



# **Saving Science from Politics:**

**Nine Essential Reforms of the Legal System**

By Rena Steinzor, Wendy Wagner, and Matthew Shutz

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## 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 Bauman Foundation, the Beldon Fund, and the Deer Creek Foundation for their generous support of its work in general.

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## Defending Clean Science

Sound policymaking depends on open access to unbiased science. In recent years, however, the scientific process has been polluted by politics and ideology, calling into doubt the credibility of the science and scientists that inform the regulatory process. Center for Progressive Reform Member Scholars have written extensively on the laws and regulatory policies that can help ensure researchers are free to develop, share, and debate their work without interference from special interests whose power or profits might be affected.

### Our work in this area includes:

- **Rescuing Science from Politics: Regulation and the Distortion of Scientific Research**

Edited by Wendy Wagner and Rena Steinzor  
Cambridge University Press, 2006

CPR Member Scholars with expertise in law, science, and philosophy contributed chapters to this book, exploring the ways that special interests can abuse the law to intrude on the way that scientists conduct research. Wagner and Steinzor close the book with an examination of the principles that should support any reforms aimed at protecting scientists (independence, transparency, and a public infrastructure for science) and suggest some concrete legal and regulatory changes.

- **Sequestered Science: Secrets Threatening Public Health**

by Rena Steinzor and Matthew Shutz  
<<[http://www.progressivereform.org/articles/Secrecy\\_703.pdf](http://www.progressivereform.org/articles/Secrecy_703.pdf)>>

In this White Paper, we explain how the legal system enables, and often promotes, a culture of secrecy that obscures science on the adverse effects of consumer products and toxic chemicals. Key provisions of several environmental, health, and safety laws are compared, with a focus on their disparate treatment of confidential business information. The paper also debunks several justifications typically offered to support the argument that information relevant to public health should be sequestered.

- **Strategies for Closing the Chemical Data Gap**

by John S. Applegate and Katherine Baer  
<<[http://www.progressivereform.org/articles/Closing\\_Data\\_Gaps\\_602.pdf](http://www.progressivereform.org/articles/Closing_Data_Gaps_602.pdf)>>

Following up on an earlier CPR report (“Overcoming ‘Environmental Data Gaps:’ Why What EPA Doesn’t Know about Toxic Chemicals Can Hurt,” CPR White Paper 510), we analyze the underlying causes of the gap between the legal system’s demand for information about chemicals and the existing supply of available data. We examine the relative advantages and disadvantages of a variety of ways to fill or bridge the data gap, keeping in mind the ultimate goal of protecting people and the environment.

## Executive Summary

Several years ago, a group of scholars at the Center for Progressive Reform (CPR) set out to develop legal reforms that would reshape the legal and political dynamics that determine how scientific research informs regulatory decisions. The impetus for this project was the recognition that opponents of protective regulations did not limit their objections to policy debates, but also attacked the research supporting such decisions in ways that undermine scientific integrity.

Private sponsors recruit prominent scientists to sign ghost written articles based on skewed research (as in the Vioxx episode) or try to censor research results that they do not like. Researchers face spurious claims of scientific misconduct and peer review panels lack balance or include members with blatant financial conflicts of interest. Special interests seeking to influence the policymaking debate submit studies without the underlying data that is critical to evaluating their validity or claim that information crucial to understanding a chemical's toxicity is a trade secret and must be withheld from the public. Even when companies know that exposures to their products have caused harm, they fail to file "adverse effects reports" so the problems can be investigated. These political assaults on regulatory science have already cost us dearly, delaying the battle to control climate change and prolonging government efforts to protect people and the environment.

Two years ago, we wrote a book, *Rescuing Science from Politics: Regulation and the Distortion of Scientific Research* (Cambridge 2006), which explains these phenomena and analyzes their adverse effects on the development of disinterested and complete research. *Rescuing Science* also proposed some initial ideas for how Congress, the courts, and federal agencies could restore the independence of science in the regulatory process. The book is based on three fundamental and incontrovertible principles that should guide any legal reforms designed to promote clean science: independence, transparency, and a robust public infrastructure to support research.

This white paper is the logical next step in developing concrete, workable reforms to federal law and regulation based on those broad principles. In Table 1 (next page), we recommend major changes to law and legal practice to launch a full-fledged rescue of science from politics.

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**TABLE 1.**  
**Nine Essential Reforms**

Recommendation	Problem	Reasoning/ Means of Implementation
1. Level the playing field for publicly funded and privately funded science.	Scientists conducting federally funded research must make available all of their underlying data pursuant to a statute known as the “Shelby Amendment” or the “Data Access Act.” But privately funded research used to inform the regulatory process is exempt from these requirements, creating a sharply tilted playing field for informing regulatory policymaking.	The requirements that apply to publicly funded science should also apply to privately sponsored science.
2. Require Disclosure of Sponsor-Controlled Research	Special interests routinely demand that agencies use “sound” science to make regulatory policy, which should mean that such science is conducted by disinterested researchers who are able to operate independently in designing, conducting, and reporting the results of their studies. Over the last three decades, however, the bulk of research that informs health and safety policymaking is privately sponsored. Empirical studies have shown that private sponsorship skews the outcome of the research, especially when sponsors insist on control over study design and impose pre-publication review requirements. Despite this evidence, most regulatory agencies remain ignorant of these conditions, which could affect the weight the government gives to privately sponsored studies.	Studies submitted to federal agencies should always be accompanied by statements disclosing the amount of control sponsors had over the design and publication of research. Federal officials should request this information when researchers do not submit it voluntarily, and if they are unable to obtain this information, they should explain how they assessed the reliability of the research and the weight they ultimately afforded the conclusions.
3. Strengthen adverse effects reporting	Companies that manufacture toxic chemicals have substantial amounts of information regarding the potential risks those chemicals pose to workers, the public at large, and the environment. Yet, as in the case with DuPont’s failure to disclose risks posed by perfluorooctanoic acid (PFOA, a chemical used in manufacturing Teflon), companies withhold significant amounts of information from federal regulators. EPA considered DuPont’s failure to report sufficiently serious to trigger the unusually high penalties of \$10.25 million in fines and another \$6.25 million in compulsory Supplemental Environmental Projects.	Public and private entities that become aware of potentially significant risks caused by hazardous substances in consumer products, chemicals sold in commerce or used in manufacturing, or disposed in a manner that causes human exposure must disclose any known information regarding these risks to regulatory authorities. Exposure data, research related to environmental transport, and studies on toxicogenomics must be shared. EPA should explore new methods for gathering adverse effects information that seek the assistance of the medical profession, the insurance industry, and the plaintiffs’ bar.
4. Separate science from policy	In 2007, the Department of Interior Inspector General reported on the case of Julie MacDonald, a political appointee who routinely instructed conservation biologists to change their research reports so that Endangered Species Act protections could be undermined. MacDonald is the most egregious example of a pattern of behavior in this and other federal agencies.	Scientific studies used to inform regulatory policy should be disclosed and docketed in the administrative record before the decisionmaking process begins to prevent political appointees and other interested parties from pressuring scientists to edit or distort their findings.

**TABLE 1.**  
**Nine Essential Reforms (continued)**

Recommendation	Problem	Reasoning/ Means of Implementation
5. Protect whistleblowers	Many of the worst abuses of regulatory science were brought to public attention by courageous agency employees who risked their careers in protest of the politicization of independent research. Too often, whistleblowers cannot protect themselves from harsh retaliation as a result of loopholes in existing laws.	Whistleblowers who disclose instances of interference or suppression that compromise the conduct and reporting of science used in the regulatory process must be protected from retaliation by expanding record-keeping requirements so that political interference may be detected more easily, changing the allocation of federal positions between the career and excepted service, establishing federal scientific integrity regulations, and improving and expanding existing whistleblower protections.
6. Establish a legal cause of action for harassed scientists	When epidemiologists began to prove links between inhalation of second-hand smoke and lung disease, tobacco company representatives called their superiors to question their competence. Academic scientists have been threatened with lawsuits, subpoenaed by courts, and compelled to withdraw articles submitted from publication, all without receiving legal support from their institutions.	Scientists subject to harassment, including frivolous charges of scientific misconduct or open record requests and other legal processes (e.g., subpoenas, interrogatories) that are unreasonable in scope or demand, should have the right to seek damages by filing an action in federal court.
7. Restore balance and transparency to the peer review process	Congress passed the Federal Advisory Committee Act (FACA) to ensure that when private sector parties gather in committees to advise the government, such consultations are disclosed to the public and the committees reflect a balance of views on the issues. These protections have been eroded in practice and by the courts, exempting too many peer review panels from transparency requirements and resulting in stacked advisory panels. For example, in 2002, then-Secretary of Health and Human Services Tommy Thompson re-shuffled Center for Disease Control's (CDC)'s Advisory Committee on Childhood Lead Poisoning Prevention to eliminate long-serving experts on the consequences of infant and toddler exposure, replacing them with people who had never done any work on the subject.	All members of outside committees that advise federal agencies must disclose a full suite of information about their propensity for conflicts of interest or bias. Agency efforts to screen for these biases and conflicts of interest must be subject to public notice and comment. Finally, agencies empanelling advisory committees should sharply limit their use of conflict-of-interest waivers and prohibit those with waivers from voting on committee recommendations.
8. Prevent overbroad trade secret claims from compromising public health and natural resources	When companies submit research about chemicals in commerce, they routinely stamp it "confidential business information" (CBI), sequestering even basic toxicological information from public release. EPA requires companies to provide upfront substantiation for such claims in the context of its Toxic Substances Control Act (TSCA) § 8(e) program, with the result that the number of CBI claims drops sharply.	Crucial toxicological and ecotoxicological information should be exempt from CBI claims. Any entity claiming CBI must provide upfront substantiation regarding why the protection is warranted. CBI protections should expire within five years unless a compelling case for a limited extension is made.
9. Create an environmental science registry	The FDA's clinical studies registry is designed to prevent duplication of research and prevent private sponsors from suppressing studies that do not turn out as well as they hoped - for example, by showing that a chemical could have an adverse effect on public health or the environment. No comparable disclosure requirement applies to studies conducted on the environmental effects of common chemicals or pesticides.	A registry of scientific studies modeled on the Food and Drug Administration's clinical-trials registry should be established for chemicals and pesticides.

## Introduction

Many of the statutes Congress has enacted to protect the health and safety of consumers, workers, and the environment depend in part on scientific research to inform federal agencies' implementation of their mandates. The statutes recognize that agencies sometimes must act before "definitive" science documenting the nature and scope of the harm is available because taking precautions is far preferable to allowing pollution to kill or otherwise threaten public health and natural resources. Staff at the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), National Highway Transportation Safety Administration (NHTSA), and other federal agencies are expected to gather the scientific research relevant to their decisionmaking process and then use this science to set protective standards. Inevitably, the available science is uncertain and incomplete, complicating the task of creating workable regulations that properly manage risks.<sup>1</sup> This entire process must be accomplished under the watchful eye of the regulated community and public interest organizations. As a result, the science behind agency decisions often becomes the center of vehement, if sometimes obscure, debates about how best to manage risks.

Even though the science used for regulation is highly contentious, surprisingly few guidelines govern the agencies' use of this science, particularly with respect to research sponsored by private sector entities ("private science"). Science supported by the government ("public science") is subject to a number of oversight mechanisms. But private science used for regulation is generally exempt from examination with respect to inappropriate sponsor control over decisions regarding study design and publication, scientific misconduct, data transparency, and other crucial qualities. Additionally, federal agency officials often are not required to share internal, agency-generated research and scientific analyses, and are not compelled to docket internal debate about the available science. Consequently, several obscure procedures, or policymaking "black boxes," surround the integration of science into agency policy that undercut both the reliability and legitimacy of the resulting policy decisions.

The two touchstones of clean science are transparency and independence. The concept of transparency affects three stages in the production and use of research. First, regulatory agencies depend on scientific research that can be and has been validated because the data, models, methods, and other critical pieces of the research are open to review. Second, all research relevant to public health and environmental regulation must be communicated to the appropriate agency in a timely and accurate manner, ensuring that the "best available science" is truly available to the agency. Finally, open access to the government's decisionmaking process - transparency as to *how* the science is used - is an essential component of clean science. Combining these three elements of transparency promotes broader involvement in the regulatory process, ideally improving the end result.

The principle of independence is equally important because the credibility of a researcher's work is closely tied to her ability to follow science where it leads her without regard to outside economic or political pressures. Scientists engaged in research that could affect public health or the environment and impose costs on the regulated community must be allowed to conduct their research free of any impediments or restrictions on their rights to publish or otherwise communicate their results to outside parties. They must have the opportunity to choose research projects, design neutral studies, assess their data, and report their results based solely on their best scientific judgment.

The reforms we propose are progressive responses to the problems that surround the integration of science into agency policy and emanate from the two fundamental principles of promoting transparency and protecting independence in regulatory science. These proposals are important steps, designed to staunch misuse of the legal system so that scientists have space to develop their own responses to these inevitable pressures. However, the ultimate solutions to the pervasive and debilitating politicization of science must come from within the scientific community itself.

The Data Access Act's lopsided approach frustrates the fundamentals of scientific and regulatory transparency.

