



# Cozying Up:

**How the Manufacturers of Toxic Chemicals  
Seek to Co-opt Their Regulators**

**by CPR Member Scholar Rena Steinzor  
and Policy Analyst Wayland Radin**



## About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation, and improved public access to information. The Center for Progressive Reform is grateful to the John Merck Fund and the Johnson Family Foundation for their support of our toxics work.

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## Deceptive Partnerships

Given the charged debate in Washington over proposals to impose environmental or health and safety restrictions on industry, Americans might reasonably assume that toxic chemicals undergo rigorous, independent testing before they enter the stream of commerce. The reality of chemical regulation is disturbingly different and far less protective of public health and the environment. When Congress passed the 1976 Toxic Substances Control Act (TSCA)—one of the most important federal statutes to regulate potentially dangerous chemical products—tens of thousands of chemicals were “grandfathered,” meaning they were allowed to remain on the market without additional tests to prove their safety.<sup>1</sup> The tens of thousands of new chemicals that have come on the market over the last 35 years undergo a perfunctory, 90-day “pre-manufacture review” by the Environmental Protection Agency (EPA), which under even the best circumstances must rely on a comparison of the chemical structure of the new chemical to the structures of existing chemicals and whatever information the manufacturer has chosen to submit regarding the chemical. This “hear no evil, see no evil” system means that the hazards of chemical exposure are often revealed long after a chemical is pervasive in the environment. Bisphenol A is still used in a host of consumer products despite the fact that scientific studies link it to increased susceptibility to prostate and breast cancers, reproductive system defects and abnormalities, hormonal imbalances, brain development abnormalities, gender confusion, heart disease, and diabetes.<sup>2</sup>

As troubling, when the toxic effects of exposure to an untested chemical emerge, regulators must depend on “best available” science in order to decide whether to restrict the ways the chemical is marketed and used.<sup>3</sup> This approach gives manufacturers strong incentives to generate their own studies exonerating their products in an effort not only to keep chemicals on the market without restrictions but also to avoid liability for injuries caused by past exposures.

Because research by a chemical’s producer is often the primary resource available to regulators who make crucial public health decisions, independent experts have examined whether industry-sponsored studies produce different results than comparable government-funded work. These analyses cover a wide range of adverse effects, but they all reveal that industry sponsorship makes it significantly more likely that these studies reach conclusions more favorable to the sponsors than would research conducted by neutral scientists. An empirical review of 1,140 biomedical studies determined that “industry-sponsored studies were significantly more likely to reach conclusions that were favorable to the sponsor than were non-industry studies.”<sup>4</sup> Concerned by these findings, but unwilling to reject industry-sponsored science out of hand, the world’s most prestigious scientific journals require authors to disclose the source of their work so that potential biases are evident to readers.<sup>5</sup> These disclosures alert readers to the need to scrutinize study design, implementation, and findings more carefully.

Chemical manufacturers have long chafed under these restrictions because they know that once a study is labeled as an industry work product, most people are unwilling to

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take its conclusions at face value, and some will find them unconvincing on any level. This discomfort has generated a search for ways to make industry research appear more credible. One of the most effective methods of doing so is to recruit government scientists as co-authors for journal articles about the chemical in question. A second strategy is to obtain the active participation of government officials in industry-sponsored efforts to formulate “consensus” policy pronouncements regarding research design and risk assessment. These deliberations rarely include representatives from independent scientific organizations or public interest organizations, and government officials are typically a small minority of participants in comparison to scientists employed or largely funded by chemical manufacturers. Although their industry sponsors claim that such efforts represent “partnerships” that are balanced and therefore persuasive, in fact the limited number of participating government scientists do not and cannot rehabilitate the credibility of these fundamentally biased discussions.

The International Life Sciences Institute (ILSI) and Toxicology Excellence for Risk Assessment (TERA) are the most effective and active leaders in this intensifying effort to convert industry research into the result of an “industry/government partnership.” Both are self-styled “tripartite” organizations that purport to represent a broad consensus among scientists from industry, government, and academia. ILSI is primarily funded by large agribusiness and TERA receives substantial financial support from chemical manufacturers and their customers. Both firms are structured as non-profit corporations. They rarely produce their own research, but rather compile and assess the research performed by other industry-sponsored scientists.

For example, ILSI has a subsidiary, the Health and Environmental Sciences Institute (HESI), which has convened the “Risk Assessment in the 21st Century Technical Committee” (RISK21). Its purpose is to create and advocate risk assessment policies that would result in far more lenient controls on toxic chemicals by federal and state regulators. Similarly, when state regulators in Wisconsin began to consider limits on the chemical byproducts produced when two widely used herbicides break down in the environment, the manufacturers of the herbicides hired TERA to convene an expert panel to develop a “reference dose” (RfD) for the chemicals. (An RfD is an estimate of the daily oral exposure to a chemical that will not result in adverse health effects.<sup>6</sup>) The result was an article co-authored with government scientists that advocated drinking water limits up to 280 times higher than the limit Wisconsin regulators had set.

Government scientists have a commendable interest in developing their professional skills and judgment by participating in scientific dialogues sponsored by the private sector. They make mistakes when they lend their names to industry-sponsored articles or committee deliberations designed to influence regulatory policy. Not only do such activities undermine the independence of their government employers, they undermine public confidence in regulatory agencies. Disclaimers to the effect that a government scientist is speaking in her “personal” capacity do little to restore public confidence.

