However, we believe that scientists who are directly employed by the chemical industry, or employed by consulting firms with clients that include corporate chemical manufacturers or their trade associations, should be considered to have the conflicts of their employers. This is especially relevant to the CAAC SAB, which will be addressing broad issues with widespread impacts on the development of IRIS assessments generally, in addition to chemical-specific issues.

The mission of the SAB is to provide credible and independent scientific analysis and advice to government. The Board cannot accomplish this vital mission if its committee members have conflicts of interest or a strong bias toward the perspective of regulated industries. The CAAC should make strong efforts to protect its independence, integrity, and competency as its most valuable assets.

---

<sup>46</sup> Rhomberg LR, Goodman JE, Prueitt RL. The Weight of Evidence Does Not Support the Listing of Styrene as "Reasonably Anticipated to be a Human Carcinogen" in NTP's Twelfth Report on Carcinogens. *Hum Ecol Risk Assess.* 2013 Jan;19(1):4-27.

<sup>47</sup> Rhomberg LR, Bailey LA, Goodman JE, Hamade AK, Mayfield D. Is exposure to formaldehyde in air causally associated with leukemia?--A hypothesis-based weight-of-evidence analysis. *Crit Rev Toxicol.* 2011 Aug;41(7):555-621.

<sup>48</sup> Rhomberg LR, Goodman JE, Haber LT, Dourson M, Andersen ME, Klaunig JE, Meek B, Price PS, McClellan RO, Cohen SM. Linear low-dose extrapolation for noncancer health effects is the exception, not the rule. *Crit Rev Toxicol.* 2011

## **CONCLUSION**

We look forward to following the activities of the CAAC. Thank you for the opportunity to provide comments.

Respectfully,

*Jennifer Sass, Ph.D.*  
Senior Scientist, NRDC