## Improving the Data Access Act

The asymmetrical design of the federal Data Access Act (DAA) is the first problem that Congress and federal policymakers should address. This statute, sometimes referred to as the “Shelby Amendment,” in honor of its author, Sen. Richard Shelby (R-AL), instructs the White House Office of Management and Budget (OMB) to amend the rules governing *federal* grant disbursement to make scientific data created with the support of federal funds publicly available through the Freedom of Information Act (FOIA). Enacted as a rider to a 4,000-page omnibus appropriations bill, the DAA reads in full:

Provided further, That the Director of OMB amends Section 1.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act: Provided further, That if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental cost of obtaining the data.<sup>2</sup>

As the text reveals, the Act does not address accessibility of the growing amounts of data generated by the *private* sector that is used to justify positions on regulatory policies. This lopsided approach frustrates the fundamentals of scientific and regulatory transparency, which apply to all research - not just research supported by the government - if participants in the regulatory process want to use it to influence a final action.

Writing in the *Harvard Journal on Legislation* shortly after the DAA was signed into law, Senator Shelby explained his rationale for introducing the amendment.<sup>3</sup> While acknowledging the importance of transparency of regulatory science, Senator Shelby said that his primary motivation for sponsoring the legislation was a dispute with EPA over access to the underlying data in a federally funded study used to support revisions to the ozone and particulate matter National Ambient Air Quality Standards.<sup>4</sup> The “Six Cities Studies” showed adverse effects on respiratory and pulmonary functions among human subjects who exercised in chambers contaminated by these pollutants at levels comparable to ambient air in some major cities. Senator Shelby was incensed when neither EPA nor the researchers would disclose the underlying data.<sup>5</sup> Thus the DAA was born, applicable only to federally funded research.

In its effort to devise guidance explaining to agencies how they should implement the DAA, OMB proposed several ideas that ignited a firestorm of protest from the scientific community. Specifically, the scientific commenters raised concerns about the statute’s inattention to human subject privacy concerns, intellectual property protection as related to the Bayh-Dole Act’s award of patent rights on the basis of federally funded research, potential harassment by those who might be subject to more stringent regulation as a result of federally funded research, and the possibility that the timing of data accessibility could disrupt the traditional rhythm of scientific discovery. After two rounds of proposed

revisions, OMB's final changes, embodied in Circular A-110, were adopted with the following key features that limited the reach of the Act in a way more consistent with the views of the scientific community:

- The public can use FOIA to access only research data (1) “relating to published research findings” that are (2) “used by the Federal Government in developing an agency action that has the force and effect of law.”<sup>6</sup>
- Research data that scientists must divulge upon request from any agency do not include:
  - “Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
  - “Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy...”<sup>7</sup>

The constraints on the DAA imposed by OMB in response to public comments reflect an effort to promote transparency in the scientific process while at the same time allowing for speedy development of regulation and protection of confidential information and scientific independence. Apparently OMB did an adequate job of balancing these competing interests, because the scientific and public interest communities - who had initially lobbied for repeal of the DAA - abandoned that position after the final revisions to Circular A-110. Given that the Circular A-110 limitations to the DAA's scope appear generally to protect scientists in a reasonable way while advancing the goals of regulatory transparency, we propose expanding the coverage of the DAA to a broader range of scientific studies.

*First, we recommend that Congress extend the DAA to cover the results of privately funded research.* This proposal, on its own, is relatively uncontroversial. The American Association for the Advancement of Science, the Association of American Universities, and the National Research Council have expressed support for sharing research data relevant to public policy debates,<sup>8</sup> and the public interest community has maintained that the DAA's asymmetrical applicability runs contrary to principles of transparency and accountability. Industry groups also support equal treatment for all science. The American Chemistry Council's Long-Range Research Initiative, which sponsors new research aimed at improving chemical risk assessment, requires grantees to make their data accessible.<sup>9</sup>

*We further recommend that the Act's coverage extend to data that support regulatory actions beyond those with “the force and effect of law.”* This reform is necessary because regulatory agencies use scientific research to support many decisions that may not rise to the level of having “the force and effect of law” but nonetheless have a significant impact on their efforts to protect human health and the environment. For example, risk assessments developed for EPA's Integrated Risk Information System (IRIS) database do not have any legal effect on their own but are highly influential in regulatory decisions throughout the world. Similarly, U.S. climate change policy is in its infancy, and the scientific basis for decisions about whether and how to act is under intense scrutiny. The substitution of voluntary or

We recommend that Congress extend the Data Access Act to cover the results of privately funded research.



incentive-based programs for binding legal requirements in various other fields puts a premium on the transparency of the science used to justify such decisions. The same is true for decisions to refrain from addressing health and safety problems on the grounds that they are not pressing concerns (e.g., OSHA's failure to regulate diacetyl, a toxic chemical used in the manufacture of popcorn sold to consumers).<sup>10</sup> In the field of endangered species protection, the decision to not list an imperiled species as threatened or endangered should be supported by research that is subject to transparency rules.

*Rather than limiting data access to research supporting the vaguely worded “agency action with the force and effect of law,” we recommend that coverage should instead reference the Administrative Procedure Act (APA) definitions of “agency action” and “agency proceeding.”* Under the APA an agency action is defined as “the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act.”<sup>11</sup> An agency “proceeding” means “any regulatory process as defined by [the terms ‘rule making,’ ‘adjudication,’ or ‘licensing.’]”<sup>12</sup> The advantage of using these terms is that years of agency practice and legal precedent will help inform decisions about whether particular data should be accessible. Additionally, the inclusion of instances where the agency fails to act based on scientific research will now be subject to greater accountability. However, these reforms do not adequately expand the universe of regulatory decisions that trigger FOIA-based data access procedures.

*To bring a broad universe of regulatory decisions under the umbrella of a revised DAA, we further recommend expanding data access rights to cover research that informs “significant guidance documents,” as defined by Executive Order 13422.*<sup>13</sup> A “guidance document” is “an agency statement of general applicability and future effect other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.”<sup>14</sup> We suggest expanding data access requirements only to cover *significant* guidance documents as a way of promoting transparency without excessively impinging on administrative flexibility.<sup>15</sup> Most agency actions that are not finalized through the rulemaking process are of limited applicability and significance - they guide internal deliberations or clarify minor ambiguities in more formal regulations. It is important to protect the agencies’ ability to develop these documents quickly so that they can be revised continually to reflect new information. But at the same time, the public has a legitimate interest in the accessibility of data that support things like influential risk assessments and reports on “education, health care, drug usage, crime, welfare, the environment, and Social Security”<sup>16</sup> that in turn support regulation or legislation. The definition of “significant guidance document” in Executive Order 13422 provides a workable starting point for striking a balance between transparency and efficiency.

During the public comment period on proposed revisions to Circular A-110, OMB considered broader data access rights akin to those we have just suggested, but backed off the idea after determining that the proposal was “burdensome and time-consuming, and would intrude into the agency’s deliberative process.”<sup>17</sup> However, this conclusion was based on an

incorrect assumption about the timing of data access rights. The DAA states that data access rights take effect when an agency has “used” the research. OMB correctly determined that in the context of notice and comment rulemaking an agency can be viewed as having “used” research findings when those findings are publicly and officially cited in a *Federal Register* rulemaking notice.<sup>18</sup> But when agencies undertake less formal actions without preparing explanatory documents for the *Federal Register*, OMB found it “unclear” how the statute would operate.<sup>19</sup> OMB considered only one admittedly unworkable approach to solving the problem:

[A]n agency might be viewed as having “used” research findings if those findings: (1) were relied upon in an internal agency memorandum sent to a decisionmaker; (2) were discussed in an agency staff level communication, such as an email message; or (3) were simply available for the agency staff to read, regardless of whether there was any evidence that the staff relied upon the findings in carrying out their work.<sup>20</sup>

This scheme would certainly be burdensome, time-consuming, and an intrusion on agencies’ deliberative process, but these problems arise because this scheme would shift the determination of whether research findings were “used” to a premature point in the decisionmaking process. As in the context of notice and comment rulemaking, an agency should not be considered to have “used” research findings unless they are publicly and officially cited. That is, outside the context of notice and comment rulemaking, an agency has only “used” research findings when a document citing those findings is published in final form or in draft form for public comment.

To summarize, the DAA should be considered the starting point from which Congress launches a broader program to ensure transparency in the creation and use of all regulatory science, not just publicly funded science. An improved data access policy should have the following characteristics: all research data, regardless of funding source, should be publicly accessible if research findings based on that data are used by the federal government in support of an agency action, agency proceeding, or significant guidance document. Research findings are “used by the federal government” when the agency publicly and officially cites them. These principles, clarified by the discussion above, strike an appropriate balance between transparency and efficiency.

Private funding increases the likelihood that the researcher will have significant financial ties to a person, corporation, or other organization that could benefit either directly or indirectly from her research.

## Eliminating Funding Bias and Sponsor-Controlled Research

The most recent estimates from the National Science Foundation indicate that private funders were responsible for more than fifty percent of the \$143 billion dollars spent on basic and applied research in the US in 2006.<sup>21</sup> The objectivity of this work might legitimately be questioned for multiple reasons. For one, private funding increases the likelihood that the researcher will have significant financial ties to a person, corporation, or other organization that could benefit either directly or indirectly from her research. Meta-analyses of research results in the fields of pharmaceuticals, toxics, and pesticides often suggest that the identity of the sponsor affects the outcome of scientific studies.<sup>22</sup> Researchers suggest that the problems run deeper than simple bias in interpreting data - privately funded science sometimes suffers from methodological biases that corrupt the data. In the field of pharmaceuticals, these methodological biases can include enrollment of relatively healthy patients, insufficient selection or dosage of comparator drug, inadequate sample size, or inappropriate length of patient follow-up.<sup>23</sup> Besides these predetermined methodological decisions, during the study itself, researchers have discretion in making decisions about which effects are recorded and analyzed.<sup>24</sup> At each stage in the research process, funding bias can affect the outcome of a study.

Skepticism about the objectivity of privately funded research also has roots in sponsors' attempts to put limitations on researchers' independence. In hopes of protecting the financial interests implicated by the research they sponsor, private funders have engaged in a practice of contracting with researchers who will agree to allow their sponsors to dictate aspects of their work. Examples include sponsor-prescribed trial design, limited access to data, restricted participation in data interpretation, and incomplete editorial and publication rights.<sup>25</sup> Though the problem is most acute in fields of research where studies are linked directly to big-market consumer products (e.g., pharmaceuticals), the problem is not limited to private research sponsors. Government agencies including the Department of Defense and Federal Aviation Administration are also guilty of attempting to limit researchers' rights to data and results.<sup>26</sup>

Private sector sponsors advance numerous justifications for limits on scientists' independence. One line of reasoning is that sponsors deserve the opportunity to capture returns on investment before copycat products are developed. Another is the argument that private sector sponsors will have less incentive to fund research if they cannot control the dissemination of results that could trigger liability or more stringent regulatory standards. Firms that have large-scale, diversified research programs (e.g., Merck, the manufacturer of Vioxx) also want to be able to halt some research projects at "critical development milestones" in order to optimize allocation of research money.<sup>27</sup> Regardless of the justification, these impediments to independent scientific research are harmful because they reduce the credibility of individual projects by creating a presumption of sponsor manipulation.

Two groups with an institutional interest in maintaining independence in scientific research have adopted policies designed to create incentives that will encourage both researchers and

their sponsors to avoid contractual limitations on independence. Major research universities have developed policies that prohibit engaging in research projects contingent on limited publication rights,<sup>28</sup> thus shrinking the pool of accomplished researchers available to sponsors who want to constrain scientific independence. In addition, the International Committee of Medical Journal Editors (ICMJE) has adopted a policy that requires authors to submit a written declaration regarding their level of control over the research that supported an article submitted for review.<sup>29</sup> *The New England Journal of Medicine*, *the Journal of the American Medical Association (JAMA)*, and other major journals have said that they will not review or publish articles unless the authors' disclosure statement indicates a substantial level of control over the research and reporting of results.

Despite these efforts, sponsor control over research and publication continues to be a problem because the interplay between researchers, funders, and the researchers' home institutions is much more complex than it might seem at first blush. To begin, university policies that protect publication rights may be less complete than is needed to significantly affect contract negotiations. A survey of the 100 U.S. institutions with the most funding from NIH in 1998 uncovered only 11 university policies that specified a time limit for delay of publication or presentation of research results to allow review by corporate sponsors.<sup>30</sup> However, a more recent study, conducted after the ICMJE revised its policy on authors' autonomy, found that a vast majority of medical schools "would not approve provisions giving industry sponsors the authority to revise manuscripts or decide whether results should be published."<sup>31</sup> Former Harvard University President Derek Bok suggests that enforcement may be the real problem, noting that "company research directors report that they seldom have difficulty obtaining as much secrecy as they want."<sup>32</sup> A shift in the types of institutions that are obtaining funding is also a factor. Nonacademic research groups (contract research organizations, or CROs) that "can do the job for less money and with fewer hassles than academic investigators" are getting an increasing share of research funding because they are more likely to accept limitations on independence and are not as motivated by the potential for publication in research journals.<sup>33</sup>

Despite the growing body of evidence suggesting funding bias is a serious problem, regulatory agencies still use research to support regulatory action without necessarily knowing the source of funding for that research or whether the authors had complete research and publication independence. Some leading biomedical journals have adopted a policy of requiring disclosure of sponsor control over any research submission.<sup>34</sup> The information requested from researchers provides transparency as to the identity of sponsors, the types of support provided, the role of the sponsor in the research process, and the researchers' level of control over the study and data.<sup>35</sup> *To improve transparency in regulatory science, federal agencies should follow this model, requiring that studies submitted to the agency be accompanied by disclosure statements that provide all of this information. When agency officials want to use a study that they discovered in searching the literature, they should be required to contact the principal investigator and request this information.*

## Improving Adverse Effects Reporting

Congress inserted provisions in TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that require regulated parties to inform EPA when they develop or discover information that suggests threats to public health or the environment. But these requirements have not been updated in decades and are increasingly inadequate.<sup>36</sup> Under TSCA, for example, registration of a chemical with EPA triggers a continuing obligation on regulated firms to submit to EPA any information they obtain that “reasonably supports the conclusion” that a chemical or mixture they manufacture, import, process, or distribute “presents a substantial risk of injury to health or the environment.”<sup>37</sup> Similarly, FIFRA § 6(a)(2) states that pesticide registrants have an ongoing duty after registration to submit to EPA any “additional factual information regarding unreasonable adverse effects on the environment” caused by the pesticide.<sup>38</sup> Failure to adhere to these disclosure mandates can lead to significant civil or criminal penalties,<sup>39</sup> but the government must discover the withheld information before it can punish the firm that keeps it secret.