## Empirical Evidence of Industry Bias

Because industry-generated science is so influential with respect to public policy, researchers have conducted empirical reviews to determine the extent to which a project's funding source influences its outcome. Those studies revealed that industry-sponsored research is significantly more likely to produce results that exonerate chemicals and other products than studies funded by government or other entities.<sup>7</sup> In addition to the survey of studies conducted in the biomedical field described above, the industry influence on scientific research has been documented in research regarding second-hand smoke, nutrition, and chemical exposures. For instance, a study of review articles about second-hand smoke found that 94 percent of articles authored by researchers affiliated with the tobacco industry determined that the smoke posed no health risk.<sup>8</sup> A survey of articles regarding the potential health effects of the controversial chemical bisphenol A revealed that 94 of the 104 government-funded studies reported adverse effects at low doses but none of the 11 industry-funded studies did.<sup>9</sup> In the nutrition and food science arena, a review of articles regarding the risks and benefits of several beverages, including soft drinks, found that studies funded by soda manufacturers were four to eight times more likely to reach conclusions that were favorable to the sponsors than non-industry studies.<sup>10</sup> An empirical analysis of studies concerning the health effects of several widely used toxic chemicals found that 60 percent of studies conducted by non-industry scientists concluded that the chemicals were hazardous, but only 14 percent of industry-sponsored studies arrived at the same conclusion.<sup>11</sup>

As these studies suggest, industry funding affects scientific outcomes and thus suggests that there is substantial corporate control over the construction of these studies, including the methods, data collection, analysis, and publication of the study results.<sup>12</sup> Study sponsors are even able to define the scope of the research and methodology used in the lab in order to minimize the possibility that this work will uncover adverse effects.<sup>13</sup> Sponsors may also reserve their authority to rewrite the article or block its publication entirely. Policies that require authors and organizations to disclose conflicts of interest are critically important because they suggest how the users of such research should evaluate it. For instance, if a research article includes full disclosures of authorship rights and responsibilities, critical readers can look for evidence that the researchers' sponsors used contracts or other mechanisms to establish control over outcomes or messaging.

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## The Structure and Funding of ILSI and TERA

ILSI is one of the oldest and most prominent organizations established by the chemical industry to influence scientific conclusions about agencies' risk assessment policies. Founded in 1978 by Coca-Cola, Pepsi Cola, General Foods, Kraft, and Procter & Gamble, ILSI focuses on science policy decisions that may affect the food, agriculture, and pharmaceutical industries. ILSI's membership remains limited to large corporations active in the food and drug industries.<sup>14</sup> It is governed by a board of trustees, half of whom are drawn from member companies, including Coca-Cola, Monsanto, and other large international corporations.<sup>15</sup> ILSI functions as the parent organization for 14 worldwide branches that are active in science policy in their respective regions and a Research Foundation. ILSI also supervises its separately chartered sister organization, the Health and Environmental Sciences Institute (HESI).

HESI organizes conferences and committees that publish reports on policies that run the gamut of risk assessment practice, from hazard identification to dose-response modeling to exposure science. Representatives from the chemical industry chair many of HESI's committees.<sup>16</sup> Committee members include academics and even government scientists who work on regulatory programs that affect ILSI-HESI corporate funders.<sup>17</sup> The HESI-sponsored interactions between government scientists and the entities that they regulate occur outside of the established regulatory process, potentially giving regulated entities exceptional influence over government policies. Industry often claims that the products of these interactions represent a scientific "consensus" even when independent academics and scientists from public interest organizations are conspicuously absent.<sup>18</sup>

In 2010 ILSI North America brought in \$3.4 million in revenue, HESI received another \$3.5 million and ILSI itself received \$3.2 million.<sup>19</sup> (This financial information was drawn from publicly available IRS documents that do not require, and thus did not provide, any information about which organizations provided the funding.) ILSI's lack of clear disclosure of funding sources is problematic because the bulk of its funding presumably comes from its corporate members, which can lead to the sponsorship bias issues described above.

TERA was founded in 1995 and primarily focuses on conducting risk assessments for its clients, which include chemical manufacturers, their customers, and a handful of government agencies. TERA also operates the Alliance for Risk Assessment (ARA), a closely related organization that has organized conferences and workshops regarding new risk assessment methods.<sup>20</sup> ARA recently convened a series of workshops to address the suggestions regarding the future of risk assessment the National Research Council made in its 2009 *Science and Decisions: Advancing Risk Assessment* document (a.k.a. the "Silver Book").<sup>21</sup> EPA and other government agencies are among sponsors that include chemical manufacturers and industry trade groups but do not include public interest groups or independent science organizations.<sup>22</sup>

TERA is governed by a ten-person board that includes industry representatives and academics. Directors serve three-year terms with the exception of Michael Dourson, founder and president, who is a perpetual member of the board. Prior to founding TERA, Dr. Dourson spent 15 years at EPA where he worked on several toxics projects, including the creation of EPA's Integrated Risk Information System. Dr. Dourson has also worked with the National Academy of Sciences and is a member of both EPA's and California's science advisory boards.

TERA had gross revenue of about \$2.4 million in 2010, 32 percent of which came directly from industry.<sup>23</sup> Government agencies, including EPA, the Food and Drug Administration, and the National Institute for Occupational Safety and Health accounted for approximately 40 percent. "Non-profit" sources, including the affiliated ARA, represented approximately 30 percent.<sup>24</sup> Those non-profit sources are often dependent upon chemical manufacturer support. For example, TERA convened a panel regarding the carcinogenicity of hexavalent chromium that was funded by the non-profit Aerospace Industries Association (AIA). AIA is in turn funded by corporations that rely extensively on hexavalent chromium in their manufacturing, including Boeing and Alcoa. Additionally, at least some of TERA's government funding has come not from EPA or other agencies charged with protecting public health, but from agencies like the Department of Defense, which relies on toxic chemicals and has millions of dollars of potential liabilities arising out of those uses.<sup>25</sup>

Two case studies of recent ILSI and TERA advocacy make clear the goals and implications of their advocacy of science policies that favor their corporate sponsors.

