

# Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research

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## I. INTRODUCTION

The imperative that agencies use "sound science" in developing their regulations has become a major preoccupation of the political branches. In only a few years, Congress passed two appropriations riders that provide extensive new mechanisms for the public to critique the science used by agencies.<sup>1</sup> The executive branch quickly followed suit, promulgating regulations to implement these two laws, as well as proceeding on its own "sound science" missions. In the space of less than one year, the Office of Management and Budget ("OMB") circulated for public comment draft peer review requirements for the scientific review of agency science,<sup>2</sup> and the Environmental Protection Agency ("EPA") launched a full scale program to improve the quality of the models it uses in regulation,<sup>3</sup> as well as "Assessment Criteria" to be used by agency officials in reviewing the quality of third-party (primarily state) science.<sup>4</sup> This near-obsession with the quality of regulatory science has become so serious that industry consultants sent letters to major universities

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<sup>1</sup> These riders are known as the Data Access Act and the Data Quality Act. The Data Access Act (also known as the Shelby Amendment) was passed as a rider to the Omnibus Appropriations Act for Fiscal Year 1999, Pub. L. No. 105-277, 112 Stat. 2681-495 (1998). The Data Quality Act was passed as a rider to an appropriations bill, section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, 114 Stat. 2763A-153-55 (2001).

<sup>2</sup> OFFICE OF MANAGEMENT AND BUDGET, PEER REVIEW AND INFORMATION QUALITY, PROPOSED BULLETIN (Aug. 2003), available at [http://www.whitehouse.gov/omb/inforeg/peer\\_review\\_and\\_info\\_quality.pdf](http://www.whitehouse.gov/omb/inforeg/peer_review_and_info_quality.pdf).

<sup>3</sup> See Memorandum from Christine Todd Whitman, Environmental Protection Agency Administrator, to Assistant Administrators, Associate Administrators, Regional Administrators and the Science Policy Council (Feb. 7, 2003), available at [http://www.thecre.com/pdf/whitman\\_memo.pdf](http://www.thecre.com/pdf/whitman_memo.pdf).

<sup>4</sup> A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, 68 Fed. Reg. 39,086 (2003) (announcing the availability of the new guidelines online at <http://www.epa.gov/quality/informationguidelines>).

warning them that any research their faculty produces that is later used for regulation must meet the government's multifaceted "sound science" requirements.<sup>5</sup> Even federal courts have become involved by presiding over a complaint that the government's climate change models are not reliable and should be withdrawn from public dissemination.<sup>6</sup>

At the same time that "sound science" reforms are proliferating, there is a surge in academic concern about the objectivity and quality of private or "sponsored" science used for public policy. Regulated parties who sponsor research that informs regulation of their products or activities have incentives to influence the research in ways that ensure favorable outcomes. Yet since research design and reporting is inherently layered with discretionary judgments that are difficult to discern without replicating the research directly, systemic biases in these judgments are difficult to detect from the outside. As long as sponsors control the research at some or all points in the research process, adverse results can be suppressed and the design and reporting of experiments can be biased in ways that produce results that support the sponsor's interests, rather than offer a disinterested examination of potential harms.

Despite their rather obvious points of convergence, these two sets of concerns have remained separate over the past decade. Worrisome evidence of compromised private research is effectively ignored as the "sound science" reforms take aim primarily at publicly funded research.<sup>7</sup> As a result, oversight of the quality of regulatory science is growing increasingly bimodal: public research is subject to increased scrutiny, while private research remains largely insulated from outside review and meaningful agency oversight.

In this Article, we argue that to the extent there is a problem with regulatory science in health and safety regulation, the "sound science" reforms miss the target by taking aim at public, rather than private science. We develop this argument in three parts. First, in Part II of the Article, we identify the critical role that private information plays in regulation, and how under-reporting of harms could lead to far greater harms and risks than society is willing to tolerate. We then present evidence supporting a conclusion that private research is often compromised, especially as compared to federally funded research, in ways that underreport adverse effects and lead to a misleadingly rosy picture of the safety of a sponsor's products or wastes. Next, in Part III, we identify how the laws, and especially the "sound science" reforms, get the problem precisely backward by focusing oversight checks on federally funded research and exempting, or at least providing far less internal and external oversight of, research sponsored by affected parties. Finally, in Part IV, we describe ways to equalize the review of publicly and privately sponsored research. In the absence of this equal treatment, regulated parties will continue to have few incentives to produce private research of high quality, while at the same time they will critique public research when the findings are adverse to their interests.

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<sup>5</sup> See Letter from Jim Tozzi, Center for Regulatory Effectiveness, to American Association of University Professors (Aug. 6, 2003), available at <http://www.thecre.com>.

<sup>6</sup> See, e.g., Andrew C. Revkin, *Suit Challenges Climate Change Report by U.S.*, N.Y. TIMES, Aug. 7, 2003, at A21.

<sup>7</sup> Part II.B, *infra*.

## II. THE IMPORTANCE OF HIGH QUALITY PRIVATE SCIENCE FOR ENVIRONMENTAL AND PUBLIC HEALTH PROTECTION

Public health regulators make life and death decisions when they promulgate standards to protect the public health. If the research they rely upon to make these decisions is compromised, then there may be more losses, perhaps substantially more, than the regulators or the public onlookers are willing to tolerate. An accumulating body of evidence suggests that some of the private science that forms the primary, and sometimes the exclusive, input for regulatory decisions regarding public health and safety lacks important scientific safeguards that could result in research that underreports harms to health and the environment. In this Part, we first discuss the important role that private science plays in regulation. We then turn to the ways in which the harms in this sponsored science might be underreported by sponsors who reserve control over the research.

### A. CRITICAL ROLE OF PRIVATE SCIENCE TO REGULATION

Privately sponsored science often provides the exclusive information for making decisions about the safety of pesticides and chemicals. Under both the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")<sup>8</sup> and the Toxic Substances Control Act ("TSCA"),<sup>9</sup> manufacturers of new products are required to provide the agency with all available information on the safety of the products as a condition to marketing, and in some cases are required to conduct new research on product safety.<sup>10</sup> Manufacturers who market existing pesticides and chemicals are also occasionally required to conduct research to help regulators assess the product's safety.<sup>11</sup> Many of these mandatory tests are specified under relatively rigid protocols that leave little room for discretionary reporting.<sup>12</sup> But as tests become more substance-specific and less capable of being conducted in a controlled laboratory setting—for example, studying reproductive and developmental effects in organisms exposed to a substance in the environment—the amount of researcher discretion in the design and reporting of findings inevitably increases.

The laws that regulate the release of pollutants depend less fundamentally on private research in setting regulatory standards, but nevertheless make use of any science that is available, including privately sponsored science. As a result, risk assessments used to set contaminant levels in drinking water and exposure standards for worker protection are often based in part on private science.<sup>13</sup> This voluntarily

<sup>8</sup> Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136 et seq. (2000).

<sup>9</sup> Toxic Substances Control Act ("TSCA"), 15 U.S.C. §§ 2601-2629 (2000).