These legal standards depend too much on the discretion of the firms who manufacture, sell, or use the products that pose the risk. Under TSCA, reporting is triggered by three judgments: whether the information (1) reasonably supports (2) a conclusion that the substance presents (3) a substantial risk of injury. Under FIFRA, three alternative factors govern whether information is reportable: whether it is (1) additional, (2) factual information (3) regarding adverse effects.<sup>40</sup>

*To strengthen these requirements and ensure that evidence of adverse effects is reported to the government, we recommend four reforms:*

- *Promulgation of new TSCA regulations that require regulated parties to disclose any research that provides significant knowledge that would allow scientists to assess the risk of a chemical circulated widely in commerce;*
- *Issuance of EPA “safety net” guidance under FIFRA specifying that information beyond specifically enumerated types of studies must be submitted if it would serve the same purpose as the listed data;*
- *Enactment of a free-standing, cross-cutting requirement that manufacturers and users of hazardous agents in the form of either products or wastes must report instances where exposures - estimated using either reasonable worst-case methods or methods to estimate the expected value of exposure - could pose a significant threat to human health; and*
- *Expansion of efforts to collect risk data from private institutions, including the plaintiffs’ bar, the insurance industry, and the medical profession.*

## The PFOA Episode

The December 2005 settlement agreement between EPA and DuPont over DuPont's failure to comply with TSCA § 8(e) highlights the problems with compliance. In 1978, DuPont began studying the human health effects of perfluorooctanoic acid (PFOA, a chemical used in manufacturing Teflon).<sup>41</sup> By 1981, the company had compiled reports about PFOA in pregnant workers and their offspring, developing "the first direct human evidence of PFOA crossing the placenta in humans,"<sup>42</sup> a startling discovery that greatly increased the risks posed by exposure to even low doses of the chemical. In addition, DuPont conducted two different studies of PFOA in the blood of residents of the community surrounding a West Virginia plant where the chemical was used and three inhalation exposure studies using rats and chemicals similar to PFOA. The company failed to submit the results of any of these studies to EPA upon completion.

The first evidence of these studies did not reach EPA until 2001, when attorney Robert Billott discovered documentation of the studies while investigating a class action lawsuit against DuPont for suspected PFOA contamination of groundwater surrounding a West Virginia plant. Billott sent copies of the studies to EPA, which began a § 8(e) enforcement action soon thereafter.<sup>43</sup> EPA and DuPont settled the enforcement case for penalties totaling \$10.25 million and Supplemental Environmental Projects worth \$6.25 million,<sup>44</sup> unusually heavy penalties in an unfortunately rare type of enforcement action. The precise number of injuries that could have been prevented by more timely disclosure has yet to be determined, but we do know that one child born to a DuPont employee working in the PFOA plant "was born with a severe nostril and eye defect and another was born with an unconfirmed eye and tear duct defect,"<sup>45</sup> and that workers in a Minnesota PFOA plant have exhibited an increased risk of death from prostate cancer and stroke.<sup>46</sup>

## New TSCA Section 8(e) Regulations

The PFOA settlement highlights the potential for abuse of TSCA § 8(e).<sup>47</sup> The only legally enforceable reporting standard is the statute itself, since EPA has never issued any regulations that clarify what types of information the agency expects to be reported, giving companies too much room to evade these requirements on the grounds that they did not "expect" a risk to be "substantial." EPA has two guidance documents on the subject,<sup>48</sup> but the history of § 8(e) non-compliance suggests that the guidance is insufficient.

Between February 1991 and May 1996, EPA ran a Compliance Audit Program that encouraged companies to search for and disclose any TSCA-relevant risk information by establishing a \$1 million ceiling on penalties that would be imposed against any single company for failure to comply with § 8(e).<sup>49</sup> Eighty-nine companies participating in the program found over 11,000 previously unreported studies,<sup>50</sup> suggesting that there is a serious problem of non-compliance.

Scrapping existing guidance and beginning anew with legally enforceable regulations would allow EPA to make a strong policy statement in favor of transparency in privately funded research.

A problem with § 8(e) highlighted by the DuPont case is the fact that the statute and guidance are susceptible to circumvention by corpuscularization. “Corpuscularization” is the tactic of highlighting the inherent and unavoidable incompleteness of any given scientific study to frame it as not scientifically valid.<sup>51</sup> DuPont argued that the evidence of cross-placental PFOA exposure and PFOA contamination of water supplies do not reasonably support a conclusion of substantial risk because the information pertained to exposure alone and did not make a causative link between exposure and harm.<sup>52</sup> To put the argument in stark terms, the company seems to suggest that scientific studies are only subject to § 8(e) reporting if the results of the study reach definitive conclusions that a given number of people became ill as a result of exposure. If that argument were true, it would give short shrift to the fact that evidence of a chemical’s ability to cross the placenta and reach a fetus dramatically expands the potential for adverse exposure to babies in utero.

Moreover, DuPont’s reasoning contradicts well-established scientific standards for regulatory risk assessment, which involve taking a “weight-of-the-evidence” approach. Scientists of relevant disciplines consider all available studies that will improve our understanding of release, fate and transport, exposure, cellular response, and many other factors.<sup>53</sup> Properly understood, TSCA § 8(e) reflects the principle that a broad range of scientific research is necessary for proper risk assessment and that no study can survive the test of proving causation on its own. Therefore, any study that could play an important role in assessing risk should be covered by adverse effects reporting requirements.

The disconnect between regulated parties’ understanding of the § 8(e) requirements and the EPA enforcement office’s understanding of the requirements (as exemplified by the DuPont case) could be resolved by improvements to EPA guidance or establishment of new regulations. We recommend the latter option. Scrapping the existing guidance and beginning anew with legally enforceable regulations would allow EPA to make a strong policy statement in favor of transparency in privately funded research. It would also better implement Congress’ mandate for disclosure of any scientific research that could provide significant knowledge about toxic substances that would allow scientists to assess risk.

*EPA should develop new TSCA regulations that require regulated parties to disclose any research that provides significant knowledge that would allow scientists to assess the risk of a chemical circulated widely in commerce, especially High Production Volume chemicals (those produced or imported into the U.S. in quantities of one million pounds or more per year). Exposure data, research related to environmental transport, studies on toxicogenomics, and a host of other research not necessarily disclosed under the current guidance would be shared.*

### **Adding a FIFRA ‘Safety Net’ Provision**

Under FIFRA, Congress used different language to describe the adverse effects information that should be reported to EPA. For pesticides, a particular scientific study should be submitted under FIFRA § 6(a)(2) if it presents “information regarding unreasonable adverse effects.” Unlike the TSCA adverse effects reporting program, EPA actually established a

detailed set of regulations governing adverse effects reporting under this vague statutory standard.<sup>54</sup> Since the first iteration of the regulations in 1978, EPA has taken “a very broad view of the statutory scope of section 6(a)(2),” explaining “that reportable information need only ‘pertain or relate to unreasonable adverse effects on the environment; it does not have to indicate, establish, or prove the existence of such effects.’”<sup>55</sup> Despite espousing this viewpoint, EPA adheres to an enforcement policy that greatly limits the statute’s effectiveness.<sup>56</sup>

Instead of crafting regulations that would implement the “broad view” of § 6(a)(2)’s coverage, EPA chose to limit coverage to only that information which “the Agency considers relevant to determining whether a registered pesticide continues to meet the standards of registration.”<sup>57</sup> The regulations thus list certain types of toxicological, ecological, and human epidemiological studies that EPA wants registrants to submit “and essentially exempts from the reporting requirements information not covered by the Rule.”<sup>58</sup> Under threat of civil and criminal liability, registrants must submit:

- Toxicological studies...<sup>59</sup>
  - Showing toxic effects in a different tissue than previously reported;
  - Showing toxic effects at a lower dose, after a shorter exposure period, or after a shorter latency period;
  - Showing toxic effects at a higher frequency;
  - Showing toxic effects in a different species/strain/sex/generation of test animal; and
  - Leading to a lower toxicity indicator like an LD50, LC50, or irritation index.
- Ecological studies...<sup>60</sup>
  - Leading to a lower LD50, LC50, or EC50 than previously reported;
  - Showing chronic effects at lower levels; and
  - Using different test species and indicating lower LD50 or LC50.
- Human epidemiological studies...<sup>61</sup>
  - Showing any correlation between exposure and adverse effects, regardless of whether the registrant considers the correlation significant.
- Surface or ground water screening studies...<sup>62</sup>
  - Measuring the chemical in a concentration higher than an EPA-established Maximum Contaminant Level (MCL), Health Advisory Level (HAL), reference dose (RfD), or reference concentration (RfC).

This regulatory scheme has the benefit of making reporting requirements objective, thereby limiting the discretion afforded to registrants in deciding whether to submit a specific piece of research. However, such specificity also limits the utility of the statute. By limiting itself to a “laundry list” approach, EPA indirectly encourages the sequestration of information that would be useful to scientists and the public in studying and managing the risks posed by toxic chemicals.

*EPA should supplement existing FIFRA disclosure requirements with a “safety net” provision that requires disclosure of evidence not specifically listed that would provide the equivalent function of informing re-registration risk assessments of covered pesticides.*

### **Cross-cutting Adverse Effects Reporting of ‘Significant Threats’**

Recent headlines make it abundantly clear that a great deal of critical health and environmental risk information has been suppressed, leading to delays in appropriate government response.<sup>63</sup> At least some of this suppression can be blamed on incomplete and ineffective regulatory requirements governing adverse effects reporting. *We recommend that Congress pass a free-standing law that requires any entity, including the federal government, that produces goods in commerce within the United States to report any information that suggests a “significant threat” is posed by exposure to any “hazardous agent” contained in those products and the wastes they become.*

The two fundamental challenges in creating this new reporting requirement will be ensuring broad coverage of hazardous agents and establishing a low reporting threshold. At a minimum, the reporting requirement should cover “hazardous substances” as defined in Superfund,<sup>64</sup> the active and inactive ingredients of pesticides,<sup>65</sup> substances covered by the Federal Hazardous Substance Act,<sup>66</sup> petroleum products, and materials regulated by the Atomic Energy and Nuclear Regulatory Commissions. This proposal would expand existing Superfund reporting requirements by eliminating exemptions for petroleum products, the normal use of pesticides, and nuclear materials. However, it is considerably narrower than the Superfund requirement that any “release” or “threatened release” into the “environment” trigger reporting obligations.<sup>67</sup> Instead, application of the new law would depend on an “objectively reasonable belief” that potential exposure levels could pose a significant risk. Potential exposure levels should be estimated using either reasonable worst case methods or methods to determine the expected value of exposure. Companies should be encouraged to over-report in the first years of the statute. Agencies must undertake routine enforcement from the new law’s effective date, with penalties gradually increasing as its parameters are defined by relevant agencies and the courts.

We recommend that reports would be submitted to agencies with primary authority over the product or waste in question: environmental risk information would go to EPA, workplace risk information to OSHA, consumer product risk information to CPSC, and pharmaceutical and food risk information to FDA. Each agency would have a uniform set of remedies available and would coordinate cross-media exposures. We recognize that reviewing adverse effect reports would be time-consuming and demand additional resources above and beyond what agencies now have available. In comparison to the costs of unrecognized risks, we believe these additional expenditures would be a bargain.

## New Approaches to Gathering Risk Information

Another important point highlighted by the PFOA case is that manufacturers are not the only sources of adverse effects information. In fact, the case illustrates the importance of the tort system as a source of information.<sup>68</sup> But while the discovery powers available to plaintiffs' attorneys and the incentives to find "smoking gun" documents increase the likelihood of uncovering information that an agency might like to use in crafting protective regulation, those attorneys are also obligated to work toward their clients' best interests, which sometimes means exchanging sealed settlements for larger payouts. EPA and Congress should consider working with other entities, especially the medical profession, the insurance industry, and the plaintiffs' bar, to access risk information.<sup>69</sup>

The FDA Amendments Act of 2007 provides an example of an agency-driven program designed to uncover new information that would be useful to further supplement agencies' current primary reliance on regulated parties to produce post-market information on the adverse effects of their products. This new statute instructs FDA to develop "active post-market risk identification and analysis methods" for all approved pharmaceuticals that will enable the agency to identify trends and patterns in adverse events caused by the drugs.<sup>70</sup> FDA is supposed to collect data from insurance claims, patient survey data, and any other data source deemed appropriate. The data collection methods developed by FDA under new amendments to its authorizing statute might have the potential to be modified to improve EPA's ability to identify adverse events resulting from exposure to environmental toxins.