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## Alachlor, Acetochlor and the Weakening of State Protection

Alachlor and acetochlor are popular herbicides used to control weeds on millions of acres of American farmland, particularly in corn, wheat, and soybean fields. Both chemicals are banned in the European Union but their use is on the rise in the United States because the broadleaf weeds and grasses they target are developing resistances to other herbicides.<sup>26</sup> Alachlor is the second most used herbicide in the United States.<sup>27</sup> The resurgence of these chemicals, as well as their prevalence in the drinking water supplies of agricultural states, has led some state agencies to institute tighter regulations on the herbicides and the chemicals they become as they break down in the environment. While the states were developing improved safety standards to protect public health and the environment, Dow and Monsanto, the manufacturers of these chemicals, funded a panel of scientists to review toxicological studies and derive their own “safe” levels of exposure.

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The panel was organized through TERA and included scientists employed by government agencies tasked with ensuring pesticide and herbicide safety.<sup>28</sup> The panel consisted of five TERA employees, including its president and director, three government scientists, and a professor. The government scientists were from EPA, the Maine Department of Agriculture, and the California Environmental Protection Agency, while the professor was from the University of Florida. The representatives from Maine and EPA refused the travel expenses and honoraria offered by TERA.<sup>29</sup> The University of Florida professor and representative from the California Environmental Protection Agency accepted the offered funds.

In addition to being effective herbicides, alachlor and acetochlor pose environmental and human health hazards. Acute exposures, like those suffered by farmworkers who spread the chemicals or work in the fields after they have been applied, can cause skin and eye irritation. People who live near agricultural lands are similarly exposed because wind disperses the herbicides before they are absorbed into the soil or washed off into nearby waterways that serve as sources of drinking water. Chronic exposure to the chemicals can lead to cancer or endocrine disruption. Scientists have linked long-term exposures to liver, kidney, and spleen damage.<sup>30</sup>

Both chemicals are also toxic to animals. Acetochlor, for instance, affects development cycles in aquatic species, resulting in accelerated metamorphosis in amphibians and changes in gene expression and brain function of minnows.<sup>31</sup> Changes in the mortality of species lower on the aquatic food chain can rapidly accelerate up the chain and disrupt entire ecosystems.

To make matters worse, both acetochlor and alachlor break down into degradates that are also toxic to human health and the environment. The degradates alachlor-ESA, alachlor-OXA, acetochlor-ESA, and acetochlor-OXA are even more prevalent in water supplies than their parent chemicals and are cause for significant concern for some scientists and regulators because of their potential health effects. A 1994 study of acetochlor and similar herbicides in 12 Midwestern states found alachlor-ESA in all 104 surface water samples tested.<sup>32</sup>

That same study detected alachlor-ESA in almost two thirds of groundwater samples.

EPA has set some regulatory limits on alachlor and acetochlor, but it has also allowed new and increased uses of acetochlor, and has decided not to regulate their degradates. These decisions at the federal level, along with the pervasiveness of the degradates in drinking water in agricultural states and emerging research concerning toxicity and carcinogenicity of the parent chemicals, spurred Minnesota and Wisconsin to establish their own limits on some of the degradates. (See text box). In 2009, shortly after these states began regulating, TERA's subsidiary ARA organized a panel of scientists to review toxicological data and existing studies to derive their own reference doses for the chemicals. Monsanto and Dow provided direct financial support to the panel and also paid TERA for organizing the panel and facilitating the workshop.

### Pesticide Regulations at the State Level

The Minnesota Department of Health established drinking water standards limiting acetochlor-ESA and -OXA. Wisconsin's Natural Resources Defense Board successfully established a limit for alachlor-ESA in groundwater in 2007 after an earlier effort was scuttled by a legislative committee for failing to acquiesce in Monsanto's demand that they be allowed to fund and include their own study in the regulatory process. Wisconsin's regulatory limit ended up relying on Monsanto sponsored research anyway since it is one of the few entities that has studied the degradates at all. While both states were ultimately successful in setting standards for degradates, the herbicide manufacturers blunted Minnesota's 2007 attempt to set its surface water standard for acetochlor. At the end of the rulemaking process, the regulatory limit had been raised to more than double the initial proposal and was based on at least three studies conducted by Monsanto. Dow and Monsanto strongly opposed the states' pursuit and implementation of these standards because they will ultimately restrict how much of the herbicides can be used, and thus sold, in regulating states.

The TERA panel reviewed several studies that suggested degradates pose serious health risks, including the Monsanto drinking water study that Wisconsin regulators used to set the state's standard for alachlor-ESA. However, the panel ultimately recommended Reference Doses (RfDs) for alachlor-ESA and -OXA that were based on more recent studies conducted by Monsanto that administered the chemical in the animals' food. The panel's rationale was that the more powerful adverse effects noticed in the drinking water study could be attributed to dehydration. The panelists, as well as the industry authors of the drinking water studies, speculated that the animals were dehydrated because they found the dosed water unpalatable.<sup>33</sup> So, instead of the drinking-water studies, the panelists used feed-based studies, including two conducted by Central Toxicology Laboratory, to recommend RfDs for acetochlor-ESA and -OXA. Using just these four industry-sponsored dietary studies, the TERA panel developed RfDs that would lead to drinking water standards significantly higher than those the states deemed adequately protective of human health. The panel recommended RfDs of 5600ppb for alachlor-ESA and 1400ppb for both acetochlor-ESA and -OXA. Wisconsin adopted a standard of 20ppb for alachlor-ESA while Minnesota set standards for acetochlor-ESA and -OXA at 300ppb and 100ppb, respectively. The TERA panel's recommendations were published in *Regulatory Toxicology and Pharmacology*, a journal with strong industry ties.<sup>34</sup>

**Table 1: The TERA Panel's Recommended Values Far Exceed Those Set by States**

	<b>Alachlor</b>	<b>Alachlor ESA</b>	<b>Alachlor OXA</b>	<b>Acetochlor</b>	<b>Acetochlor ESA</b>	<b>Acetochlor OXA</b>
<b>EPA</b>	2ppb	None	none	Restrictions on crop types.	None	None
<b>Wisconsin</b>		20ppb		7ppb		
<b>Minnesota</b>		70ppb (Risk Assessment Advice)		3.6ppb	300ppb	100ppb
<b>North Carolina</b>		0.4ppb				
<b>TERA</b>		5600ppb <sup>35</sup>	5600ppb		1400ppb	1400ppb

When EPA's standard RfD to drinking water conversion is applied to the panel's recommendations it becomes clear that those recommendations are significantly less protective of public health than the standards adopted by the states.<sup>36</sup> The panel's recommendation for alachlor-ESA, for instance, is 280 times higher than the standard Wisconsin adopted.