<sup>10</sup> See, e.g., FIFRA, 7 U.S.C. § 136d(a)(2) ("If at any time after the reregistration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator."); TSCA, 15 U.S.C. §§ 2607 (c), (e) (same); *id.* § 2604(b) (requiring premarket toxicity testing as a condition to registration of new pesticides).

<sup>11</sup> See, e.g., FIFRA, 7 U.S.C. § 136a-1; TSCA, 15 U.S.C. § 2603(a).

<sup>12</sup> Under FIFRA, the Environmental Protection Agency ("EPA") has developed a chart setting out the series of tests that a manufacturer must conduct before a pesticide is permitted to enter the market. See 40 C.F.R. pt. 158 (2003) (setting forth a "basic core set" of more than 100 studies that would assist in determining the effects of pesticides); *Id.* § 158.340 (providing a table for all testing requirements and guidelines under FIFRA). Not all of these tests specify rigid testing protocols, however. See, e.g., 40 C.F.R. §§ 158.290, 158.490, 158.590 (testing to determine respectively the environmental fate of pesticides, impacts on wildlife, and effects on nontarget insects).

<sup>13</sup> The extent of private science underlying our scientific understanding of toxic substances has not been systematically studied or documented. Anecdotal accounts, however, reveal that a

produced research, in contrast to mandated research produced under the pesticide and chemical regulation statutes, is typically done without the benefit of rigid protocols and thus its quality is even more difficult to evaluate.

#### B. WHY THE QUALITY OF PRIVATELY SPONSORED SCIENCE CAN BE COMPROMISED

At the same time that privately sponsored research provides a critical input to regulation, there is growing evidence that it can be compromised in ways that might underreport or even suppress evidence of harm. Sponsors face strong incentives to design and report research in ways most favorable to their interests and to suppress adverse results provided they can do so without detection. In the past, more than a few products or pollutants have been left effectively unregulated because the manufacturer or polluter concealed evidence of the true harm or obscured adverse results. Privately sponsored science, if done without guarantees of research independence, thus violates one of the most fundamental norms of science; namely, that research be disinterested.<sup>14</sup>

Evidence of underreporting of harms in private research is most common in the biomedical arena, although there is growing evidence in the environmental and public health arenas as well.<sup>15</sup> Unfortunately, many of these unscientific practices are missed by regulators.<sup>16</sup> In a world with infinite resources, any biases that infect research would ultimately be caught through third-party, disinterested replication of the research. Given the scarce resources and considerable scientific gaps in environmental regulation, however, resources are rarely if ever available to replicate the scant research that does exist. In addition, the trade secret classification of the chemical composition of many of these products, coupled with the lack of public funding, means that the amount of public replication of private research results is limited. As a result, sponsors often enjoy an effective monopoly on the scientific information base regarding their products. The ways that privately sponsored science can be and has been compromised are discussed below.

#### I. Falsification of Data and Research Findings

Falsification of research is the most serious, but fortunately the least common, problem with privately sponsored research used for regulation. Falsification is difficult for regulators to detect, short of replicating the research, but because the penalties for committing fraud are often devastating, sponsors generally avoid this

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significant portion of research used to regulate products is industry-sponsored. See, e.g., U.S. ENVIRONMENTAL PROTECTION AGENCY, INTEGRATED RISK INFORMATION SYSTEM, ATRAZINE, at <http://www.epa.gov/iris/subst/0209.htm> (last updated July 12, 2004) (showing EPA's Integrated Risk Information System or IRIS databases identifying nine studies available on the oral dose toxicity of atrazine, eight of which were conducted by Ciga-Geigy Corp. and the ninth was indeterminate with regard to sponsor) [hereinafter ATRAZINE]; see also SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED THE VIRTUE OF BIOMEDICAL RESEARCH? 146 (2003) (observing that "[a]mong the tens of thousands of clinical trials occurring each year, most are funded by for-profit companies seeking to gain FDA approval for new drugs, clinical procedures, or medical devices.").

<sup>14</sup> See, e.g., ROBERT K. MERTON, *The Normative Structure of Science*, in *THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS* 267, 275 (J. Guston ed., 1973) (identifying honesty, objectivity, and disinterestedness as norms constituting the universal "methods of science").

<sup>15</sup> See Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 80 CORNELL L. REV. 773 (1997).

<sup>16</sup> See Wendy E. Wagner, *Commons Ignorance: How the Environmental Laws Have Failed Us*, DUKE L.J. (forthcoming 2004).

means of manipulating research. Criminal and civil sanctions, impaired firm reputation, and distrust by regulators all can result from a single falsified study.<sup>17</sup> Moreover and in any case, there may be ways short of fraud to control the outcome of research as discussed below.

Yet even though falsification of research in regulation is uncommon, it is not unprecedented. The most notorious examples of fraudulent research in environmental regulation occurred with a contractor who falsified a number of results in conducting required safety testing for pesticide manufacturers in the 1970s.<sup>18</sup> These data fabrications saved the consulting organization time and resources, but were not evidently intended to produce preordained results for specific pesticides.<sup>19</sup> Falsification of measurements collected as part of mandatory self-monitoring requirements has also been documented. For example, the Coal Mine Health and Safety Act of 1969<sup>20</sup> requires coal operators to collect bi-monthly air samples of the underground work environment to identify excess levels of coal mine dust in order to reduce the risk of coal workers pneumoconiosis among the miners.<sup>21</sup> The mine operator sends the dust exposure samples he collects to a U.S. Department of Labor's Mine Safety and Health Administration ("MSHA") laboratory for analysis, and if the results exceed a permissible level, the mine operator receives a citation and monetary penalty.<sup>22</sup> When these provisions were originally proposed, coal miners scoffed at the idea, likening it to self-enforcement for traffic violations; imagine a system when the driver is asked to voluntarily send the state police a notice that they have driven over the speed limit so they can be sent a traffic ticket. Widespread abuses of the self-reporting system were uncovered in the 1990s, when the MSHA laboratory discovered that mine operators had tampered with hundreds of dust samples. Suspicious samples were identified as coming from approximately one-third of the mines covered by the law; more than 200 mine operators (including at least one of the nation's largest) and their contractors were eventually convicted on criminal charges.<sup>23</sup>

## 2. Ends-Oriented Biases in Design and Reporting of Research

Sponsors can also design or report regulation-relevant research in ways that are favorable to their interests, but fall short of being clearly fraudulent or dishonest.<sup>24</sup>

<sup>17</sup> See, e.g., False Statements Accountability Act of 1996, 18 U.S.C. § 1001 (2000) (providing for fines or imprisonment for falsification or concealment of material facts from the federal government).

<sup>18</sup> See Thomas O. McGarity, *Beyond Buckman: Wrongful Manipulation of the Regulatory Process in the Law of Torts*, 41 WASHBURN L.J. 549, 562 (2002) (describing incidents of forged toxicology reports required under FIFRA). For other incidents of fraudulent or misleading reports and data submitted to regulatory agencies under the Food Drug and Cosmetic Act, see *id.* at 559-63. Additionally, in an older study of Food and Drug Administration ("FDA") audits of clinical research on drugs, between 7 and 12% of the research sampled revealed serious deficiencies in the research, some of which involved made-up data and research fraud.