## Improving Whistleblower Protections

Effectively protecting whistleblowers is another way to identify suppression and manipulation of science used for regulation. Generally speaking, whistleblower-protection laws are designed to ensure that employees who speak out against improper or illegal activities are not fired, demoted, or otherwise retaliated against by their employers. The laws could be a useful tool for protecting scientists who make good faith allegations of research misconduct or disclose in some other fashion evidence of impediments to independent scientific inquiry.

Unfortunately, existing laws do not provide adequate protection for scientific whistleblowers.<sup>71</sup> For instance, the Whistleblower Protection Act, the main statute protecting federal employees from retaliation, prohibits adverse employment actions in response to a federal employee's disclosure of information that she reasonably believes evidences either (1) "a violation of any law, rule, or regulation;" or (2) "gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety."<sup>72</sup> A federal employee who has evidence of interference with scientific integrity might claim that disclosure of that information would be covered by the protection for speaking out against an abuse of authority, but that is not an argument clearly supported by the statute.

For privately employed scientists, existing whistleblower statutes are even more ambiguous. Several environmental statutes - for example the CAA, CERCLA, and the CWA - extend whistleblower protections to privately employed individuals who participate in the enforcement of those laws (e.g., by testifying before Congress or a judicial proceeding or by assisting in regulatory proceedings).<sup>73</sup> But the availability of the protections afforded by statutes will often turn on whether the employee's whistleblowing results in the commencement of a proceeding to administer or enforce some other provision of statute. Disclosing evidence of interference with scientific integrity is not clearly covered by these statutes.

Finally, the structure of whistleblower protection, insofar as it relies primarily on back-end, reactive protections, is an unsatisfactory system. Federal scientists should be able to rely on well-designed decisionmaking procedures and clearly defined role boundaries for political appointees so that the need to become a whistleblower does not arise.

### Front-End Protections: Improving Administrative Recordkeeping

Recent rulemakings are littered with examples of White House staff and agency political appointees secretly rewriting draft rulemaking notices and scientific reports to distort the candid opinions of career scientists and even outside peer reviewers. These alterations were revealed only through whistleblowers and persistent investigative reporting. Endangered species decisions,<sup>74</sup> climate change reports,<sup>75</sup> and the Bush Administration's proposals to control mercury from power plants<sup>76</sup> have all been compromised by ideological re-drafting

of scientists' work. Expanded administrative recordkeeping requirements could prevent - or at least minimize - such inappropriate interference by creating a public record of the evidence whistleblowers need to support their claims.

The Administrative Procedure Act (APA) requires federal agencies to keep a paper trail of their decisionmaking process in an administrative record, but the record compiled by an agency is often suspiciously limited to a collection of documents that justify the agency's final decision. Conspicuously absent from the record are documents that indicate what the scientists said before the policymaking debate began. *In the interest of regulatory transparency and as a way to protect federal scientists, we suggest that agencies consider revising their record-keeping policies to memorialize agency scientists' pre-decisional findings.*

The requirements governing what materials must be included in an administrative record come from a variety of sources. The APA itself simply says that a court "shall review the whole record" when reviewing agency decisions but does not describe the types of documentation that must be in the record.<sup>77</sup> Some statutes, like the CAA and CERCLA, enumerate certain materials that must be kept in the administrative record for particular rulemakings.<sup>78</sup> DOJ has issued a guidance document on compiling an administrative record which implores agency staff to include a broad range of materials in the record. The guidance states that officials should include "documents and materials whether they support or do not support the final agency decision" and "documents and materials that were before the agency at the time of the challenged decision, even if they were not specifically considered by the final agency decisionmaker."<sup>79</sup> Yet the inclusionary tone of the DOJ guidance and the broad language of the APA do not ensure a fully developed administrative record. Entrenched agency practice, supported by the longstanding legal privilege for documents that could expose the deliberative process, is unduly generous in providing agency staff excess discretion to limit the documentation of pre-decisional internal debate regarding scientific documents.

The contours of the deliberative process privilege have been explored by the federal courts in lawsuits over agencies' rejection of FOIA requests. FOIA defines the deliberative process privilege as protecting "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency."<sup>80</sup> As defined by the FOIA case law, this privilege shields from public view documentation of agency work that is "pre-decisional" (generated prior to adoption of agency policy) and "deliberative" (reflective of the give-and-take of the consultative process).<sup>81</sup> The justifications for the deliberative process exemption are three: (1) to protect "creative debate and candid consideration of alternatives," (2) to protect "the public from confusion that would result from premature exposure to discussions occurring before the policies affecting it had actually been settled upon," and (3) to protect "the integrity of the decisionmaking process itself by confirming that 'officials would be judged by what they decided[,] not for matters they considered before making up their minds.'"<sup>82</sup> It is the first of these three justifications - a desire to protect candor in agency deliberations - that is generally

"We ought to protect scientists from those that would try to suppress or distort their scientific work."

— REP. HENRY  
WAXMAN,  
MARCH 14, 2007

considered the “key question” in deliberative process cases.<sup>83</sup> In the words of Chief Justice Warren Burger, “[h]uman experience teaches that those who expect public dissemination of their remarks may well temper candor with a concern for appearances and for their own interests to the detriment of the decisionmaking process.”<sup>84</sup> Based on this common experience, the federal courts continue to uphold agency officials’ discretion to limit the administrative record to a fraction of the documentation that would provide a clear picture of the decisionmaking process.

Our proposal to expand the publicly available administrative record sits at the interface of two opposing public policy norms: the desire to increase regulatory transparency in order to maximize accountability, public trust, and engagement in the regulatory process versus the desire to protect internal deliberations in order to encourage candor and flexibility, which in turn improve job satisfaction among career staff. We are sensitive to concerns about maintaining independence in agency deliberations, but we also recognize that the status quo, which favors limited recordkeeping, is contributing to the growing distrust of federal regulatory agencies.

Important administrative law court cases support our proposal to require fuller disclosure of the deliberative process. Under the *United States v. Nova Scotia Food Products Corp.* case, agencies must disclose enough of the scientific data that support a rule to enable interested parties to provide meaningful comments on proposed rules and courts to assess whether the rule is based on administrative consideration of all relevant factors.<sup>85</sup> Fuller disclosure of deliberative documents would assist agencies in satisfying these procedural requirements.

What types of records should expanded recordkeeping requirements reach? *Agencies should consider explicitly exempting the products, analyses, and discussions of scientific research from the deliberative process privilege, even if they are produced by agency scientists. Given the recent problems with political interference with scientific reports, however, it may ultimately rest with Congress to adopt statutory requirements that agencies docket all pre-decisional scientific studies and analyses by agency experts if the agencies do not increase disclosure in this area on their own. This approach would help protect whistleblowers by minimizing the blurring of lines between science, science policy, and pure policy.*<sup>86</sup>

### **Front-End Protections: Reforming the Civil Service**

Improving administrative recordkeeping requirements is a first step in clearly delineating between the roles of agency scientists and policymakers, improving the integrity of federal decisionmaking and, ultimately, preventing whistleblower problems.<sup>87</sup> However, recordkeeping requirements alone are insufficient. Limiting the depth of political appointments into agencies’ management structures would help empower career staff. In addition to preventing individuals beholden to changing administrations from intruding in the technical work of agency scientists, congressionally mandated limits on political appointments could improve agency morale and lead to stronger resistance to improper political pressure.<sup>88</sup> Congress should consider changing the allocation of federal positions between the career and excepted service.

## Front-End Protections: Establishing Federal Scientific Integrity Regulations

Finally, to prevent cases of political manipulation of science that lead to whistleblower protection problems, federal agencies need to establish unambiguous statements about the rights and responsibilities of all employees with respect to scientific integrity. On several occasions - most recently following the scandal of Julie MacDonald abusing her power and manipulating endangered species decisions<sup>89</sup> - the Department of Interior has attempted to create enforceable ethics guidelines; however, the initiatives have failed to produce useful standards of practice. Congress should consider mandating that all federal agencies adopt regulations that prohibit agency officials from “coercing or intimidating scientists or altering or mischaracterizing scientific conclusions and information.”<sup>90</sup> Requiring the adoption of regulations through notice and comment rulemaking will ensure transparency in the process and will result in the creation of legally binding rights and duties.

## Back-End Protections: Improving and Expanding Existing Whistleblower Protections

Rep. Henry Waxman (D-CA) has introduced legislation to address scientific integrity by adding a new provision to the Whistleblower Protection Act that defines illegal “abuse of authority” as, among other things, “any action that compromises the validity or accuracy of federally funded research or analysis” and “the dissemination of false or misleading scientific, medical, or technical information.”<sup>91</sup> This change is essential to adequately protect federal employees from retaliation. *Amendments to other statutes (e.g., CAA, CWA, CERCLA) based on the proposed changes to the Whistleblower Protection Act might be a good solution to problems of political interference with science in the private sector. Private sector employees should be protected when they adhere to their ethical duty to report actions that compromise the validity or accuracy of research or result in the dissemination of false or misleading information.*

Expanding whistleblower protection statutes requires changes to the bureaucratic mechanisms relied upon to investigate whistleblower cases. These cases are funneled through the Labor Department’s Occupational Safety & Health Administration (OSHA), which, along with the Federal Circuit Court of Appeals, has greatly curtailed the protections available through whistleblower protection statutes.<sup>92</sup> *Congress and the federal agencies should consider establishing alternative ways for whistleblowers to lodge complaints.*

Congress could create a specialized scientific ombudsman’s office staffed by people trained in the distinctions between and potentials for overlap of scientific and policy judgments. Ombudsmen could be empowered to insist on review of a scientist’s complaints by top-level officials, take their concerns directly to legislative oversight committees, or even prepare reports that would become part of the administrative record available to reviewing courts.<sup>93</sup> Agencies’ inspectors general might also be able to provide the independence and will to investigate allegations of whistleblower retaliation that OSHA lacks.

## Establishing a Legal Cause of Action for Harassed Scientists

Congress should also address the use of legal processes to harass scientists. A prominent example is the case of Dr. Paul Fischer, a researcher at the Medical College of Georgia, who investigated the effect of Camel cigarette advertising campaigns on children.<sup>94</sup> When San Francisco attorney Janet Mangini sued the R.J. Reynolds Tobacco Company because it had failed to put warning labels on promotional products, Reynolds subpoenaed Dr. Fischer's records. He was not a party to the case or a witness for either side, and his study had not been cited in Mangini's filings, yet Reynolds' lawyers ordered him to produce mountains of materials, from original test materials to "all correspondence relating to the research" to "the names and telephone numbers of all of the children who participated in the study."<sup>95</sup> Concerned about violating confidentiality agreements signed with each of the participants' parents before conducting the research, Dr. Fischer hired a lawyer to have the subpoena quashed because it was overbroad and unjustified. Reynolds then pursued the same strategy of obtaining all of Dr. Fischer's research documents using the State of Georgia's Open Records statute, and this time Reynolds succeeded. Throughout these legally sanctioned attacks, the Medical College of Georgia refused to support Dr. Fischer. Ultimately he resigned from his tenured position in disgust.

The abuse of Dr. Fischer is only one example of legally backed harassment of independent scientists.<sup>96</sup> Rep. Joe Barton's inquiry into the work of climate scientist Michael Mann, abusive use of state open record requests against public university researchers, and defamation claims filed against scientists provide other recent examples of how special interests have abused legal processes to attempt to intimidate them and deter them from pursuing their research.<sup>97</sup> As Donald Kennedy, the editor of *Science*, observes:

Many [scientists] are wary of work that may find use in some regulatory proceeding. They wonder whether the data underlying their findings may be subject to examination and reinterpretation, perhaps with some "spin" supplied by the revisionists. They know that charges of research misconduct could arise from hostile access to their scientific work. They know they are vulnerable to personal attack from those whose interests may be adversely affected by the product of their research.<sup>98</sup>

Scientific misconduct allegations have also been filed against federally funded researchers by those who were adversely affected by the researchers' work.<sup>99</sup> Even though the scientists are generally exonerated, these non-meritorious allegations of research misconduct financed by special interests can still have a serious and lasting impact on the accused. In the short-term, productive work is interrupted while the accused devotes time and energy to responding to the allegations. Notebooks, computers, and other lab equipment are sometimes off-limits during the investigation, and interactions with colleagues can become strained. In the longer term, even scientists who have been exonerated have had their labs

closed down, lost their jobs, and accumulated staggering legal debts.<sup>100</sup> Any allegation of misconduct can cast a pall over a scientist's work, harming her reputation and prospects for future grants.

The common thread running through all of these examples of scientific harassment is that the affected researcher has little recourse other than to wait out the often tedious legal proceedings. *Creating a limited cause of action that would allow harassed scientists to recover compensatory and punitive damages for unduly burdensome subpoenas, spurious allegations of research misconduct, bad faith open records requests, or any other abuse of legitimate legal processes would give scientists a tool that they could use to ensure compensation for their inconvenience.*<sup>101</sup> It would also have the important effect of raising the costs to those engaged in these types of excessive activities. However, because we do not want to inadvertently outlaw vigorous disagreement over unsettled science, there must be a high and clear threshold for this limited cause of action.

Any allegation of misconduct can cast a pall over a scientist's work, harming her reputation and prospects for future grants.