## Risk21 and the Co-optation of the National Academies' Silver Book

Drug licensing, pesticide registration, and toxic chemical regulation are shaped by the complex science of toxicological risk assessment. As just one example of the complications involved in the practice of risk assessment, scientists can use a variety of methods to account for uncertainties when they extrapolate chemicals' potential low-dose effects on humans from high-dose studies conducted with animals. Depending on the method used, regulatory decisions about how best to protect the public can vary widely. In order to address these sorts of problems and with an eye toward protecting human health, government risk assessors use standard assumptions and guidelines that they develop through public processes and with the advice of experts from academia, private industry, NGOs, and other government agencies. ILSI has a history of trying to preempt government-driven policy development through establishment of its own "tripartite" committees.

A recent example of an ILSI-HESI committee that is working to reshape federal risk assessment policies by building close relationships with government scientists is the ongoing Risk Assessment in the 21st Century Technical Committee (RISK21). Highlighted by a well-attended conference in January 2011, RISK21 has brought together more than 100 scientists and regulators, the majority of whom are representatives from the chemical industry.<sup>37</sup> RISK21 is co-chaired by Syngenta's principal scientist and Dr. Alan Boobis, a professor at the Imperial College London who was previously a member of ILSI's board of trustees and has authored numerous industry-sponsored articles. Pesticide Action Network Europe (PANE) extensively researched Dr. Boobis' publishing history and ties to ILSI, and concluded that he is clearly biased toward the chemical industry, stating: "Alan Boobis was chair of the ILSI board of trustees and a fierce defender of industry's agenda in his work."<sup>38</sup> PANE further determined that a list of his "publications reads like a list of ILSI opinions and ILSI meeting reports," which "gives the impression that Boobis is a ghost writer for ILSI."<sup>39</sup>

In addition to 19 chemical manufacturers and affiliated organizations RISK21 participants include the Consumer Product Safety Commission, the Department of Agriculture, the Environmental Protection Agency, the Food and Drug Administration, and the National Institutes of Health.<sup>40</sup> RISK21 has four sub-teams working on agendas that are closely related to important and controversial areas in the development of risk assessment practice.

- **The Exposure Science Sub-team:** Accurately determining the extent to which certain populations are exposed to toxic chemicals is of critical importance to both risk assessment and risk management, particularly in terms of protecting those that might be more susceptible to toxic effects, such as children and the elderly. The RISK21 exposure team, led by a representative from the National Institutes of Health working closely with a scientist from Arysta, a large chemical manufacturer, works to characterize exposure to chemicals with an emphasis on "real-world" exposures and a "data-driven" approach. An exclusive emphasis on existing exposures is minimally protective of

human health because it fails to account for potential new or unpredicted exposure scenarios.<sup>41</sup> Choosing whose “real-world” exposures are relevant to regulatory decisions is also an important exercise, given the problem of toxic hot spots near Superfund sites, power plants, and chemical facilities.

- ***The Dose-Response Sub-team:*** Dose-response science attempts to determine the relationship between exposure to a chemical and specific toxic effects. Most toxicological research involves dosing animals with a chemical, measuring the response, and then extrapolating from that data human-relevant dose-response curves. The relationship is governed by complex biological processes and is one of the most important aspects of risk assessment. The RISK21 dose-response team, led by representatives from Dow and University of Nebraska, aims to quantitatively incorporate dose-response information into risk assessments with a strong focus on mode of action analysis.<sup>42</sup> Focusing solely on mode of action analysis has the potential to over-emphasize certain obvious chemical effects in the body while losing sight of the overall toxic effects caused by exposure and highly complex biological processes.<sup>43</sup>
- ***The Integrated Evaluation Strategies Sub-team:*** “Integrated evaluation strategies” is a catch-all for HESI’s push away from current risk assessment practices, including animal testing, and toward a heavy reliance on *in vitro* testing and rapid assessments of individual chemicals. Other expert organizations, like the National Academies’ National Research Council have acknowledged that the new techniques are not yet reliable and are “at least a decade away.”<sup>44</sup> An EPA scientist and a former Syngenta scientist lead the RISK21 team, which is developing a framework that relies on new technologies for evaluating the toxicity of chemicals that is “more accurate and utilizes fewer resources than the current paradigm.”<sup>45</sup> Forcing a reliance on these technologies to save time and resources would result in potentially drastic adverse effects on human health and the environment because they can oversimplify the biological processes that are affected by the chemicals’ toxic effects.<sup>46</sup>
- ***The Cumulative Risk Sub-team:*** One of the most important, and most frequently overlooked, aspects of risk assessment, cumulative risk science attempts to account for the wide variety of factors that contribute to the toxic effects that result from chemical exposure. The RISK21 team is led by scientists at ExxonMobil and the University of Milan and focuses on creating a method for assessing health risks of combined exposures to multiple chemicals in the context of other stressors. The RISK21 team downplays scientists’ ability to determine whether multiple stressors combine at levels relevant to humans. In contrast, the NAS recommends that EPA “draw on other approaches, including those from ecologic risk assessment and social epidemiology, to incorporate interactions between chemical and nonchemical stressors in assessments.”<sup>47</sup> Congress recognized the importance of cumulative exposures, requiring EPA to consider cumulative risk when determining pesticide tolerances under the Food Quality Protection Act.<sup>48</sup>