<sup>19</sup> *Id.* at 562.

<sup>20</sup> 30 U.S.C. ch. 22 (2000).

<sup>21</sup> See *id.* §§ 813, 842-43.

<sup>22</sup> See *id.* §§ 813, 814(f).

<sup>23</sup> James L. Weeks, *The Fox Guarding the Chicken Coop: Monitoring Exposure to Respirable Coal Mine Dust, 1969-2000*, 93 AM. J. PUB. HEALTH 1236 (2003).

<sup>24</sup> Professor Krimsky endeavors to isolate this type of ends-oriented bias, which appears to affect the outcome of the research in statistically significant ways. See generally KRIMSKY, *supra* note 13, at 141-44; see also Sidney A. Shapiro, *Divorcing Profit Motivation from New Drug Research: A Consideration of Proposals to Provide FDA With Reliable Test Data*, 1978 DUKE L.J. 155, 163

In the design of the research, there are often choices to be made by the researcher about test subjects, laboratory conditions, lengths of time of the study, and what types of observations to report, even for rigidly specified protocols.<sup>25</sup> In a self-designed study of the effects of pesticides on birds, for example, the researcher might make decisions about which effects to notice and record in the data log, and then later, which effects to statistically analyze. If each of these incremental discretionary decisions is made in a way most favorable to the sponsor, the results can ultimately tend toward one side of the results spectrum.<sup>26</sup>

Similarly, decisions about how to report effects in a study can be affected by a researchers' predisposition towards the outcome. Some adverse effects can be downplayed or explained away in the written findings, while the positive outcomes of the study can be overemphasized. In one study of 192 random clinical trials conducted on prospective drugs, for example, the researchers found that the written reports of the research did not adequately describe the adverse effects of the drugs under study or explain why a patient stopped taking the drug.<sup>27</sup>

Evidence that parties with direct conflicts of interest can sometimes design and report results in ways that are favorable to their interests, rather than in ways that best represent the research, has been extensively documented.<sup>28</sup> The "funding effect," where the results of privately sponsored research are statistically compared against the results of publicly funded research on similar regulation-relevant questions, shows consistent and rather dramatic sponsor-bias in the final results.<sup>29</sup> For example, one study published in the *Journal of the American Medical Association* reports: "By combining data from articles examining 1140 studies, we found that industry-sponsored studies were significantly more likely to reach conclusions that were favorable to the sponsor than were non-industry studies."<sup>30</sup> In research of the tobacco industry, there is even statistical evidence that this sponsored research is of lower quality, a conclusion based on findings of independent reviewers who were blinded to identifying characteristics of the affiliations of the authors.<sup>31</sup> Although the funding effect shows only a correlation and does not prove

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(discussing this problem in research by drug companies on the safety of drugs); Shankar Vedantam, *Antidepressant Makers Withhold Data on Children*, WASH. POST, Jan. 29, 2004, at A1.

<sup>25</sup> In conducting laboratory tests on the toxicity of a substance, for example, researchers might focus exclusively on recording the tumors (if the experiment is designed to test for cancer) and will not even record or take written notice of other types of surprise adverse reactions that occur in the course of the study.

<sup>26</sup> See KRIMSKY, *supra* note 13, at 142-44 (describing the discretionary decisions that arise in conducting studies on the safety and efficacy of drugs); *id.* at 155-58 (describing evidence of sponsors "tweaking the protocols" when under legal pressure).

<sup>27</sup> See John P.A. Ioannidis & Joseph Lau, *Completeness of Safety Reporting in Randomized Trials: An Evaluation of 7 Medical Areas*, 285 JAMA 437 (2001).

<sup>28</sup> See generally DAN FAGIN & MARIANNE LAVELLE, *TOXIC DECEPTION: HOW THE CHEMICAL INDUSTRY MANIPULATES SCIENCE, BENDS THE LAW, AND ENDANGERS YOUR HEALTH* 33-50 (1996) (discussing evidence of fraud and bias in industry-conducted or sponsored studies on the safety of substances).

<sup>29</sup> See KRIMSKY, *supra* note 13, at 145-50, 154, 158 (discussing numerous studies finding a "funding effect" published in the *Journal of General Internal Medicine*, *British Medical Journal*, *New England Journal of Medicine*, and the *Journal of the American Medical Association*); Joel Lexchin et al., 326 BRIT. MED. J. 1167-76 (2003).

<sup>30</sup> Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 463 (2003).

<sup>31</sup> See Deborah Barnes & Lisa Bero, *Scientific Quality of Original Research Articles on Tobacco Smoke*, 6 TOBACCO CONTROL 19 (1997).

or explain bias in the design or reporting of findings of sponsored research, biases (or strong financial conflicts) remain one of the leading explanations for the effect.<sup>32</sup>

Other evidence of undue sponsor influence in regulation-relevant research is more anecdotal, but nevertheless worrisome. In a number of individual research projects, some sponsors have exerted dramatic control over the outcome of the research, to the point of designing the study, framing the research question, and even editing and ghost-writing the article by hiring scientists willing to "collaborate" closely with the sponsoring industry under contracts that require sponsor control of the research.<sup>33</sup>

Additionally, several prominent scientific journal editors lament the ways regulated parties have abused publication practices to provide a misleadingly positive picture of the body of research that has bearing on their products. Some sponsors, for example, have been caught publishing the same study in different journals under different author names with no cross-references, making it appear that the research support in favor of their product or activity is based on several independent studies, rather than simply a re-reporting of the same findings.<sup>34</sup> Since commissioned studies are viewed in the scientific community as being less credible than studies without affected sponsors, disclaimers are increasingly required as a condition to publication.<sup>35</sup> To circumvent this requirement, some sponsors have developed ways to "launder" their research support through nonprofit shells to create the illusion that they play no role in research that supports their interest.<sup>36</sup> Parties

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<sup>32</sup> See KRIMSKY, *supra* note 13, at 147.

<sup>33</sup> One of the editors of the Journal of the American Medical Association has argued that ghost-writing is occurring in biomedical articles at an alarming pace. Companies will pay the big names to appear on the byline in place of the ghostwriters, who contribute only their prestige to the study. Drummond Rennie et al., *When Authorship Fails: A Proposal to Make Contributors Accountable*, 278 JAMA 579, 580 (Aug. 20, 1997); see also Antony Barnett, *Revealed: How Drug Firms 'Hoodwink' Medical Journals*, OBSERVER, Dec. 7, 2003, available at [http://observer.guardian.co.uk/uk\\_news/story/0,6903,1101680,00.html](http://observer.guardian.co.uk/uk_news/story/0,6903,1101680,00.html).