## Improving the Federal Advisory Committee Act

Stronger legal and regulatory controls on agencies' use of science advisory boards are essential to counter the trend toward political manipulation of this vital stream of science advice to the policy process. One of the most important institutional devices for translating scientific studies into public policy is the federal advisory committee. Agencies engaged in complex rulemakings that require application of advanced scientific research often seek advice and counsel from experts in the field who are not full-time government employees. Through the use of advisory committees, agencies are able to get the best advice from scientists who are well-respected in their fields and ensure that they understand how a range of disciplines interact to inform the resolution of difficult questions.<sup>102</sup> Advisory committees also improve accountability in agency decisionmaking by giving independent, disinterested outside experts an opportunity to critique how agency scientists are approaching a problem. Finally, and perhaps most important, the "stamp" of approval by an expert body helps insulate the agency from criticism by the political branches and the courts.<sup>103</sup>

Advisory committees are ubiquitous in the modern regulatory system. Thousands of advisory boards, subcommittees, and informal advisory groups meet each year to provide federal agencies with their perspectives on policy and regulation. Counting only the formally chartered advisory committees, there are some 62,000 committee members whose viewpoints help shape the regulatory landscape.<sup>104</sup>

The Federal Advisory Committee Act (FACA) is Congress's attempt to ensure that advisory committees include balanced viewpoints and are devoid of undue influence by special interests. FACA sets forth certain procedural requirements for the establishment and operation of advisory committees, including requirements that each committee be established by charter,<sup>105</sup> that all meetings and their purpose be publicized in advance,<sup>106</sup> that transcripts and other meeting materials be made publicly available after the meeting,<sup>107</sup> and that meetings be open to the public.<sup>108</sup> All of these requirements were designed to leverage public notice and participation as a means of ensuring that advisory committees provide neutral advice.

In its first 35 years of existence, FACA has been an effective tool for improving transparency of federal advisory bodies. Since FACA is not limited to science advisory committees, however, its effectiveness could be improved through amendments designed to address two problems unique to science advice. First, the law imposes a responsibility on federal agencies to balance the viewpoints of committee members and ensure no special interest has undue influence on the committee, but it provides little in the way of specific requirements for managing scientific conflicts of interest. Second, FACA provides insufficient guidance to agencies to ensure that their processes governing the selection and use of science advisors are transparent to the public.

## Committee Composition

The committee selection process occurs in two stages. First, an agency must ensure the right mix of committee members (both from a disciplinary and intra-disciplinary perspective). Second, an agency must ensure that the individuals appointed to the committee are able to render objective judgments about the weight of evidence before them.

## Choosing the Right Types of Committee Members

At the first stage, choosing the right mix of committee members involves two considerations. The first issue is that committee members can either be selected as “special government employees” (SGEs) or “representatives.” Representatives are chosen to voice the opinion of a specific interest group, e.g., pesticide formulators or environmental advocates. Because they are chosen to provide a specific viewpoint - to harbor a specific bias - they are not subject to conflict-of-interest review. SGEs, on the other hand, are supposed to provide neutral advice and are subject to the same conflict-of-interest statute as full-time government employees,<sup>109</sup> so they are required to report financial interests that could create a real or apparent conflict of interest.

Agencies have broad discretion in choosing the employment status of advisory committee members, and agencies appear to vary in their approach to these issues. The FDA and EPA tend to employ advisors as SGEs, while GAO found that the Departments of Agriculture, Energy, and Interior rely almost exclusively on representatives to fill their advisory committees, even though many of these committees would have been better served by SGEs.<sup>110</sup> It may be the administrative burden of reviewing SGEs’ conflicts of interest that creates an incentive to simply appoint committee members as representatives;<sup>111</sup> but the efficiencies gained through the use of advisory committees<sup>112</sup> and the value of their recommendations should counterbalance those concerns.

General Services Administration (GSA) regulations state that agency heads are responsible for ensuring that committee members’ interests and affiliations are reviewed for compliance with federal conflicts-of-interest statutes,<sup>113</sup> and for making the decision as to whether committee members are appointed as representatives or SGEs.<sup>114</sup> *Seating representatives of special interests as advisory committee members can threaten the balance of the panel. All members of science advisory boards should therefore be SGEs. GSA regulations could be clarified by explaining that agency heads can best assure compliance with federal conflicts-of-interest statutes by maximizing the number of committee members appointed as SGEs, particularly on committees whose charges focus on scientific issues.*

The other committee membership issue that agencies need to address at a general level is the task of ensuring balanced viewpoints. Under current GSA regulations, agencies must develop a plan that ensures a committee will be balanced according to the functions and

Seating representatives of special interests as advisory committee members can threaten the balance of the panel.

tasks to be performed.<sup>115</sup> The guidance provided to agencies implementing this requirement instructs the agencies to consider the following factors in developing the plan:

- The advisory committee's mission;
- The geographic, ethnic, social, economic, or scientific impact of the advisory committee's recommendations;
- The types of specific perspectives required, for example, such as those of consumers, technical experts, the public at large, academia, business, or other sectors;
- The need to obtain divergent points of view on the issues before the advisory committee; and
- The relevance of state, local, or tribal governments to the development of the advisory committee's recommendations.<sup>116</sup>

*Ideally, this list would also include an express requirement that agencies consider the scientific disciplines necessary to proper resolution of their charges.* So, for example, if a committee is charged with evaluating the toxicity of a chemical based on a host of clinical and epidemiological studies, that committee should have members who are experts in clinical toxicology and epidemiology. This compelling need for the correct mix of scientific disciplines seems rudimentary, but its fulfillment has become more difficult as the complexity of scientific risk assessments has grown.

### Choosing the Right Individuals: Screening for Bias and Conflicts of Interest

Moving on from the general goal of ensuring that agencies seek out the right types of committee members, we need to address the subsequent problem of ensuring that specific appointments do not threaten the committee's integrity. To that end, agencies must screen potential committee members for biases and conflicts of interest. At this stage a new statute and a new agency take control. Each committee member who is seated as an SGE is subject to the federal conflict-of-interest statutes enforced by the Office of Government Ethics (OGE). These statutes include the criminal conflict-of-interest prohibitions in 18 U.S.C. §§ 201 et seq. and the Ethics in Government Act of 1978,<sup>117</sup> which requires government employees to file reports regarding their financial and other interests. However, these statutes were designed to address ethical concerns related to all government employees, including full-time employees, Members of Congress, the President, and federal judges. Thus they are not a tight fit for prospective advisory committee members and each agency has had to develop its own policies for ensuring FACA committees comply with the statutes. The absence of clear guidance from OGE has led to a plethora of differing committee selection processes in the various federal agencies.

Optimizing the advisory committee selection process across federal agencies will require reforms that focus on a problem that is at its root one of definitions. What is bias? What is a conflict of interest? And when agency officials go to seat committee members, are there *de*

*minimis* biases or conflicts that they can safely assume will not color an advisor's work? FACA, the federal criminal conflicts-of-interest statutes, and the GSA and OGE implementing regulations all fail to answer these questions. Most federal agencies have only done so in a roundabout way, by using bias and conflict-of-interest screening policies that require prospective committee members to disclose certain limited information about their beliefs and financial interests. But these information disclosure requirements vary from agency to agency, meaning that the definitions of bias and conflict of interest are not uniform. Clearer guidance from GSA on what financial interests and biases are objectionable in the context of advisory committee appointments might help agencies.

The National Academies have a policy statement that addresses the definitional issue wisely and would be a good starting point for amending GSA's regulations. It reads:

Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group.

[T]he term "conflict of interest" means any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization.<sup>118</sup>

Other agencies have neglected to articulate what sorts of interests they are trying to uncover with their bias and conflicts screening policies. *Clear and concise statements like those quoted above, if printed at the beginning of every agency's conflicts disclosure form, would send an unambiguous signal to potential committee members that advisory committees are meant to produce neutral and disinterested advice. Moreover, it would set the tone for broad information disclosure that will help agency staff properly compose advisory committees' overall composition.*

The National Academies' policy statement is based on fundamental distinctions between bias and conflicts of interest. As the guidelines recognize, some degree of bias is unavoidable. Over time, through education and experience, everyone develops a degree of bias with regard to how common questions in their line of work should be answered. In fact, it is precisely this experience that makes experts valuable to peer review. On the other hand, when biases become so strong that they impinge on an individual's ability to objectively answer new questions, that person should not be given the institutional power of an advisory committee member. The process of choosing committee members should involve screening potential members to ensure that their biases are not threats to objectivity.

Improperly designed procedures aimed at uncovering biases are dangerous because of their potential to slide down the slippery slope toward the "political litmus tests" that infringe on a person's privacy and were improperly used by some federal officials in recent years.<sup>119</sup> The

National Academies' statement on bias and lack of objectivity above hints at the types of information that a legitimate committee-selection process should be designed to uncover. For one, the focus should be on views stated and actions taken in a public forum. Examples are analyses and conclusions published in research articles, statements made at conferences and other public speaking engagements, and any statements made as an expert witness. These statements are most likely to reflect an individual's most strongly held beliefs and do not invoke privacy interests. Screening for biases and potential problems with objectivity should also focus on whether an individual's public statements reflect a close tie to the positions or perspectives of a particular group's extreme views. If such a tie exists, it would cut against the principle of ensuring that FACA committees are not unduly influenced by special interests.

The National Academies' definition of conflict of interest is not limited to employment or even financial benefits. Looking at such a broad spectrum of motivations is the best way to get a full picture of an individual's interests and discern whether she might be swayed in her decisionmaking. Most agencies use a conflicts screening policy that examines, as this model does, non-financial interests and interests of a potential committee member's immediate family and business partners.

The temporal aspect of conflicts disclosure, however, is an area that needs improvement across the government. Even though a plain-text reading of the definition would indicate that the Academies demand disclosure of past and future interests, the guidance that accompanies the definition states that only interests held at the time a committee meets are important.<sup>120</sup> But past employment relationships, divested interests, or potential future research support might create a perception of a conflict of interest or bias, which can be just as detrimental to an advisory committee's legitimacy as an actual conflict. *Therefore, reformed conflicts policies should require prospective committee members to report potentially conflicting interests for some set period into the past (three to five years, at the least) and into the foreseeable future.*

Such a requirement is not unprecedented. FDA asks prospective committee members to disclose certain financial interests up to 12 months old.<sup>121</sup> Another section of the FDA conflicts-disclosure form has an indefinite "look-back" period, asking: "To your knowledge, do any of the following persons have any past involvement with the meeting/task issues: You, your spouse, minor child, general partner, organization in which you serve as an officer, director, trustee, general partner or employee."<sup>122</sup> OGE requires disclosure of all financial interests up to 12 months old in order to comply with the Ethics in Government Act of 1978.<sup>123</sup> EPA looks at financial interests from the previous two years and any interest from the past five years that might impinge on the ability to provide impartial advice.<sup>124</sup> And the *Journal of the American Medical Association* asks authors to disclose relationships with financially interested parties dating back five years and into "the foreseeable future."<sup>125</sup>

The second important concept contained in the National Academies' definition of conflicts of interest is that the definition does not set any threshold value below which conflicting

A perception of a conflict of interest or bias can be just as detrimental to an advisory committee's legitimacy as an actual conflict.

interests will be ignored. Most of the existing conflicts screening policies either set absolute thresholds for reporting (e.g., real property must be reported only if its fair market value is above \$1,000) or create some linkage between the value of an interest and percentage of personal wealth (e.g., stocks and bonds valued below 5 percent of personal wealth are considered *de minimis*). *Abolishing reporting thresholds for financial conflicts would provide a fuller picture of a prospective committee member's potential conflicts by allowing agency staff to look at an individual's cumulative investments.*

The third important concept in the NAS definition of conflicts of interest is that it turns on competitive advantages that might accrue to any firm or organization for which a prospective member is employed, thus helping to ensure disclosure of interests in firms that compete with, supply products to, or are in any other way related to a firm directly affected by an advisory committee's work. Conflict-of-interest standards should be expanded to include the competitive advantages that could be gained by an entity with which the prospective panelist is affiliated.

Another concept that deserves consideration is the possibility of vesting the power to select advisory committee members in someone other than political appointees. Current practice puts the ultimate power of committee selection in the hands of high-level agency officials who are appointed by the president. Nominations for committee membership can come from the public, career employees, and, in some cases, other government organizations like the NSF,<sup>126</sup> but the final decision about advisory committee membership rests with political appointees. This power structure compounds concerns about the neutrality of advisory committees by increasing the potential for political interference in the appointment process. Thus, to restore trust in the advisory committee system, changes to the bias and conflicts screening processes should be accompanied by changes to the balance of power in committee member nomination and appointment.

At one end of the spectrum is the idea of completely removing political appointees from the process of seating advisory committees. The National Academies are well respected and politically neutral and could be tasked with the responsibility of seating federal advisory committees. The Academies' membership comprises a diverse group of experts with specialties in nearly every field of research who could be a valuable resource for finding potential advisory committee members. Moreover, by moving the committee appointment process to a non-political arm of the government, committees will better survive changing Congresses and presidential administrations, thus enhancing the credibility of committee recommendations. Of course, completely eliminating political appointees from the committee selection process would pose some problems. For one, the current system maintains a level of accountability that would not be possible if politically insulated individuals were making final decisions. Furthermore, taking control of advisory committees away from administrative agencies might cause agencies to avoid seeking their advice.