## Current HESI Committee Leadership

### Current HESI Project Committees

#### Distinguishing Adverse from Non-Adverse/Adaptive Effects

*sanofi-aventis, Dow, Colorado State*

#### Animal Alternatives in Environmental Risk Assessment

*Procter & Gamble, L'Oréal*

#### Development of Methods for a Tiered Approach to Assess the Bioaccumulation of Chemicals

*Dow, USEPA*

#### Biomarkers of Nephrotoxicity

*Pfizer, Newcastle University, John Moores University, sanofi-aventis*

#### HESI Project Committee on Imaging for Translational Safety Assessment

*Duke University, GlaxoSmithKline*

#### The Relevance and Follow-Up of Positive Results in In Vitro Genetic Toxicity (IVGT) Testing

*Dow, sanofi-aventis*

#### Vaccines and Adjuvants Safety

*Sanofi, Medicines Evaluation Board (CBG-MEB)*

#### Evaluating Causality in Epidemiologic Studies

##### Subcommittee

*Dow, USEPA*

#### Frameworks for Alternative Chemical Assessment and Selection of Safer, Sustainable Alternatives

*Dow*

### Current HESI Technical Committees

#### Cardiac Safety

*GlaxoSmithKline Safety Assessment, College of Veterinary Medicine, Cornell University, U. S. Food and Drug Administration, Data Sciences International (DSI), Lilly Research Laboratories, AstraZeneca*

#### HESI Global Developmental and Reproductive Toxicology (DART)

*Sanofi, AstraZeneca*

#### HESI Application of Genomics to Mechanism-Based Risk Assessment

*Pfizer, National Institute of Environmental Health Sciences*

#### HESI Immunotoxicology Technical Committee (ITC)

*Pfizer, Amgen*

#### Protein Allergenicity Technical Committee (PATC)

*E.I. DuPont de Nemours and Company, Syngenta, Academic Medical Center, Amsterdam University*

#### Risk Assessment in the 21st Century

*Syngenta, Imperial College London*

Government scientists' participation in these committees and meetings allows HESI to make claims to scientific consensus where none actually exists. Government scientists' involvement with HESI and its members is inappropriate because they are engaging in potentially far-reaching policy discussions without the public notice and transparency that would attend similar discussions if pursued according to the rules that exist to govern these kinds of interactions and protect the public—for example, the Federal Advisory Committee Act, which places great emphasis on open meetings, public involvement, and reporting of committee activities.<sup>49</sup> Because the interactions between government

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scientists and industry representatives fostered by groups like ISLI-HESI and TERA-ARA generally occur before any Notice of Proposed Rulemaking, they are not recorded on any docket and are thus not made known to the public. Even more troubling is that government scientists, to the extent to which they are influenced by their interactions with industry in these pre-decisional discussions, may be unduly predisposed to favor industry during the actual rulemaking process.

## Recommendations

The Obama Administration has repeatedly reaffirmed its commitment to running a clean and transparent government. President Obama's 2009 scientific integrity memorandum states his aspirations for protecting government science from undue influences.<sup>50</sup> Shortly after its publication, EPA Administrator Lisa Jackson published her own memorandum pledging transparency with respect to scientific analysis at the Agency.<sup>51</sup> Unfortunately, the administration's initiatives have had mixed success. As this report indicates, serious problems can occur when EPA scientists interact with industry scientists in circumstances that industry spokespeople characterize as "partnerships" with government. Portraying such discussions as balanced collaboration appears to be an attempt to whitewash ends-oriented deliberations that have as their primary goal the weakening of controls on toxic chemicals.

So that it can attract and retain the best scientists, the government should encourage agency scientists to participate in events organized by private sector scientific organizations that do not attempt to influence government policy in ways that favor their industry financial supporters. Such events allow government scientists to remain current on the latest developments in research and interact with other scientists in their field without exploiting their status as civil servants to make any recommendations seem less biased. For instance, the American Association for the Advancement of Science hosts a yearly forum on Science & Technology Policy.<sup>52</sup>

Chemical manufacturers have taken advantage of agency scientists' interest in professional development by fostering the growth of organizations like ILSI and TERA, which blur the lines between professional development and policy advocacy. For instance, after NAS published the Silver Book both ILSI and TERA set up committees (RISK21, ARA's Beyond Science and Decisions) to partner with agency scientists in order to increase their influence over future federal agency risk assessment practices. Government scientists' participation in such activities undermines EPA's independence and objectivity.

Government scientists need not turn to industry and its affiliates for professional development. Professional societies and organizations such as the American Association for the Advancement of Science provide numerous opportunities to engage with colleagues in relevant fields.<sup>53</sup> And EPA policies designed to protect against individual bias on the part of agency employees should be revised to incorporate stronger protections against undue industry influence when agency employees are pursuing professional development opportunities.<sup>54</sup>

### ***Guaranteeing Transparency, Eliminating Conflicts, Balancing for Bias***

The Federal Advisory Committee Act (FACA) sets out the basic legal framework that safeguards the integrity of federal agencies' consultation with outside experts.<sup>55</sup> FACA's findings declare that "the public should be kept informed with respect to ... [the] purpose, membership, [and] activities."<sup>56</sup> Although FACA only applies to committees established or controlled by government agencies, the principles it sets forth indicate the huge gap between what can rightly be called a collaboration among stakeholders and the biased processes that ILSI and TERA sponsor. Those principles include:

- Committee membership must be balanced for bias, taking into account "a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and function of the advisory committee."<sup>57</sup>
- Before accepting appointment, potential committee members should fully disclose their other affiliations.<sup>58</sup>
- FACA committee members are subject to federal ethics and conflict of interest laws.<sup>59</sup>
- Committee meetings must be open to the public.