As a result, some prominent research journals refuse to publish literature reviews or editorials where the author has a conflict of interest in the outcome, since the extent and effect of the bias is difficult to detect through the usual methods of replication and validation familiar to science. See, e.g., INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, UNIFORM REQUIREMENTS FOR MANUSCRIPTS SUBMITTED TO BIOMEDICAL JOURNALS, at <http://www.icmje.org> (last updated Nov. 2003) ("Editors may use information disclosed in conflict of interest and financial interest statements as a basis for editorial decisions.").

<sup>34</sup> See, e.g., Rennie et al., *supra* note 33, at 580 (observing that "[r]epeated publication of the same work, with or without minor additions, inflates bibliographies and is common. When similar parts of the same trial are published repeatedly under different authors' names, without cross-referencing, the record is distorted in the name of promotion, and meta-analysis is confounded to the detriment of care."); Drummond Rennie, *Fair Conduct and Fair Reporting of Clinical Trials*, 282 JAMA 1766, 1766 (1999) (discussing specific examples of the over-publication of and failure to cross-reference to clinical trials).

<sup>35</sup> See, e.g., Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 337 (1992) (describing Merrell's research conducted after litigation in Bendectin cases as a "lose-lose proposition" because "[i]f they showed an effect, the studies would be used against the company" and if they did not "[a]ny slight technical flaw in the design or execution of the experiment would be exploited by plaintiffs to undermine Merrell's findings").

<sup>36</sup> See, e.g., Deborah E. Barnes and Lisa Bero, *Industry-Funded Research and Conflict of Interest: An Analysis of Research Sponsored by the Tobacco Industry through the Center for Indoor Air Research*, 21 J. HEALTH POL. POL'Y & L. 515-42 (1996); Alicia Mundy, *Hot Flash, Cold Cash*, WASH. MONTHLY, Jan. 1, 2003, at 35 (reporting on drug companies' influence on a nonprofit called The Society for Women's Health Research, which includes substantial corporate giving and representation on corporate board; this influence is ultimately reflected in the Society's position on various issues).

trying to influence regulation have also commissioned review articles and convened expert panels that purport to summarize existing research on a topic—such as the health effects of environmental tobacco smoke—even though in reality the commissioned review articles or reports are intended (and contractually guaranteed) to portray existing research in the light most favorable to the sponsor.<sup>37</sup>

### 3. Suppression of Adverse Results

Finally and perhaps most serious is the ability of sponsors to suppress research when the results are adverse to their interests. Unlike fraud, suppressing adverse results can sometimes be done with discretionary judgments that are not illegal.<sup>38</sup> For example, sponsors can abort research before it is completed, and base this decision on limited resources or some purported design flaw in the study. For research that is completed, sponsors can still justify withholding the results based on discretionary judgments that the research design or reporting was incomplete or flawed in some way or that follow-up research is needed to confirm or validate the findings.<sup>39</sup> All of these judgments are difficult to question from the outside and can often be justified, however weakly, even if the suppression is discovered.

In practice, suppression of research has been a recurring problem with privately sponsored research. Sponsors sometimes contractually reserve the right to suppress publication of the research they fund and are not reticent to use this right if the study results are adverse to their interests.<sup>40</sup> Some corporate actors have selectively limited access to potentially damaging information about their products and activities in ways that substantially harmed public health.<sup>41</sup> For example, Johnson &

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<sup>37</sup> The skillful use of review articles has been identified as one strategy used by at least the tobacco industry. Deborah E. Barnes & Lisa A. Bero, *Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions*, 279 JAMA 1566 (1998) (finding that the most strongly supported explanation for the discrepancy in reviews assessing the impact of passive smoking was whether or not they were written by authors affiliated with the tobacco industry). The creation of hand-picked or “stacked” expert panels is even more commonplace. See, e.g., STANTON GLANTZ ET AL., *THE CIGARETTE PAPERS* 32-33 (1996) (summarizing that Tobacco Industry Research Committee (“TIRC,” later named Council for Tobacco Research (“CTR”)) was formed jointly by tobacco companies with the publicly identified purpose of “fund[ing] independent scientific research” on hazards of cigarettes, while internal documents reflect its true purpose was “for public relations . . . to convince the public that the hazards of smoking had not been definitively proven”); RICHARD KLUGER, *ASHES TO ASHES: AMERICA’S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* 164-67, 205-12, 227-29, 466-68 (1996) (describing the activities and mission of the tobacco industry’s TIRC/CTR); ALICIA MUNDY, *DISPENSING WITH THE TRUTH: THE VICTIMS, THE DRUG COMPANIES, AND THE DRAMATIC STORY BEHIND THE BATTLE OVER FEN-PHEN* 119 (2001) (discussing how the manufacture of Fen-Phen convened an expert panel to review the drug, but how many of the experts selected had allegiances to the company).

<sup>38</sup> See Sameer S. Chopra, *Industry Funding of Clinical Trials: Benefit or Bias?*, 290 JAMA 113, 113-14 (2003), available at <http://jama.ama-assn.org/cgi/reprint/290/1/113.pdf> (discussing researcher biases that can influence the interpretation of clinical research results).

<sup>39</sup> See, e.g., Goldie Blumenstyk, *The Price of Research*, CHRON. HIGHER ED., Oct. 31, 2003, available at <http://chronicle.com/free/v50/i10/10a02601.htm> (discussing how industry sponsor of herbicide-related research attempted to delay publication of the adverse results, at least according to the researcher).

<sup>40</sup> See, e.g., Bruce M. Psaty & Drummond Rennie, *Stopping Medical Research to Save Money: A Broken Pact with Researchers and Patients*, 289 JAMA 2128, 2128-29 (2003) (discussing the efforts of Apotex Inc. to conceal research, including the halting of two trials under a confidentiality clause and issuing legal warnings under the guise of confidentiality to prevent the principal investigator from publishing the study results or disclosing risks to patients).

<sup>41</sup> See, e.g., MUNDY, *supra* note 37, at 133-34 (citing attempts to conceal how many reports of pulmonary hypertension Fen-Phen received); FAGIN & LAVELLE, *supra* 28, at xxi (discussing the ability of the tobacco companies to mislead the public and keep their products on the shelves despite

Johnson,<sup>42</sup> A.H. Robins,<sup>43</sup> Merrell Dow,<sup>44</sup> and the asbestos,<sup>45</sup> vinyl chloride,<sup>46</sup> and tobacco<sup>47</sup> industries were all caught concealing information about their products'

mounting evidence as to the harmful nature of those products); SHELDON RAMPTON & JOHN STAUBER, TRUST US, WE'RE EXPERTS! (2001) (describing, through a number of case studies, how the tobacco companies used third-party public relations consultants to distance them from misleading information about their activities).

<sup>42</sup> See *West v. Johnson & Johnson Prods., Inc.*, 220 Cal. Rptr. 437, 445 (Cal. Ct. App. 1985) (discussing the company's reception of consumer complaints and information that would not ordinarily be available to third parties).