A hybrid system may be a more effective way to minimize political interference in the advisory committee selection process while at the same time maintaining accountability. The

National Academies are an ideal resource for committee member nominations, so a system modeled after the FIFRA Scientific Advisory Panel might be the best option. The seven members of the FIFRA Scientific Advisory Panel are chosen from a list of twelve nominees, six of whom are nominated by NIH and six of whom are nominated by NSF.<sup>127</sup> Depending on the subject matter that will be addressed, the proper arm of the National Academies (either NAS, the National Academy of Engineering, the Institute of Medicine, or the National Research Council) can be polled for nominations. Then, the agency that chartered the committee can choose the committee members after screening for biases and conflicts of interest and taking into account the advice of agency staff. High-level officials should be responsible for signing off on the final choices and approving any conflicts waivers.

### Conflict-of-interest Waivers

A question integral to any discussion of committee appointments is how the appointing officials should address waivers. As agencies seek the scientists most experienced in rarified fields, these scientists are more likely to be employed by - or have some financial relationship to - companies that could be affected by the advisory committee's decisions.<sup>128</sup> The problem becomes even more acute as the definition of "conflict of interest" expands. As a result, agencies typically grant waivers that allow the conflicted scientists to participate in committee deliberations and, occasionally, vote on the committee's final recommendations. Some public interest advocates have made the claim that advisory committees can and should be composed of only non-conflicted scientists.<sup>129</sup> However, a study by the Eastern Research Group, commissioned by FDA, came to a different conclusion based on a review of 124 standing advisory committee members at 16 committee meetings held between December 2005 and October 2006.<sup>130</sup> ERG concluded that "[t]he practical feasibility of creating conflict-free advisory committees remains uncertain."<sup>131</sup>

Given that the empirical research record on the issue of conflicts waivers is limited and that we have advocated for a broad definition of conflicts of interest, we will remain agnostic as to the feasibility of conflict-free advisory committees. *Nevertheless, we are strongly in favor of limiting the number of waivers on each committee and increasing transparency as to those waivers that are issued. With respect to the limitations on waivers, concerns about biased committee recommendations could be alleviated by limiting the number of waivers available per committee to a certain fraction of the total membership, and by prohibiting committee members who receive waivers from voting on the committee's decisions. These limitations would allow committees to benefit from the conflicted individuals' expertise while simultaneously minimizing the potential for those individuals to threaten the integrity of the committee's final decisions. In terms of increased transparency, any proposed waivers should be posted on the Internet 15 days prior to any committee meeting, along with a justification for the waiver and an explanation of the decision process used to set the composition of the committee as a whole. Increased transparency about the decisionmaking process will help to eliminate questions of credibility that regularly arise when the public finds that a committee is composed of conflicted individuals.*

## Transparency in the Appointment Process

Government-wide FACA regulations must also improve the transparency of agency processes governing the agencies' evaluation of potential members for biases and conflicts. The status quo lies at the least prescriptive end of the spectrum, relying on individual agencies to develop their own information collection policies. As a result, each agency has its own form that potential committee members must complete and its own interview process.

Furthermore, each agency has its own policy regarding waivers of conflicts of interest. This lack of uniformity is not something that we think necessarily needs to be addressed by GSA. The process of gathering and analyzing bias and conflicts information is something that would probably benefit from regulatory flexibility. For example, an individual's real property investments deserve more scrutiny when she may be the member of an advisory committee dealing with endangered species than when she may be on an FDA drug-approval advisory committee. The more important issue is transparency in the process. GSA's regulations should be revised to ensure that, regardless of the process an agency uses, the process is the same for each potential committee member and the results of the process are publicly available. *At the very least, a blank copy of each agency's conflicts disclosure form should be available online, along with a full description of the other methods used to collect information about conflicts and biases and how the collected information is analyzed.*

## Closing a Loophole in FACA Coverage

In some instances, federal agencies avoid the difficult issues of proper advisory committee selection by simply commissioning private contractors to provide the advice they need. This loophole is an issue Congress must address because it arises out of the federal courts' interpretation of FACA's statutory language. The statute only covers committees that are "established" or "utilized" by an agency.<sup>132</sup> The courts have held that contractors who are paid to provide agencies with expert advice are not "established" or "utilized" by an agency - and are therefore not covered by FACA - as long as the agency does not exercise a significant level of control over the group.<sup>133</sup> Congress should close this loophole by redefining FACA's coverage so that it is clear that the Act is meant to ensure transparency and eliminate conflicts of interest even when a private entity is managing the advisory committee process.

## Preventing Unwarranted CBI Claims

Risk information submitted to the federal government is often hidden from public view through overbroad regulatory policies designed to insulate information claimed as “trade secrets” and “confidential business information” (CBI). Statutory definitions have been incrementally expanded through agency policies and by case law in some circuits.<sup>134</sup> This process has turned non-mandatory and limited statutory exemptions in TSCA, FIFRA, and the FDCA into broad exclusions that routinely frustrate the statutory goal of improving regulation through information disclosure. Agencies also defer in the first instance to the regulated party to determine what information should be classified as CBI.<sup>135</sup> CBI claims need not be substantiated in advance, at least under most of the public health and environmental statutes.<sup>136</sup> Instead, the justification for a CBI classification is reviewed, if at all, by the agency only after the information has been requested under FOIA.<sup>137</sup> At that time, if the agency determines the CBI claim is unjustified it can release the information (after informal proceedings).<sup>138</sup> However, if the agency official is wrong, they could face personal civil and criminal charges for disclosing trade secret information.<sup>139</sup> A 2001 memo from Attorney General John Ashcroft suggests that the executive branch has reversed its longstanding policy of operating under a “presumption of disclosure.”<sup>140</sup> In such a permissive environment, it is perfectly rational for companies to overclaim CBI in their regulatory submissions, and the evidence suggests that this is exactly what they do.<sup>141</sup>

The consequences of overly vigorous CBI claims are difficult to quantify, but they appear to impinge, potentially significantly, on the accessibility and utility of important research and scientific information. For example, risk information submitted to EPA could be useful to other federal and state officials, but statutory requirements to keep that information confidential often prevent efficient information-sharing. Problems arise for non-EPA staff in realizing that the information exists, getting proper security clearances, and ensuring that file rooms and computer systems provide adequate protection.<sup>142</sup> This secrecy limits innovation in risk prevention and risk management.<sup>143</sup> Keeping risk information hidden from the public also limits the credibility of agency decisions.<sup>144</sup> Without access to this information, the public is asked to simply trust that the agency is making appropriate and well-informed decisions.

*We propose four separate reforms that address the agencies’ current, permissive approach to trade secret protections for information that informs health and environmental regulation:*

- *The classes of information subject to CBI protection should be explicitly limited;*
- *All information that is submitted to the government and alleged to be worthy of trade secret/CBI protection should be accompanied by a thorough explanation of why such protection is warranted;*
- *In the rare instances where the government sequesters trade secrets or CBI, protections should “sunset” unless submitters justify the extension of protection; and*
- *The Executive Branch should reestablish a “presumption of disclosure” under FOIA.*

## Types of Information that Should Never Be Sequestered

*Certain toxicological, ecotoxicological, and other physicochemical information should never be kept secret because of its importance to the protection of public health, worker safety, and natural resources.* Both TSCA and FIFRA prohibit EPA from granting CBI protection to certain health and safety information.<sup>145</sup> However, the TSCA and FIFRA prohibitions have exceptions that allow CBI claims when the health and safety information could possibly be used to understand a firm's manufacturing processes or the composition of a proprietary chemical mixture.<sup>146</sup> These exceptions, though narrowly tailored, are tied to a FOIA process that opens significant loopholes and enables firms to hide useful information from the public.<sup>147</sup> Under TSCA, 95 percent of § 5 premanufacture notices have CBI claims<sup>148</sup> and 25 percent of § 8(e) adverse effects reports have CBI claims.<sup>149</sup>

Amendments to domestic statutes and regulations that exempt the above classes of information from trade secret/CBI protections will ensure that useful risk information is publicly available. However, positive legislative action may not even be necessary once the EU's REACH regulations take effect.<sup>150</sup> The REACH legislation lists the following information as that which must be always publicly available:<sup>151</sup>

- The name of the substance;
- The classification and labeling of the substance: Under a prior EU directive, substances can be classified as “explosive,” “oxidizing,” “flammable,” “toxic,” “harmful,” “corrosive,” “irritant,” “sensitizer,” “carcinogenic,” “mutagenic,” “toxic for reproduction,” or “dangerous for the environment.” If classified as one or more of the preceding, the substance must be labeled as such;<sup>152</sup>
- Physicochemical data: information about the chemical properties of the substance,<sup>153</sup> as well as about pathways and environmental fate;
- Results of toxicology and ecotoxicology studies;
- Any derived no effect level or predicted no effect concentration;
- Guidance on safe use; and
- Analytical methods for detecting the substance in humans or the environment (if requested by the Chemicals Agency).

Presumably, any risk information submitted to a U.S. regulatory agency would have to be submitted to the European Chemicals Agency, would be available to the public through that Agency, and would therefore destroy any link between disclosure by the U.S. agency and any economic harm.

Nevertheless, EPA and other agencies could still go one step further and explicitly identify classes of information, as REACH does, that are not entitled to protection. For example, under 40 C.F.R. § 2.207, EPA has the authority to make “class determinations” regarding the availability of CBI protection under FOIA for clearly defined types of information. A class determination stating that the information listed above is not eligible for CBI

EPA should identify classes of information that are not entitled to CBI protection.



protection due to its public availability through the European Chemicals Agency would be a simple way for federal officials to affirm a policy of promoting scientific transparency.

### Upfront Substantiation

In addition to limiting the types of information deserving confidential protection, we propose reforming the procedures that the private sector must follow to request protection. Under existing policies, requesting CBI protection is virtually cost-free, resulting in an overabundance of unwarranted CBI claims. A submitter can simply stamp a document as CBI: Only in limited circumstances are firms required to provide a justification for requesting confidential protection.<sup>154</sup> *In order to ensure a proper balance between secrecy and transparency, firms should be required to provide a detailed, upfront substantiation of their claim that public disclosure of specific information would result in substantial adverse competitive impact.*

Evidence exists that requiring substantiation of CBI claims is an effective way to prevent overbroad claims. A 1992 study by the Hampshire Research Associates found that CBI claims drop by as much as 50 to 60 percent when EPA requires upfront substantiation.<sup>155</sup> EPA has undertaken a systematic effort to review CBI claims made under TSCA and to challenge those that seemed overbroad. Agency officials challenge about 14 TSCA CBI claims per year and firms withdraw “nearly all of the claims challenged.”<sup>156</sup> By requiring firms to provide upfront substantiation of their CBI claims when the claims are first made, the government could avoid the administrative and public health costs of sequestering information that does not deserve confidential protection.

Requiring upfront substantiation would simply mean asking for clear documentation of the decision process firms should already be employing. The same regulations that inform firms of their right to request CBI protection for the information they submit to EPA also clearly state the substantive criteria that the Agency uses to determine whether confidentiality is warranted. Any firm that requests CBI protection should first assess the request according to the regulatory criteria.

Documenting this assessment and submitting it to EPA along with the alleged CBI should impose only minimal additional administrative costs. In fact, EPA conducted some research in the 1990s to determine the additional costs to firms if they were required to provide

**TABLE 2.**  
**Hours for Confidential Business Information Claims (in 1997 dollars)**

Task	Clerical Hours (\$24.33/hr)	Technical hours (\$59.52/hr)	Managerial hours (\$81.61/hr)	Total hours
Upfront substantiation of chemical identity	0.26 - 0.26	1.08 - 1.82	0.48 - 1.05	1.82 - 3.13
Upfront substantiation of plant site information	0.12 - 0.12	0.54 - 1.12	0.23 - 0.79	0.89 - 2.03

upfront substantiation of CBI claims related to chemical identity or plant site information submitted under the TSCA § 8(a) Inventory Update Rule and found the following:<sup>157</sup>

If we take these data to indicate that substantiating a CBI claim only takes a matter of hours, our proposal to impose such a small burden on firms in order to promote transparency and improve public health seems reasonable.

In 1994, EPA actually published in the Federal Register a limited proposal to improve substantiation practices. After first indicating that the Agency was considering imposing an upfront substantiation requirement on all TSCA §§ 8(c), (d), and (e) filings,<sup>158</sup> the final proposal in the Federal Register suggested only requiring upfront substantiation when the chemical identity is claimed confidential in these filings.<sup>159</sup> The final proposal was never codified, but this episode shows that EPA recognizes the utility of upfront substantiation, particularly where CBI claims are prevalent and the allegedly confidential information would be useful if disclosed to the public.<sup>160</sup> Congress, too, recognizes the importance of upfront substantiation of CBI claims in the toxics arena, evidenced by the fact that the Emergency Planning and Community Right-to-Know Act (EPCRA) mandates upfront substantiation of any CBI claim.<sup>161</sup>

### Sunsets on CBI Claims

Over time, changes in market conditions and the state of technology tend to decrease the economic justification for CBI protection. The benefit to manufacturers - and therefore the justifications for sequestering risk information - decreases over time due to the high depreciation rate of information.<sup>162</sup> Products are reformulated, patents expire, and competitors gain access to proprietary information through other means. At the same time, hazardous products are distributed through the marketplace, increasing environmental and human exposure and, consequently, driving up the value of that risk information as a tool for eliminating hazards.