The National Academies endorse similar principles in the rules governing their committees.<sup>60</sup> The international health community has also taken steps to preserve the integrity of its committee deliberations. The World Health Organization (WHO) requires disclosures to be made before scientists can participate in meetings and places great emphasis on disclosing the relationship between the administrative unit or organization with which a scientist is interacting and any commercial entities.<sup>61</sup> WHO committees foster transparency by inviting neutral outside scientists to observe the committee proceedings. WHO also requires disclosures to be made before scientists can participate in advisory meetings, including "any interests that could constitute a *real, potential or apparent* conflict of interest, with respect to his/her involvement in the meeting or work, between a) commercial entities and the participant personally, and b) commercial entities and the administrative unit with which the participant has an employment relationship." (emphasis added)<sup>62</sup> The stipulation that scientists must avoid potential or apparent conflicts of interest is critical. The ILSI and TERA activities described above do not meet this appropriately rigorous standard, much less the threshold requirements of balancing advisory panels for bias and conducting committee deliberations in public.

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We urge EPA and other agencies to take steps to put an immediate end to these collaborations that benefit industry and undermine trust in government. Specifically:

- EPA and other government agencies should withdraw their employees from participation in activities sponsored by ILSI and TERA immediately.
- Government agencies should adopt ethics rules that:
  - Prohibit government scientists from co-authoring articles with industry-sponsored experts regarding matters that may be considered by their respective agencies, including individual toxicological risk assessments;
  - Prohibit government employees from participating in private sector activities that are designed to influence a decision under the jurisdiction of the employer agency if such expert will be asked to endorse the final work product produced by the group.
- Government agencies should establish programs to ensure that these ethics standards are being met, including review by trained ethics officers of individual requests to undertake extracurricular activities; limits on the time spent on such activities; and affirmative recommendations regarding appropriate private sector organizations. In formulating lists of qualified organizations, agencies should take into consideration standards for balance, transparency, and conflict of interest used by professional societies when they accredit entities that provide continuing education in their respective fields.