<sup>43</sup> A.H. Robins, the manufacturer of the Dalkon Shield, actively concealed the adverse results from the very limited safety testing it did conduct. See, e.g., *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1240 (Kan. 1987) (awarding punitive damages based on corporate misconduct, including evidence that A.H. Robins "commissioned studies on the Dalkon Shield which it dropped or concealed when the results were unfavorable" and "consigned hundreds of documents to the furnace"). Cf. MORTON MINTZ, AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALCON SHIELD 122 (1985) (referencing memo by Kenneth Moore, Project Coordinator of Robins's Dalkon Shield, reporting that Robins's main purpose in funding research was "to make available for publication extremely good Dalkon Shield results"). For example, Robins initiated a two-year study that was never made available to the medical profession on the effects of the Dalkon Shield on baboons eight months after it started selling the product. "Among eight [of the baboons tested], one 'perished,' and among ten, three suffered perforation of the uterus . . ." *Id.* at 123 (quoting testimony of Dr. John W. Ward, Director of Toxicology and Assistant Director of Scientific Development). Following an escalation of concern by company employees over the potential of Dalkon Shield's string to carry bacteria from the vagina to the uterus, Robins retrieved 303 used strings for examination by a staff scientist, Dr. Thomas C. Yu. Dr. Yu found defects in all but 35 of the strings. Dr. Yu's boss swore that Robins maintained "no written records of the exams or the results." *Id.* at 134-35. There is also some suggestion that Robins destroyed sensitive Dalkon Shield documents in order to better defend against litigation. See Francine Schwadel, *Robins and Plaintiffs Face Uncertain Future: Chapter 11 Filing Postpones 5,100 Dalkon Shield Cases*, WALL ST. J., Aug. 23, 1985, at 4.

<sup>44</sup> Merrell Dow's culpability in the controversial breast implant litigation was in large part due to its stubborn refusal to research the adverse effects of silicone in the body cavity (even at the insistence of the Food and Drug Administration), in light of their own preliminary and secret in-house evidence suggesting that the implants were leaking and harmful. See, e.g., *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1127-28 (9th Cir. 1994) (affirming punitive damage award based in part on evidence that company concealed adverse results of clinical studies and knew that long-term studies were needed). In *Hopkins*, the court stated:

Dow obtained results of a study in which four dogs received silicone gel implants that resembled the implants that Dow was then marketing. The results demonstrated that after six months, the implants appeared to be functioning properly, but that after two years, inflammation surrounding the implants demonstrated the existence of an immune reaction. Dow did not publicly release the results of this research for several years, and when it did ultimately release the results, Dow omitted the negative findings and implied that the implants were safe.

*Id.* at 1119; see also Rebecca Weisman, *Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle*, 23 GOLDEN GATE U. L. REV. 973, 987 n.122 (1993) (quoting Dow Corning discovery documents and summary of scientific studies). Dow Corning also conducted a study in 1974 that revealed that silicone could "trigger strong reactions of the immune system," but Dow Corning denied such a reaction at an FDA hearing in 1991. *Id.* at 988 n.123. Finally, in 1987 Dow Corning was aware that some of its employees had falsified documents regarding silicone breast implants, but Dow Corning did not alert the FDA to these misstatements until 1992. See *id.*

<sup>45</sup> The record of asbestos manufacturers' attempt to conceal or downplay the hazards of asbestos is well documented. See generally PAUL BRODEUR, OUTRAGEOUS MISCONDUCT: THE ASBESTOS INDUSTRY ON TRIAL (1985) (chronicling asbestos litigation throughout the industry). Some of the more dramatic examples include animal studies on asbestosis in the 1930s, the findings of which, by agreement, belonged to the investors until they agreed to disclose them to the public, notes detailing Johns-Manville Co.'s health review committee meeting during which executives "developed a corporate policy of not informing sick employees of the precise nature of their health problems for fear of workmen's-compensation claims and lawsuits," and successful company efforts to persuade

adverse health impacts. The manufacturer of an antidepressant, Paxil, was recently sued by New York State for concealing unfavorable results from clinical trials done on children, leading to demands from the scientific and medical community that pharmaceutical companies be required to publicly disclose the results of all clinical trials, regardless of whether reporting of the results of the research is legally mandated.<sup>48</sup> In the occupational health arena, a textile manufacturing company—wielding a confidentiality agreement—pressured occupational medicine researchers to suppress data showing adverse effects on workers in the nylon flocking industry.<sup>49</sup> A large number of companies have also resisted mandatory reporting requirements on the adverse effects of their products.<sup>50</sup>

### III. UNEQUAL SCRUTINY OF THE QUALITY OF PRIVATE RELATIVE TO PUBLIC RESEARCH

As the previous section details, the quality of privately sponsored research is often compromised by bias, yet environmental regulatory decisions nevertheless must depend upon it in setting protective standards. As a result, public health and environmental regulatory decisions based on private science could systematically underestimate the risks of a product or waste stream.

By contrast, publicly funded research, by virtue of its greater assurance of research independence, would seem to be much less inclined to be encumbered with systematic biases that affect research findings.<sup>51</sup> The diverse motives and backgrounds of the researchers doing public health research, which generally include scientists from consultant laboratories, EPA, and academia, further dissipate the

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the editor of a trade magazine that growing scientific studies on "asbestos . . . [should] receive the minimum of publicity." *Id.* at 116-17, 118-19, 145.

46 See GERALD MARKOWITZ & DAVID ROSNER, *DECEIT AND DENIAL: THE DEADLY POLITICS OF INDUSTRIAL POLLUTION* (2002).

47 The tobacco industry vigorously concealed both its research on the carcinogenic and on the addictive properties of cigarettes. See, e.g., GLANTZ ET AL., *supra* note 37, at 15 (concluding that by the early 1960s Brown & Williamson Tobacco Company and its parent, British American Tobacco, "had developed a sophisticated understanding of nicotine pharmacology" but did not disclose this understanding to consumers); *id.* at 58-107 (outlining documentary evidence of industry's knowledge of and research on addictive properties of nicotine); PHILIP J. HILTS, *SMOKESCREEN: THE TRUTH BEHIND THE TOBACCO INDUSTRY COVER-UP* 38-40 (1996) (describing cover-up of rich research conducted internally on carcinogenic properties of cigarettes and Brown & Williamson's "document retention" policy that involved shipping all of this research and underlying documentation out of country).

48 See, e.g., Eliot Marshall, *Buried Data Can Be Hazardous to a Company's Health*, 304 *SCIENCE* 1576 (2004). For the scientific and medical community's demands for a public registry of all clinical trials, see Andrew Herxheimer, *Open Access to Industry's Clinically Relevant Data*, 329 *BRIT. MED. J.* 64 (2004). See American Medical Association, *American Medical Association Recommends that DHHS Establish a Registry for all U.S. Clinical Trials*, at <http://www.ama-assn.org/ama/pub/article/1616-8651.html> (June 15, 2004).