The idea of sunsets on CBI claims covering risk information was actually floated by EPA in 1994 as part of a broader initiative to change the Agency's CBI policy.<sup>163</sup> And the Government Accountability Office (GAO) has found that industry representatives who were asked about sunsets on CBI claims found the proposal reasonable.<sup>164</sup> While the justification for imposing sunsets on CBI claims under toxics law is simple, the technical details of implementing this reform are not. Research on the useful life of CBI protection in the field of risk information is essentially non-existent, likely because maintaining that protection is costless for firms under current regulation (thus eliminating the incentive to research the utility of continuing to protect information). This lack of research makes the task of choosing sunsets arbitrary. In other fields, empirical research suggests that five years is a typical useful life for patent and trade-secret protections.<sup>165</sup> To put this conclusion in context, the FDA typically grants five-year exclusive marketing rights for new drugs and pesticides are generally protected by 20-year patents. *Since risk information on its own is unlikely to destroy a firm's competitive advantage and a sunset would allow for continued*

*CBI protection upon proper justification, we suggest a five-year sunset on all claims made under TSCA and FIFRA.*

### **Freedom of Information Act Retrenchment**

Even if changes to the CBI policies under TSCA, FIFRA, and other information-gathering statutes decrease incentives for regulated parties to hide information, public requests for unprotected data could be rejected by agency staff who are wary of running up against officials who support recent trends in federal policy that constrict FOIA's open-government mandates.<sup>166</sup> FOIA Exemption 4 gives federal officials the power to withhold information requested by the public if that information is a "trade secret" or commercial or financial information obtained from a person that is privileged or confidential."<sup>167</sup> The breadth of information covered by this exemption has expanded in recent years as the result of troubling court decisions and shifting Justice Department policies.<sup>168</sup>

The overarching trend in judicial interpretation of FOIA Exemption 4 is to read the exemption "in the broadest possible manner, ignoring other interpretations that balance the economic reasons for protecting business information against the goal of promoting government transparency."<sup>169</sup>

Current Justice Department policy on the exemption similarly favors secrecy over open government. Attorney General John Ashcroft, in an October 2001 memo to all federal agencies, announced that decisions to disclose information through FOIA that could have been withheld by claiming a statutory exemption "should be made only after full and deliberate consideration of the institutional, commercial, and personal privacy interests that could be implicated by disclosure of the information."<sup>170</sup> Moreover, the memo stated that DOJ would defend all decisions to withhold information "unless they lack a sound legal basis or present an unwarranted risk of adverse impact on the ability of other agencies to protect other important records."<sup>171</sup>

This policy "flouts legislative intent and previous administrative practice."<sup>172</sup> Under Attorney General Janet Reno, the executive branch operated under a "presumption of disclosure" whereby DOJ would only defend decisions to withhold information from the public "in those cases where the agency reasonably foresees that disclosure would be harmful to an interest protected by that exemption."<sup>173</sup> *Whether by Executive Order or revised Justice Department policy, the executive branch should reestablish the longstanding "presumption of disclosure" under FOIA. Congressional action may be necessary to overcome established agency policies and court decisions.*

## Establishing a Science Registry

*The goal of expanding access to privately funded toxics research might be best achieved through additional programs that would complement expanded adverse effects reporting requirements, specifically the creation of a national registry for studies investigating the toxicological properties of common chemicals.* One such program was first developed in the pharmaceuticals arena, where researchers are required to register their work in a clinical-trials registry. A clinical-trials registry allows scientists to post a notice that they are conducting research on the effects or efficacy of a pharmaceutical product in a centralized and publicly accessible database.

The most successful clinical-trials registry is operated by the National Institutes of Health (NIH). ClinicalTrials.gov is an online database developed in accordance with the FDA Modernization Act of 1997, which mandated registration of all private and public clinical trials conducted to support investigational new drug applications for pharmaceuticals that could be used to treat “serious and life-threatening conditions.”<sup>174</sup> The process of registering a clinical trial begins early in the research process. Before any patients are enrolled, the principal investigator must submit certain basic information about the trial’s design to NIH. The details include the name of the sponsor and principal investigator, a description of the study (including information about the disease or condition being studied and intervention being tested), and the outcome measures being tested.<sup>175</sup>

Congress has since expanded the registration mandate to cover all controlled, clinical investigations other than Phase I studies (short-term, limited-exposure studies designed to ensure pharmaceuticals meet basic safety standards prior to further investigation to test efficacy).<sup>176</sup> A similar program could be designed to bring the transparency benefits of a research registry to a broader set of scientific disciplines. This idea has been implemented or proposed in a number of other fields, from genetics<sup>177</sup> to nanotechnology.<sup>178</sup>

The clinical-trials registry was designed in response to a problem that also plagues toxicological research: the suppression and selective reporting of adverse and equivocal research. In the pharmaceutical research industry, researchers, funding institutions, and medical journals are keenly interested in two types of trials: those showing that new treatments are improvements over existing clinical practices, and those showing that two approaches to treatment are equivalent.<sup>179</sup> Equivocal trials and those showing that a new treatment is inferior are less likely to boost pharmaceutical manufacturers’ profits or affect physicians’ practices or Medicare and Medicaid coverage and, as a result, are more likely to get scuttled while in progress or left unpublished once the data are analyzed. In other fields of research, suppression of adverse results is also pervasive, though it is motivated more by manufacturers’ desire to avoid additional regulation than by publication incentives. Examples include the DuPont/PFOA case cited previously<sup>180</sup> and the tobacco industry’s persistent sequestration of studies related to nicotine pharmacology.<sup>181</sup>

Presumably, many of the benefits of a clinical-trials registry that accrue to the pharmaceutical field would be transferable to other fields of research if the registry concept were expanded.

By knowing what their colleagues and competitors are doing, scientists can design new work to resolve the questions left unanswered by existing work.

NIH has made ClinicalTrials.gov indexed and searchable, so once researchers have registered their work (which they are generally required to do prior to enrollment of the first patient), any member of the public can access certain details about the goals of the trial, its status, its sponsor, and other useful information. This design was originally conceived as a recruitment tool for investigators and potential patients. But it is the other benefits that would be most useful in the context of other research fields.

For scientists, the primary benefit might be providing insight into the state of ongoing research that has not yet reached the publication stage. By knowing what their colleagues and competitors are doing, scientists can design new work to resolve the questions left unanswered by existing work (e.g., does an alternate exposure pathway change the toxicology of a certain chemical?). For organizations that fund research, the registry could be a useful tool for avoiding redundant work. For state and federal regulators, it could be a resource for finding experts at the cutting edge of research in a particular area. Interested parties can also track individual studies to ensure that they are continuing toward completion and not abandoned when results do not conform to expectations.

A threshold problem in designing and implementing an expanded science registry is defining the scope of the registry - the types of research that must be registered. Outside the field of pharmaceuticals, studies are not identified as “Phase I” through “Phase IV,” so that aspect of simple design in the ClinicalTrials.gov database cannot be duplicated. Instead, coverage could be defined based on intended outcomes. For instance, the database could initially be limited to studies designed to develop or refine a carcinogenicity profile or other toxicological profile for a substance in the TSCA Inventory or covered by a pesticide registration under FIFRA. This approach fails to cover research on new substances and on the fundamental principles of toxicology, but it promotes transparency in those studies that could be the most useful in toxics regulation.

A second significant issue is enforcement. When the clinical-trials registry first came online, it was plagued by infrequent registration of trials. FDA staff found that, from January to September 2002, only 49 percent of industry-sponsored clinical trials that should have been registered were.<sup>182</sup> During its first five years, from its inception in February 2000 until May 20, 2005, researchers registered 13,153 clinical trials on the registry.<sup>183</sup> But then between May 20, 2005 and October 11, 2005, another 9,561 trials were registered (a 73-percent increase in the size of the database in less than five months).<sup>184</sup> This dramatic spike in the number of registered trials has been linked to a policy shift by the ICMJE.<sup>185</sup> In September 2004, the editors of *JAMA*, *The New England Journal of Medicine*, *The British Medical Journal*, and numerous other influential publications announced that they would refuse to accept articles based on unregistered trials that began patient enrollment after July 2005.<sup>186</sup> A similar statement by a group of prominent journal editors in other fields of research might be the best way to expand the use of research registries.

One final question about implementation that ties the idea of expanded registries back to the adverse effects reporting and Shelby Amendment discussions is the question of whether expanded research registries should be “results registries.” Unlike ClinicalTrials.gov, a results registry has all of the information about the design of a trial, plus a summary of the results once the trial has run its course. Results could be posted in many different ways, each with potential pitfalls, but the simplest way may be the best: When a registered study is the basis for a peer-reviewed article, a link to the article or an abstract should be posted on the registry. Though this method makes it less likely that the results will be posted in language that is clear and comprehensible to the lay public, it ensures that only peer-reviewed conclusions are posted.

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## Conclusion

Congress and the Executive Branch have developed a system in which decisions about how to set protective standards are guided in large part by objective scientific evidence. So long as this is the case, these two branches of government, along with the judiciary, must do what they can to limit distortion of science and harassment of scientists by ideological and economic special interests. The proposals described in these pages are rooted in the bedrock principles of scientific independence and transparency, and, if implemented, would improve the integrity of the science policy decisions that shape our environmental and public health protections.