## Endnotes

- <sup>1</sup> Prior to enacting TSCA (15 USC §§ 2601-2692), Congress passed the Federal Hazardous Substances Act (FHSAs) (15 USC §§ 1261-1278) to regulate “any substance or mixture of substances … [that] may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.” FHSAs, however, explicitly exempted pesticides, food, drugs, and cosmetics.
- <sup>2</sup> See Protecting the Public from BPA: An Action Plan for Federal Agencies, Center for Progressive Reform, 2012. [http://www.progressivereform.org/articles/BPA\\_Action\\_Plan\\_1202.pdf](http://www.progressivereform.org/articles/BPA_Action_Plan_1202.pdf).
- <sup>3</sup> Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(3)(A)(i).
- <sup>4</sup> Justin E. Bekelman, Yan Li, & Cary P. Gross, “Scope and Impact of Financial Conflicts of Interest in Biomedical Research,” *JAMA* 289 (2003): 454.
- <sup>5</sup> See, e.g., International Committee of Medical Journal Editors, [http://www.icmje.org/ethical\\_4conflicts.html](http://www.icmje.org/ethical_4conflicts.html).
- <sup>6</sup> EPA Risk Assessment Glossary, <http://www.epa.gov/risk/glossary.htm#r>.
- <sup>7</sup> For a full discussion of the “funding effect,” see Thomas McGarity & Wendy Wagner, *Bending Science: How Special Interests Corrupt Public Health Research* 24, Harvard U. Press (2008).
- <sup>8</sup> Deborah E. Barnes & Lisa A. Bero, “Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions,” *JAMA* 279 (1998): 1566.
- <sup>9</sup> Frederick S. vom Saal & Claude Hughes, “An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A Shows the Need for a New Risk Assessment,” *Environmental Health Perspectives* 113 (2005): 926.
- <sup>10</sup> Leonard I. Lesser et al., “Relationship between Funding Source and Conclusion among Nutrition-Related Scientific Articles,” *PLoS Medicine* 4 (2007): 5.
- <sup>11</sup> Rosenstock L, Lee LJ. Attacks on science: The risks to evidence based policy. Am J Public Health 2002;92:14-8; Fagin D, Lavelle M. Center for Public Integrity. Deception: how the chemical industry manipulates sciences, bends the law and threatens your health. Seacaucus, NJ: Birch Lane Press, 1997:57.
- <sup>12</sup> Bending Science, *supra* note 7.
- <sup>13</sup> The ways in which study sponsors influence the outcomes of studies are often entirely legal which has led some commentators to propose an independent coordinating organization that would control study design and parameters. David C. Volz and Kevin C. Elliott, *Mitigating Conflicts of Interest in Chemical Safety Testing*, *Environ. Sci. Technol.* (July 27, 2012). <http://pubs.acs.org/doi/full/10.1021/es3028296>.
- <sup>14</sup> ILSI Q&A, [http://www.ilsi.org/Pages/ILSI\\_QA.aspx](http://www.ilsi.org/Pages/ILSI_QA.aspx) (“ILSI members are companies from the food, agricultural, chemical, pharmaceutical, and biotechnology and supporting industries.”). See also, ILSI North America 2010 IRS Form 990, <http://www.guidestar.org/organizations/52-2337019/ilsi-health-environmental-sciences-institute.aspx#idReportSectionStatus>.
- <sup>15</sup> The full list of companies represented on the ILSI board as of 2011: Nestle, Kraft Foods, sanofi-aventis, Coca-Cola, Archer Daniels Midland, Kellogg’s Europe, Monsanto, Lotte Company, Kikkoman corporation, Pepsico, Groupe Danone, General Mills, and Planitox, [http://www.ilsi.org/Features/ILSI\\_AR\\_2010\\_Web.pdf](http://www.ilsi.org/Features/ILSI_AR_2010_Web.pdf).
- <sup>16</sup> See, e.g., HESI Project Committees, <http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=3296>.
- <sup>17</sup> *Id.*
- <sup>18</sup> See, e.g. HESI’s Agricultural Chemical Safety Assessment (ACSA) Technical Committee: “The mission of the HESI Agricultural Chemical Safety Assessment (ACSA) Technical Committee was to develop a consensus across sectors (government, academia, and industry) on a credible and viable testing approach for assessing the safety of crop protection chemicals.” (<http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=3444>).
- <sup>19</sup> ILSI North America 2010 IRS Form 990, <http://www.guidestar.org/organizations/52-2337019/ilsi-health-environmental-sciences-institute.aspx#idReportSectionStatus>.
- <sup>20</sup> ARA Membership document, available at <http://www.allianceforrisk.org/ARA%20Membership.doc>.
- <sup>21</sup> Alliance for Risk Assessment, Beyond Science and Decisions: From Problem Formulation to Dose-Response Assessment, [http://www.allianceforrisk.org/ARA\\_Dose-Response.htm](http://www.allianceforrisk.org/ARA_Dose-Response.htm).
- <sup>22</sup> Alliance for Risk Assessment, Dose Response Sponsors, [http://www.allianceforrisk.org/ARA\\_Dose-Response\\_Sponsors.htm](http://www.allianceforrisk.org/ARA_Dose-Response_Sponsors.htm).
- <sup>23</sup> TERA 2010 Annual Report, <http://tera.org/about/2010%20Annual%20Report.pdf>; TERA Funding Sources, <http://tera.org/about/FundingSources.html>.
- <sup>24</sup> *Id.*
- <sup>25</sup> See TERA’s work on Perchlorate. <http://www.tera.org/art/Perchlorate/index.html>.
- <sup>26</sup> EU Phase-out for Acetochlor: <http://news.agropages.com/News/NewsDetail--6107.htm>.
- <sup>27</sup> Delaware Health and Social Services, Department of Public Health, Frequently Asked Questions: Alachlor, <http://dhss.delaware.gov/dph/files/alachlorfaq.pdf>.
- <sup>28</sup> Report of a Peer Workshop on Toxicological Assessment and Development of Reference Doses for Acetanilide Degradates, <http://www.tera.org/ART/Degradates/Acetanilides%20Meeting%20Report.pdf>.
- <sup>29</sup> Bernard Gadagbui, Andrew Maier, Michael Dourson, Ann Parker, Alison Willis, John P. Christopher, Lebelle Hicks, Santhini Ramasamy, & Stephen M. Roberts, Derived Reference Doses (RfDs) for the Environmental Degradates of the Herbicides Alachlor and Acetochlor: Results of an Independent Expert Panel Deliberation, *Regulatory Toxicology and Pharmacology*, Volume 57, Issue 2, 220-234.
- <sup>30</sup> EPA, Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Acetochlor, [http://www.epa.gov/opprrd1/REDs/acetochlor\\_tred.pdf](http://www.epa.gov/opprrd1/REDs/acetochlor_tred.pdf).
- <sup>31</sup> Li, et al., Effects of Exposure to Acetochlor on the Expression of Thyroid Hormone Related Genes in Larval and Adult Rare Minnow (Gobiocypris rarus). <http://www.ncbi.nlm.nih.gov/pubmed/19577311>.
- <sup>32</sup> Aga, D.S., Thurman, E.M., and Pomes, M.L., 1994, Determination of alachlor and its ethane-sulfonic acid metabolite in water by solid-phase extraction and enzyme-linked immunosorbent assay: Analytical Chemistry, v. 66, no. 9, p. 1495-1499.
- <sup>33</sup> Derived Reference Doses (RfDs) for the Environmental Degradates of the Herbicides Alachlor and Acetochlor: Results of an Independent Expert Panel Deliberation, *supra*, note 29.
- <sup>34</sup> *Id.*; Letter from Center for Science in the Public Interest, *Re: Regulatory Toxicology and Pharmacology*, November 19, 2002, [http://www.cspinet.org/new/pdf/final\\_letter\\_academic\\_press\\_rtp.pdf](http://www.cspinet.org/new/pdf/final_letter_academic_press_rtp.pdf).
- <sup>35</sup> Lebelle Hicks, Maine Board of Pesticides Control, Presentation, <http://www.mwua.org/wp-content/uploads/2011/09/AgriculturalPesticidesGWContaminatiOn-Hicks-web.pdf>.

<sup>36</sup> EPA assumes that the average person weighs 70kg and drinks 2 liters of water a day. EPA also assumes that drinking only accounts for 20 percent of an individual's exposure. Using TERA's alachlor-ESA RfD as an example:

$$\begin{aligned} .8\text{mg/kg-day} \times 70\text{kg} &= 56\text{mg/day} \\ 56 / 2\text{L} &= 28\text{mg/liter} \\ 28 \times .2 &= 5.6 \text{ mg/liter or } 5600\text{ppb} \end{aligned}$$

EPA, 2012 Edition of the Drinking Water Standards and Health Advisories, <http://water.epa.gov/action/advisories/drinking/upload/dwstandards2012.pdf>.

<sup>37</sup> HESI – Risk Assessment in the 21<sup>st</sup> Century, <http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=3492>.

<sup>38</sup> Pesticide Action Network Europe, A Toxic Mixture? Industry bias found in EFSA working group on risk assessment for toxic chemicals. <http://www.pan-europe.info/Resources/Reports/PANE%20-%202011%20-%20A%20Toxic%20Mixture%20-%20Industry%20bias%20found%20in%20EFSA%20working%20group%20on%20risk%20assessment%20for%20toxic%20chemicals..pdf>.