49 Frank Davidoff, *New Disease, Old Story*, 129 *ANNALS INTERNAL MED.* 327-28 (1998). A university-based researcher found a new form of interstitial lung disease, "flock worker's lung," and its capacity to affect as many as 2,500 persons employed by the nylon flocking industry in the United States. The company and the researcher's university attempted to suppress the findings; with the university responding by eliminating the occupational medicine unit and deciding not to renew the lead researcher's employment contract. See generally Wade Roush et al., *Publishing Sensitive Data: Who Calls the Shots*, 276 *SCIENCE* 523 (1997) (confidentiality agreement between researcher and textile company used to suppress data showing adverse effects on workers).

50 See *infra* Section III.A.

51 See, e.g., KRIMSKY, *supra* note 13, at 144 (describing the differences that could lead to bias in industry-sponsored research relative to publicly funded research).

likelihood that there will be systematic biases that lean dramatically one way or another. This is borne out in empirical studies of research.<sup>52</sup> In fact, the "sound science" proponents fail to provide evidence of significant problems with publicly funded science used in public health regulation.<sup>53</sup>

Yet despite the higher probability of bias in private research relative to public research, most "sound science" laws and regulations focus peer review, external complaint processes, and other quality controls almost exclusively on public research or syntheses of research findings.<sup>54</sup> At the same time, they exempt a good portion of private research from their requirements. Private research is also exempted from public scrutiny through guarantees afforded "proprietary information" and "confidential business information" ("CBI").<sup>55</sup> The laws and regulations, in other words, do precisely the opposite from what the underlying quality of the research would demand. They tend to insulate private research from scrutiny and focus attention on public research.

The ways that the quality of private research is under-regulated in relation to public research are detailed in this section.

#### A. PRIVATE RESEARCH IS OFTEN CLASSIFIED AND IS NOT PUBLICLY AVAILABLE

A great deal of private science is classified and reviewed by only a few, cleared government officials, despite the fact that open communication of research is a tenet of good science.<sup>56</sup> Most classification of private research is based on the protection of industry "trade secrets" and is intended primarily to protect proprietary formulas and manufacturing processes from use by competitors.<sup>57</sup> Current regulatory programs provide regulated parties with the option of classifying any information that they believe could be used by a competitor to their economic detriment.<sup>58</sup> As a result, manufacturers and polluters have been given wide latitude under at least FIFRA and TSCA to classify health and safety research that they believe can cause

<sup>52</sup> See *supra* notes 29 and 30 and accompanying text.

<sup>53</sup> See, e.g., Wendy E. Wagner, *The 'Bad Science' Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS 63, pt II (2003).

<sup>54</sup> See Lars Noah, *Scientific "Republicanism": Expert Peer Review and the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1034-35 (2000) (discussing Congress' use of peer review to improve agency decision-making).

<sup>55</sup> Lawrence Kaplan, Annotation, *What Constitutes "Trade Secrets and Commercial or Financial Information Obtained from Person and Privileged or Confidential," Exempt from Disclosure Under Freedom of Information Act (5 U.S.C.A. § 552(b)(4))*, 139 A.L.R. FED. 225 (1997).

<sup>56</sup> See Public Information and Confidentiality Regulations, 59 Fed. Reg. 60,446, 60,446-60,447 (Nov. 23, 1994) ("The [Environmental Protection] Agency collects chemical, process, waste stream, financial, and other data from tens of thousands of facilities in many sectors of American business. Companies frequently consider this information vital to their competitive position, and claim it as confidential business information (CBI)").

<sup>57</sup> See generally PROTECTION OF SENSITIVE BUSINESS INFORMATION AT THE ENVIRONMENTAL PROTECTION AGENCY § 1 (ROPE & GRAY 1998) (describing the "mosaic effect") [hereinafter PROTECTION].

<sup>58</sup> See, e.g., EPA, PESTICIDES: FREEDOM OF INFORMATION ACT (FOIA), CONFIDENTIAL BUSINESS INFORMATION (CBI) REVIEW, at <http://www.epa.gov/pesticides/foia/cbi.htm> (last updated July 9, 2004) (listing environment-related information that is commonly claimed as confidential) [hereinafter PESTICIDES: FREEDOM OF INFORMATION ACT]. The Occupational Safety and Hazard Administration ("OSHA") also allows employers to withhold information on chemical identities from employees by claiming they are trade secret protected, as long as they indicate they have done so on the label. See 29 C.F.R. § 1910.1200(i) (2003).

economic harm as confidential business information, often without specifying the nature of the trade secret concerns. Once the CBI claim is asserted by a regulated party, the claim of "trade secret" is generally considered valid<sup>59</sup> by the EPA until a party requests the information under the Freedom of Information Act ("FOIA").<sup>60</sup> Health and safety studies (as well as most routine claims on the corresponding chemical identity of a toxic substance) are among the information classified by industry as CBI,<sup>61</sup> even though the laws expressly disfavor this classification.<sup>62</sup> Under most existing regulations, moreover, the CBI claims require no substantiation—a manufacturer has only to stamp the documents "confidential" for the privilege to apply.<sup>63</sup> No official from the company need take responsibility for asserting the claim;<sup>64</sup> there are no penalties for asserting the claim when it is facially frivolous;<sup>65</sup> and the firm is presumed to waive the privilege if they do *not* stamp this information as confidential when first submitting it to the agency.<sup>66</sup> Based on this regulatory structure, firms openly concede that it is more cost-effective for them to

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<sup>59</sup> See 40 C.F.R. §§ 2.204(c), 2.204(d) (2003). The EPA has promulgated categorical denials of confidential business information ("CBI") for certain types of information (i.e., permit applications for National Pollutant Discharge Elimination System permits under the Clean Water Act) which presumably deter such claims and apply immediately. See, e.g., *id.* § 122.7(b) (2003) (identifying narrow categories for which "claims of confidentiality . . . will be denied").

<sup>60</sup> See *id.* § 2.204(a); Public Information and Confidentiality, 65 Fed. Reg. 80,394, 80,395 (Dec. 21, 2000) (observing that "CBI regulations generally do not require a business to submit a substantiation until disclosure becomes an issue"). Generally, it appears that a Freedom of Information Act ("FOIA") request serves as the impetus for the EPA to review a CBI claim. See, e.g., *id.* ("EPA often finds it necessary to make final confidentiality determinations as a result of FOIA requests or rulemaking."). In 1994, EPA reported that it received more than 40,000 FOIA requests a year, many of which sought confidential business information. See EPA, Public Information and Confidentiality Regulations, 59 Fed. Reg. 60,446, 60,447 (Nov. 23, 1994). Nonetheless, EPA aggressively challenged more than 700 CBI claims under TSCA in 1990 on its own (without a FOIA trigger) and appeared to make substantial headway in reducing the number of over-inclusive claims. See Julie Yang, Note, *Confidential Business Information Reform under the Toxic Substances Control Act*, 2 ENVTL. L. 219, 235 (1995) (reporting and documenting this development). The literature does not reveal whether EPA has been able to keep up with this internal review effort since 1990.

<sup>61</sup> See, e.g., PESTICIDES: FREEDOM OF INFORMATION ACT, *supra* note 58; HAMPSHIRE RESEARCH ASSOCIATES, INC., INFLUENCE OF CBI REQUIREMENTS ON TSCA IMPLEMENTATION 18-19 (1992) [hereinafter HAMPSHIRE STUDY].