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- 4 *Id.* at 370-76.
- 5 *See id.*
- 6 OFFICE OF MANAGEMENT AND BUDGET, OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations," 64 Fed. Reg. 54926, 54930 (October 8, 1999).
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- 8 AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, *AAAS Resolution: Expressing Concern About Legislation Opening all Federally Funded Research Awards to Freedom of Information Act (FOIA) Demands* (January 24, 1999), available at [http://archives.aaas.org/docs/resolutions.php?doc\\_id=400](http://archives.aaas.org/docs/resolutions.php?doc_id=400) (accessed May 9, 2008); Association of American Universities letter to OMB re: Against proposed revision to OMB Circular A-110 (March 23, 1999), available at <http://www.thecre.com/ipd/access/agency/1999-03-23.html> (accessed May 9, 2008); National Research Council, *SHARING RESEARCH DATA 29-30* (1985), available at [http://www.nap.edu/catalog.php?record\\_id=2033](http://www.nap.edu/catalog.php?record_id=2033) (accessed May 9, 2008).
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- 13 Executive Order 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review," 72 Fed. Reg. 2763 (January 23, 2007).
- 14 A "regulatory action" exempted from this definition is "any substantive action by an agency (normally published in the *Federal Register*) that promulgates or is expected to lead to the promulgation of a final regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking." *Id.*
- 15 A guidance document is considered "significant" if it is disseminated to regulated entities or the general public and may reasonably be anticipated to:
  - (A) lead to an annual effect of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
  - (B) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
  - (C) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or
  - (D) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in [Executive Order 12866]...
- 16 Shelby, *Accountability and Transparency*, *supra* note 4 at 385.
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- 38 7 U.S.C. § 136d(a)(2).
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- <sup>57</sup> *Id.* at 49372.
- <sup>58</sup> *Id.*
- <sup>59</sup> 40 C.F.R. § 159.165(a) (2007).
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- <sup>67</sup> 42 U.S.C. §§9601(22) (defining "release") and (8) (defining "environment").
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- <sup>91</sup> Whistleblower Protection Enhancement Act of 2007, H.R. 985 (110th Cong.), § 13. This bill has been passed by the House and by a Senate committee, but will not be called for a vote on the Senate floor until Sen. Colburn's hold has been removed. Sen. Colburn's hold is in place over a concern that another section of the bill, which would overturn an Executive Order regarding presidential documents, might be unconstitutional.
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- <sup>98</sup> Donald Kennedy, "Prologue," in Wagner and Steinzor, eds., RESCUING SCIENCE, *supra* note 96, at xix.
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- <sup>100</sup> Glenn Harlan Reynolds, "Thank God for the Lawyers": Some Thoughts on the (Mis)regulation of Scientific Misconduct, 66 Tenn. L. Rev. 801, 808-09 (1999) (describing the case of Dr. Rameshwar Sharma, whose laboratory was closed during a federal misconduct investigation that eventually vindicated him); see also, Kuehn, *Suppression of Environmental Science*, *supra* note 97, at 348 (noting that the editor of the *Journal of Medical Primatology* accumulated over \$2 million in legal expenses, including \$70,000 he had to pay out of pocket).
- <sup>101</sup> Some state legislatures have enacted statutes that protect public policy advocates whose participation in the regulatory process leads to harassing lawsuits by powerful commercial interests. Victims of Strategic Litigation Against Public Participation (SLAPP) suits have convinced some states to pass "anti-SLAPP" legislation that gives them recourse somewhat like what we are proposing for harassed scientists. See Wagner & McGarity, BENDING SCIENCE, *supra* note 97 at 157-80.
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- <sup>103</sup> See, e.g., *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000).
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- <sup>106</sup> 5 U.S.C. App. 2, § 10(a)(2).
- <sup>107</sup> 5 U.S.C. App. 2, §§ 10(b) - (c).
- <sup>108</sup> 5 U.S.C. App. 2, § 10(a)(1).
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- <sup>110</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, *Federal Advisory Committees: Additional Guidance Could Help Ensure Independence and Balance*, GAO-04-328, 20-23 (April 2004).
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- <sup>114</sup> 41 C.F.R. Part 102-3, Appendix A to Subpart C (2007); GENERAL SERVICES ADMIN., *Federal Advisory Committee Management - Final Rule*, 66 Fed. Reg. 37728, 37744 (July 19, 2001).
- <sup>115</sup> 41 C.F.R. § 102-3.60(b)(3) (2007).
- <sup>116</sup> 41 C.F.R. Part 102-3, Appendix A to Subpart B (2007); GENERAL SERVICES ADMIN., *Federal Advisory Committee Management - Final Rule*, 66 Fed. Reg. 37728, 37740 (July 19, 2001).
- <sup>117</sup> 5 U.S.C. Appendix 4.
- <sup>118</sup> NATIONAL ACADEMIES, "Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports" (May 12, 2003), available at [http://www.nationalacademies.org/coi/bi-coi\\_form-0.pdf](http://www.nationalacademies.org/coi/bi-coi_form-0.pdf) (accessed March 18, 2008).
- <sup>119</sup> Rep. Brian Baird Letter to Attorney General Requesting Investigation of Improper Review of Advisory Committee Candidates, Oct. 26, 2004, available at <http://science.house.gov/press/PRArticle.aspx?NewsID=46> (accessed March 18, 2008).
- <sup>120</sup> NATIONAL ACADEMIES, "Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports," *supra* note 110 at 4.
- <sup>121</sup> FDA Form 3410, available at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3410.pdf> (accessed May 9, 2008).
- <sup>122</sup> *Id.*
- <sup>123</sup> OGE Form 450, available at [http://www.usoge.gov/pages/forms\\_pubs\\_otherdocs/fpo\\_files/forms/oge450\\_2006/oge450\\_automated\\_06.pdf](http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/forms/oge450_2006/oge450_automated_06.pdf) (accessed May 9, 2008).
- <sup>124</sup> EPA Form 3110-48, available at [http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/Form3110-48/\\$File/epaform3110-48.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/Form3110-48/$File/epaform3110-48.pdf) (accessed May 9, 2008).
- <sup>125</sup> JAMA, "Instructions for Authors," <http://jama.ama-assn.org/misc/ifaora.dtd#ConflictsofInterestandFinancialDisclosures> (accessed May 9, 2008).
- <sup>126</sup> By law, the seven members of the FIFRA Scientific Advisory Panel are chosen from a list of 12 nominees, 6 of whom are nominated by NIH and 6 of whom are nominated by NSF. 7 U.S.C. § 136w(d).
- <sup>127</sup> 7 U.S.C. § 136w(d).
- <sup>128</sup> See McComas et al., *Conflicted Scientists: the "shared pool" dilemma of scientific advisory committees*, 14 PUB. UNDERSTANDING SCI. 285 (2005).
- <sup>129</sup> See letter from Center for Medical Consumers, Center for Science in the Public Interest, Consumers Union, National Physicians Alliance, U.S. PIRG, and Union of Concerned Scientists, to Andrew C. von Eschenbach, Commissioner, FDA, Dec. 3, 2007, available at [http://www.cspinet.org/new/pdf/20071203\\_final\\_letter\\_to\\_fda\\_re\\_proposed\\_coi\\_guidance\\_in\\_wake\\_of\\_erg\\_report.doc](http://www.cspinet.org/new/pdf/20071203_final_letter_to_fda_re_proposed_coi_guidance_in_wake_of_erg_report.doc) (accessed May 9, 2008).
- <sup>130</sup> Eastern Research Group, *Measuring Conflict of Interest and Expertise on FDA Advisory Committees* (Oct. 26, 2007), available at <http://www.fda.gov/oc/advisory/ERGCOREport.pdf> (accessed May 9, 2008).
- <sup>131</sup> *Id.* at 7-11.
- <sup>132</sup> 5 U.S.C. Appendix II, § 3(2)(C).
- <sup>133</sup> See generally, Steven P. Croley and William F. Funk, The Federal Advisory Committee Act and Good Government, 14 Yale J. on Reg. 451, 477-85 (1997); see also, Byrd v. EPA, 174 F.3d 239 (D.C. Cir.) (holding that FACA did not apply when EPA hired Eastern Research Group to convene a peer review panel tasked with reviewing EPA's updated report on the carcinogenic effects of benzene, despite the fact that EPA gave ERG a list of potential panelists, had the opportunity to modify ERG's choice of panelists, submitted a list of specific questions the panel must answer, and sent an employee to provide introductory remarks at the peer review panel's public meeting), cert. denied 529 U.S. 1018 (2000).
- <sup>134</sup> McGarity, *The Complementary Roles of Common Law Courts and Federal Agencies in Producing and Using Policy-Relevant Scientific Information*, *supra* note 42; Mary L. Lyndon, *Secrecy and Access in an Innovation Intensive Economy: Reordering Information Privileges in Environmental, Health and Safety Law*, 78 U. COLO. L. REV. 465 (2007); Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1699-1705 (2004).
- <sup>135</sup> Wagner and Michaels, *Equal Treatment for Regulatory Science*, *supra* note 23 at 129-35.
- <sup>136</sup> See 40 C.F.R. § 2.203 (2007).
- <sup>137</sup> See *id.* at § 2.204 (2007).
- <sup>138</sup> *Id.*
- <sup>139</sup> Lyndon, *Secrecy and Access in an Innovation Intensive Economy*, *supra* note 135, at 508-09; see Trade Secrets Act, 18 U.S.C. § 1905.
- <sup>140</sup> See *infra* note 174 and accompanying text.
- <sup>141</sup> Wagner and Michaels, *Equal Treatment*, *supra* note 23, at 133-34.
- <sup>142</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, GAO/RCED-94-103, 55 (Sept. 1994).
- <sup>143</sup> See generally, Lyndon, *Secrecy and Access in an Innovation Intensive Economy*, *supra* note 135.
- <sup>144</sup> ENV'TL. PROT. AGENCY, *Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule*, V-28 (July 29, 1999), available at [http://yosemite.epa.gov/ee/epa/riafile.nsf/vwAN/P99-8.pdf/\\$File/P99-8.pdf](http://yosemite.epa.gov/ee/epa/riafile.nsf/vwAN/P99-8.pdf/$File/P99-8.pdf) (accessed May 9, 2008).
- <sup>145</sup> 15 U.S.C. § 2613(b)(1) (TSCA § 14(b)(1)); 7 U.S.C. § 136h(d)(1) (FIFRA § 10(d)(1)).
- <sup>146</sup> *Id.*
- <sup>147</sup> Wagner, *Commons Ignorance*, *supra* note 135, at 1699-1705; Thomas O. McGarity, *The Complementary Roles of Courts and Agencies in Producing and Using Policy-Relevant Scientific Information*, *supra* note 42, at 1055-56.
- <sup>148</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458, 33 (June 2005).

## End Notes

- <sup>149</sup> Robert Gottlieb, REDUCING TOXICS: A NEW APPROACH TO POLICY AND INDUSTRIAL DECISIONMAKING 65 (1995). Gottlieb notes that 80 percent of the CBI claims made in § 8(e) notices are claims to protect the identity of the chemical.
- <sup>150</sup> REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006). The legislation creates a unified regulatory scheme for EU nations whereby all chemicals manufactured and imported into the EU must be registered with the European Chemicals Agency. The registration process mandates that each chemical be screened for toxicity and ecotoxicity and empowers the Chemicals Agency to ban or restrict the sale of the most dangerous substances.
- <sup>151</sup> EU Regulation (EC) 1907/2006 Article 119(1). Though Article 119(1) mandates that this information “shall be made available, free of charge, over the Internet,” registrants may request confidential treatment of the information. *Id.* at 10(a)(xi). This request must be accompanied by “a justification as to why publication could be harmful for his or any other concerned party’s commercial interests.” *Id.*
- <sup>152</sup> EU Directive 67/548/EEC.
- <sup>153</sup> Properties that must be reported include physical state at standard temperature and pressure, boiling point, flash point, flammability, explosive properties, vapor pressure, solubility, evaporation rate, fat solubility, etc. See EU Regulation (EC) 1907/2006 Annex II, § 9; Annex VII, § 7; Annex IX, § 7.
- <sup>154</sup> See 40 C.F.R. § 2.203 (2007); see also, Wagner and Michaels, *Equal Treatment*, *supra* note 23, at 129-35, and Lyndon, *Secrecy and Access in an Innovation Intensive Economy*, *supra* note 135, at 519.
- <sup>155</sup> Wagner and Michaels, *Equal Treatment*, *supra* note 23, at 134, citing HAMPSHIRE RESEARCH ASSOCIATES, INC., *Influence of CBI on TSCA Implementation* (1992), at figs. 2, 6.
- <sup>156</sup> U.S. GOV’T. ACCOUNTABILITY OFFICE, *Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458, 33 (June 2005).
- <sup>157</sup> ENVT’L. PROT. AGENCY, *Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule*, *supra* note 145, at III-9, III-30.
- <sup>158</sup> ENVT’L. PROT. AGENCY, *Final Action Plan: TSCA Confidential Business Information Reform*, 9 (June 20, 1994) (on file with the authors).
- <sup>159</sup> ENVT’L. PROT. AGENCY, *Proposed Rule: Public Information and Confidentiality Regulations*, 59 Fed. Reg. 60446, 60459 (Nov. 23, 1994).
- <sup>160</sup> See ENVT’L. PROT. AGENCY, *Final Action Plan: TSCA Confidential Business Information Reform*, *supra* note 159.
- <sup>161</sup> 42 U.S.C. § 11042(a)(2)(A)(ii).
- <sup>162</sup> Kitch, *The Law and Economics of Rights in Valuable Information*, 9 J. LEGAL STUD. 683, 713 (1980).
- <sup>163</sup> ENVT’L. PROT. AGENCY, *Public Information and Confidentiality Regulations*, 59 Fed. Reg. 60466, 60450 (Nov. 23, 1994).
- <sup>164</sup> U.S. GOV’T. ACCOUNTABILITY OFFICE, *Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective*, GAO/RCED-94-103, 58 (Sept. 1994); U.S. GOV’T. ACCOUNTABILITY OFFICE, *Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-548, 34 (June 2005).
- <sup>165</sup> Richard Levin *et al.*, *Appropriating the Returns from Industrial Research and Development*, BROOKINGS PAPERS ON ECONOMIC ACTIVITY, 783 (1987).
- <sup>166</sup> See generally, Shapiro and Steinzor, *The People’s Agent*, *supra* note 113, at 116-18.
- <sup>167</sup> 5 U.S.C. § 552(b)(4).
- <sup>168</sup> Shapiro and Steinzor, *The People’s Agent*, *supra* note 113, at 117; Lyndon, *Secrecy and Access in an Innovation Intensive Economy*, *supra* note 135, at 500-09.
- <sup>169</sup> *Id.* at 117, citing Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1825 (1989) and Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secrecy Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 857-82 (1980).
- <sup>170</sup> Memorandum from John Ashcroft, Attorney General, to Heads of All Federal Departments and Agencies, *The Freedom of Information Act* (Oct. 12, 2001), available at <http://www.usdoj.gov/04foia/011012.htm> (accessed May 9, 2008).
- <sup>171</sup> *Id.*
- <sup>172</sup> Shapiro and Steinzor, *The People’s Agent*, *supra* note 113, at 118.
- <sup>173</sup> Memorandum from Janet Reno, Attorney General, to Heads of Departments and Agencies, *The Freedom of Information Act* (Oct. 4, 1993), available at <http://www.fas.org/sgp/clinton/reno.html> (accessed May 9, 2008).
- <sup>174</sup> Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 113, 111 Stat. 2311.
- <sup>175</sup> 42 U.S.C. § 282(j)(2)(A)(ii).
- <sup>176</sup> Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, §§ 304(a), 801(a), 1104(2), 121 Stat. 863, 904, 975; 42 U.S.C. § 282(j).
- <sup>177</sup> NIH operates GenBank, an annotated collection of all publicly available DNA sequences. See NIH, *GenBank Overview*, at <http://www.ncbi.nlm.nih.gov/Genbank/> (accessed May 9, 2008).
- <sup>178</sup> OECD has established a Working Group on Manufactured Nanomaterials, which is planning to develop a database of all environmental, health, and safety research being conducted on nanotechnology. OECD, *Safety of Manufactured Nanomaterials: Work of OECD’s Chemical Committee*, 9, available at <http://www.oecd.org/dataoecd/34/6/37852382.ppt> (accessed May 9, 2008); Pat Rizzuto, *Science Policy: Improving Tests, Risk Assessments, Continued Work on Nanotech Key Focus*, 39 ENV. REPORTER 193 (Jan. 18, 2008).
- <sup>179</sup> INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, Editorial: *Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors*, available at [http://www.icmje.org/clin\\_trial.pdf](http://www.icmje.org/clin_trial.pdf) (accessed May 9, 2008).
- <sup>180</sup> See *supra*, notes 42-47 and accompanying text.
- <sup>181</sup> Stanton Glantz *et al.*, *THE CIGARETTE PAPERS*, 15, 58-107 (1996).
- <sup>182</sup> Robert Steinbrook, *Public Registration of Clinical Trials*, 351 NEW ENGLAND J. MED. 315, 316 (2004).
- <sup>183</sup> Deborah A. Zarin, Tony Tse, and Nicholas C. Ide, *Trial Registration at ClinicalTrials.gov between May and October 2005*, 353 NEW ENGLAND J. MED. 2279 (2005).
- <sup>184</sup> *Id.*
- <sup>185</sup> *Id.*
- <sup>186</sup> INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, Editorial: *Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors*, available at [http://www.icmje.org/clin\\_trial.pdf](http://www.icmje.org/clin_trial.pdf) (accessed May 9, 2008).



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