<sup>39</sup> *Id.*

<sup>40</sup> RISK21 2011-2012 Participating Organizations: Applied Pharmacology & Toxicology, Inc., BASF, Bayer CropScience, Chemical Regulation Directorate, Craig Barrow Consulting, CXR Biosciences, Dow Corning Corporation, DuPont, European Commission, Joint Research Center, European Center for the Validation of Alternative Methods, ExxonMobil Biomedical Sciences, Inc., Gradient Corporation, Hamner Institutes of Health Sciences, Health Canada, Humane Society of the United States, Imperial College London, Indiana University School of Medicine, Johns Hopkins University, L'Oréal Corporation, Medical College of Wisconsin, Michigan State University, Monsanto Company, National Center for the Replacement, Refinement, and Reduction of Animals in Research (NC3Rs, UK), National Institutes of Health, Pacific Northwest National Laboratory, Parker Doe Partnership, Radboud University Nijmegen, Swiss Federal Office of Public Health, Syngenta, Ted Simon Toxicology, The Coca-Cola Company, The Dow Chemical Company/Dow AgroSciences, The Procter & Gamble Company, University of Aarhus, University of Basel, University of California, Los Angeles, University of Florida, University of Guelph, University of Kansas, University of Michigan, University of Milan, University of Nebraska Medical Center, University of Ottawa, University of Texas Houston, University of Washington Medical Center, US Consumer Product Safety Commission, US Department of Agriculture, US Environmental Protection Agency, US Food and Drug Administration, Utrecht University, and Virginia Commonwealth University. <http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=3492>.

<sup>41</sup> RISK Assessment for the 21st Century Exposure Subteam Update, [http://www.hesiglobal.org/files/public/Committees/Risk21/Jan\\_2011\\_Workshop/SargentPrez.pdf](http://www.hesiglobal.org/files/public/Committees/Risk21/Jan_2011_Workshop/SargentPrez.pdf).

<sup>42</sup> RISK21, [http://www.hesiglobal.org/files/public/Committees/Risk21/Jan\\_2011\\_Workshop/CohenPrez.pdf](http://www.hesiglobal.org/files/public/Committees/Risk21/Jan_2011_Workshop/CohenPrez.pdf).

<sup>43</sup> See comments by Richard Denison at *Systems Biology-Informed Risk Assessment*, National Academies, Emerging Science for Environmental Health Decisions (June 15, 2012) <http://nas-sites.org/emergingscience/workshops/omics-informed-risk-assessment/systems-biology-informed-risk-assessment-presentations/>.

<sup>44</sup> NAS, Science and Decisions (Silver Book), at 4.

<sup>45</sup> HESI Workshop Synopsis, [http://www.hesiglobal.org/files/public/Committees/Risk21/Jan\\_2011\\_Workshop/Risk21WkshpSynopsis.pdf](http://www.hesiglobal.org/files/public/Committees/Risk21/Jan_2011_Workshop/Risk21WkshpSynopsis.pdf).

<sup>46</sup> *Id.*

<sup>47</sup> RISK Assessment for the 21st Century (RISK21): Cumulative Risk Assessment Sub-Group, [http://www.hesiglobal.org/files/public/Committees/Risk21/Jan\\_2011\\_Workshop/MorettoPrez.pdf](http://www.hesiglobal.org/files/public/Committees/Risk21/Jan_2011_Workshop/MorettoPrez.pdf); NAS, *Science and Decisions* (Silver Book), at 286.

<sup>48</sup> Food Quality Protection Act of 1996, Public Law 104-70, § 405.

<sup>49</sup> Federal Advisory Committee Act (FACA) of 1972, Public Law 92-463, 5 U.S.C. App. 2.

<sup>50</sup> President Obama, Scientific Integrity, March 9, 2009, <http://www.whitehouse.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09>.

<sup>51</sup> Administrator Lisa Jackson, Memo to EPA Employees: Transparency in EPA's Operations, April 23, 2009, <http://blog.epa.gov/administrator/2009/04/24/memo-to-epa-employees-transparency-in-epas-operations/>.

<sup>52</sup> AAAS Forum on Science & Technology Policy, <http://www.aaas.org/spp/rd/forum/>.

<sup>53</sup> The American Association for the Advancement of Science. <http://www.aaas.org/>.

<sup>54</sup> See, generally, Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR 2635. (Restrictions on receipt of gifts and compensation for outside activities); U.S. Environmental Protection Agency Scientific Integrity Policy, [http://www.epa.gov/osa/pdfs/epa\\_scientific\\_integrity\\_policy\\_20120115.pdf](http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf).

<sup>55</sup> Federal Advisory Committee Act, *supra*, note 49.

<sup>56</sup> 5 USC Appendix - Federal Advisory Committee Act § 2, 01/02/01, [http://www.gsa.gov/graphics/ogp/with\\_annotations\\_R2G-b4T\\_0Z5RDZ-i34K-pR.doc](http://www.gsa.gov/graphics/ogp/with_annotations_R2G-b4T_0Z5RDZ-i34K-pR.doc).

<sup>57</sup> The Federal Advisory Committee Act (FACA) Brochure, General Services Administration, <http://www.gsa.gov/portal/content/101010>.

<sup>58</sup> *Id.*

<sup>59</sup> See, e.g., 18 USC § 203 ("Whoever, otherwise than as provided by law for the proper discharge of official duties, directly or indirectly—

(1) demands, seeks, receives, accepts, or agrees to receive or accept any compensation for any representational services, as agent or attorney or otherwise, rendered or to be rendered either personally or by another— . . .

(B) at a time when such person is an officer or employee . . . in any agency of the United States,

in relation to any proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which the United States is a party or has a direct and substantial interest, before any department [or] agency."

<sup>60</sup> The National Academies, Policy On Committee Composition And Balance And Conflicts Of Interest For Committees Used In The Development Of Reports May 12, 2003, [http://www.nationalacademies.org/coi/bi-coi\\_form-0.pdf](http://www.nationalacademies.org/coi/bi-coi_form-0.pdf).

<sup>61</sup> Declaration of Interests for WHO Experts, [www.who.int/occupational\\_health/declaration\\_of\\_interest.pdf](http://www.who.int/occupational_health/declaration_of_interest.pdf).

<sup>62</sup> *Id.*

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