<sup>62</sup> Since trade secret protections are a general common law construct, Congress has authority to balance them against other goals, including health and environmental protection. Although the balancing is struck differently in the various environmental statutes, Congress has indicated that the balance should favor the general disclosure of information needed to determine potential adverse public health and environmental effects. See, e.g., FIFRA, 7 U.S.C. § 136h(d) (2000); TSCA, 15 U.S.C. § 2613(b) (2000).

<sup>63</sup> See 40 C.F.R. § 2.203 (2003).

<sup>64</sup> See generally 40 C.F.R. §§ 2.201-2.310 (2003). Cf. 40 C.F.R. § 350.7(c) (2003) (presenting a contrasting approach to CBI taken under the Emergency Planning and Community Right-to-Know Act ("EPCRA")).

<sup>65</sup> See generally 40 C.F.R. §§ 2.201-2.310; see also Christopher J. Lewis, Comment, *When Is a Trade Secret Not So Secret?: The Deficiencies of 40 C.F.R. Part 2, Subpart B*, 30 ENVTL. L. 143, 171-72 (2000) (making this same observation regarding the lack of disincentives for overbroad CBI claims). For a contrasting approach under EPCRA, see 42 U.S.C. § 11045(d)(1) (2000) (outlining a contrasting approach whereby the EPA can assess \$25,000 for each frivolous claim).

<sup>66</sup> 40 C.F.R. § 2.203(c) (2003). Once the information is publicly disseminated, the company loses its right to claim misappropriation of a trade secret. James T. O'Reilly, *Seeking a Truce in the Environmental Information Wars: Replacing Obsolete Secrecy Conflicts with New Forms of Sharing*, 30 ENVTL. L. REP. 10203, 10204 (2000) (discussing this point and concluding that "[t]his threat of income loss provides the economic incentive that motivates industry to oppose agencies' broader dissemination of industry-submitted technological and process data").

routinely stamp as much internal information as CBI when no substantiation is required.<sup>67</sup>

At the same time that the claim is effectively costless for industry, it can be quite costly for those trying to obtain access to the information.<sup>68</sup> To access information stamped CBI, an interested party, including a health professional, researcher, or the physician of a person exposed to the substance, must know the information exists (or probably exists);<sup>69</sup> send a FOIA request; follow up with a second FOIA request if pieces of information appear left out or unaccounted for; and be prepared to litigate if the information is not produced. The search costs are even high for the agency, since streamlined comprehensive databases and filing systems may not be possible for CBI-stamped data, and only "cleared" regulators (until recently a category that excluded all state officials)<sup>70</sup> can access the information.<sup>71</sup>

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<sup>67</sup> For example, firms have argued in opposing CBI reforms that the internal analysis required for some form of upfront substantiation of trade secret claims (i.e., determining what internal information is legitimately trade secret protected and what is not) is so time-consuming that it might violate the Regulatory Flexibility Act due to the added burden the requirement would impose on small manufacturers. It is far less costly, they argue, to err on the side of over-claiming. See, e.g., Letter from Warren E. Stickle, President, Chemical Producers and Distributors Association, & Bill Balek, President, International Sanitary Supply Association, to EPA (June 13, 2001), available at [http://www.cpda.com/Content/regulatory\\_affairs/archived/regulatory\\_affairs\\_archived\\_material.cfm](http://www.cpda.com/Content/regulatory_affairs/archived/regulatory_affairs_archived_material.cfm). At the same time, EPA's administrative costs appear quite substantial. See, e.g., Mary L. Lyndon, *Secrecy and Innovation in Tort Law and Regulation*, 23 N.M.L. REV. 1, 34-36 (1993).

<sup>68</sup> See generally GENERAL ACCOUNTING OFFICE, TOXIC SUBSTANCES CONTROL ACT: LEGISLATIVE CHANGES COULD MAKE THE ACT MORE EFFECTIVE, GAO/RCED-94-103, at 54-61 (Sept. 26, 1994) (discussing how the scientific community and others would benefit from lower cost access to TSCA data that is claimed CBI) [hereinafter TOXIC SUBSTANCES CONTROL ACT]; Susan D. Carle, Note, *A Hazardous Mix: Discretion to Disclose and Incentives to Suppress Under OSHA's Hazard Communication Standard*, 97 YALE L.J. 581, 596-600 (1988) (discussing manufacturers' tendency to claim product ingredients as trade secret protected under OSHA, making OSHA's hazard communication standard, which provides warnings to workers, effectively unenforceable).

As a result, a CBI claim raises the "search costs" for others to access the information, in some cases so substantially that interested parties will invest neither the money nor the time in obtaining the information or in learning how they might obtain it.

<sup>69</sup> For these and other scientific costs that flow from CBI claims, see Lyndon, *supra* note 67, at 34-39.

<sup>70</sup> The statute was read to foreclose allowing state officials to access information claimed as CBI. TSCA, 15 U.S.C. § 2613(a) (2000). EPA has worked to provide states access through the "contractors" provision of TSCA. *Id.* § 2613(a)(2); see Yang, *supra* note 60, at 232.

<sup>71</sup> See, e.g., O'Reilly, *supra* note 66, at 10204. "Both EPA employee access and EPA contractor access to formula and process data was sharply curtailed [after the 1976 Polaroid hearing], and the system's cumbersome operation provided frequent *Federal Register* notices when documents were shared with EPA contractors." *Id.* at 10206. As a result, some of this information is likely missed or proves practicably unobtainable to agency regulators or their citizen-oriented watchdogs because of the impediments to accessing it. See, e.g., Access to Confidential Business Information by Syracuse Research Corporation, 65 Fed. Reg. 11,777 (Mar. 6, 2000) (giving notice of access to CBI data for contractor who will use the CBI data to conduct risk assessments and related studies on health hazards).

Moreover, agency

[s]taff discussions on chemicals [classified as CBI] must be held in secure areas, documents can be reviewed only in secure environments, meeting notes themselves become confidential documents and must be logged and guarded under lock and key and computers must have their memories and permanent storage media erased after processing confidential data.<sup>72</sup>

This limited scientific review is suboptimal for ensuring the quality of the underlying data and research. One study of CBI concedes that "[w]hile there is no reason to doubt the competence of [EPA Office of Pollution Prevention and Toxics ("OPPT")] scientists, limited data access results in limited review."<sup>73</sup> "As an example, the structure-activity prediction methods used by OPPT scientists depend to a significant extent upon CBI data; they therefore can not be fully evaluated by outside scientists."<sup>74</sup>

Indeed, the increased barriers to agency staff and nonprofit groups in accessing CBI information provide still more potential benefits to firms that aggressively classify their information as trade secret protected.<sup>75</sup> A 1992 Hampshire Study<sup>76</sup> reported that federal and state agencies encountered significant barriers accessing CBI information, while labor and environmental groups said they had "given up" on seeking CBI information submitted under TSCA.<sup>77</sup> For example, in the review of biotechnology products, environmental groups reported that it took three years to acquire the CBI stamped information under FOIA; by that time, the industry's request for a license had been approved and "in many cases the environmental release of genetically engineered organisms had occurred."<sup>78</sup> The Hampshire study also noted the lack of public participation on EPA's efforts to ban asbestos, a fact that it attributed in part to the fact that a significant portion of the information on the safety of asbestos, and the agency's analysis of that information, has been classified by the regulated industry as CBI.<sup>79</sup>

Despite the potentially significant social costs in terms of reduced scientific and public oversight of private research, the EPA has few incentives to conduct more aggressive review of CBI claims. The high direct cost of reviewing all stamped

<sup>72</sup> See, e.g., TOXIC SUBSTANCES CONTROL ACT, *supra* note 68, at 5:1; see also HAMPSHIRE STUDY, *supra* note 61, at 26-27 (observing the extraordinarily limited access to CBI; "[e]ven typewriter ribbons must be secured until they are destroyed").

<sup>73</sup> *Id.* at 35.

<sup>74</sup> *Id.*

<sup>75</sup> This possibility is further reinforced by the grounds that industry sometimes gave for claiming as CBI health and safety studies reported under section 8(e) of TSCA. See HAMPSHIRE STUDY, *supra* note 61, at 18-19.

<sup>76</sup> HAMPSHIRE STUDY, *supra* note 61.

<sup>77</sup> *Id.* at 28-32.

<sup>78</sup> *Id.* at 31.

<sup>79</sup> The Hampshire Study researchers observe:

In the nearly fifteen years that this regulatory effort has been under way, public participation has been minimal, reflecting the fact that EPA has been unable to publicly release the analytical documents that support its regulatory decisions, particularly with regard to asbestos economics and potential substitute materials. This situation clearly illustrates the 'infectious' nature of CBI, in that even government-conducted analyses that rely on CBI materials themselves become CBI. It further demonstrates the potential for CBI claims to have fundamental impacts on the regulatory process, precluding effective public oversight.

*Id.* at 32.

information provides the first major impediment.<sup>80</sup> As a result of these costs, agency officials concede that they typically do not review the merits of industry CBI claims, at least for new chemical classifications.<sup>81</sup> Instead these claims are automatically retained.<sup>82</sup> Second, from the agency official's perspective, there are more costs than benefits to disputing CBI claims. Agency officials who wrongfully divulge trade secret information can be charged criminally, imprisoned for up to one year, and must be terminated from their position.<sup>83</sup> The agency also could be subjected to a "reverse FOIA" suit,<sup>84</sup> and potentially even a suit claiming compensation for the wrongful misappropriation.<sup>85</sup> By contrast, the only penalty for making an erroneous judgment *not* to disclose CBI is the possibility of a suit by the person seeking the information under FOIA.<sup>86</sup> Since FOIA requestors do not have access to the non-disclosed information or even the firm's justification for asserting the claim in some cases,<sup>87</sup> the claimants are naturally handicapped in challenging the determination that the information has competitive value.<sup>88</sup> At worst, the agency will only be forced to disclose the information.<sup>89</sup>

Studies show that firms take full advantage of this generous approach to trade secret protection and assert the claim even when doing so is clearly without merit.<sup>90</sup>

<sup>80</sup> See *id.* at 17.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.* at 17 (reporting that "except for the 8(d)/8(e) Challenge Program and challenges . . . the vast majority of claims submitted are not reviewed").

<sup>83</sup> See Trade Secret Act, 18 U.S.C. § 1905 (2000). Resource Conservation and Recovery Act and EPCRA also provide sanctions for persons who disclose trade secret information but are not employees of the government. TSCA, 15 U.S.C. § 2613 (2000); RCRA, 42 U.S.C. § 6927(b)(2) (2000); EPCRA, 42 U.S.C. § 11045(d)(2) (2000); see also Clean Air Act, 42 U.S.C. § 7414(c) (2000).

<sup>84</sup> See, e.g., *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979).

<sup>85</sup> See, e.g., *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) (finding a partial property right entitled to compensation as a result of EPA's disclosure of health and safety studies on company's pesticide).

<sup>86</sup> See, e.g., 40 C.F.R. § 350.11(b)(1) (2003) (providing person requesting information under FOIA thirty days to appeal to federal court a decision denying the request on the ground the information is CBI).

<sup>87</sup> 40 C.F.R. § 2.205(c) (2003) (giving a company's substantiation for a CBI claim automatic confidential treatment); see also 65 Fed. Reg. 80,394, 80,396 (Dec. 21, 2000) (conceding potential problems with EPA's policy of automatically classifying substantiations as CBI if the firm requests them, which in turn deprives FOIA requestors of not only the information, but the basis for the CBI claim that prohibits its disclosure).

<sup>88</sup> See Lyndon, *supra* note 67, at 35.

<sup>89</sup> It has been suggested by a FOIA expert that the agency will avoid this information as much as possible because it wants to avoid both types of lawsuits. See, e.g., O'Reilly, *supra* note 66, at 10208 ("A possible trend in administrative agency data collection may be the conscious decision to avoid collecting CBI where the access to such information ties up the agency in disputes over the post-collection disclosure of the CBI").

<sup>90</sup> EPA openly concedes that the problem of overbroad CBI claims is serious:

EPA receives a large number of submissions of various types of information claimed as CBI. Many of the claims received are very broad, and the Agency has limited resources to deal with this stream of information. As a result, large amounts of information claimed as CBI are retained by the Agency longer than necessary, and broad or non-specific CBI claims may limit public access to information that is not actually CBI.

Public Information and Confidentiality: Advance Notice of Proposed Rulemaking; Withdrawal of 1994 Proposed Rule, 65 Fed. Reg. 80,394, 80,395 (Dec. 21, 2000); see, e.g., HAMPSHIRE STUDY, *supra* note 61, at 7, 19, 21, 24, 41 (discussing the sharp increase in claims when substantiation is not required over time and across statutes, and concluding that "all available evidence supports the proposition that much of the information covered by CBI claims is not legitimately entitled to protection as TSCA CBI").

In 1990, for example, EPA reviewed CBI claims under the Toxic Substances Control Act and challenged nonmeritorious claims.<sup>91</sup> By 1992, "industry had voluntarily amended and withdrawn over 600 claims after EPA's inquiries."<sup>92</sup> CBI claims drop substantially (by as much as 50-60%) when EPA does require upfront substantiation of the nature of the trade secret protections, which it is legislatively required to do in other programs.<sup>93</sup> The Hampshire Study also found that confidential information was asserted for more than 90% of the premanufacture notices required for new toxic substances under TSCA.<sup>94</sup> In these TSCA notices, the firms almost always claimed as trade secret the chemical identity of the chemical, but they also asserted CBI protections on other pieces of information needed to assess the potential health risk of the product, including health and safety studies.<sup>95</sup> Unfortunately, however, the Hampshire Study does not give percentages for the extent of CBI claims on health and safety research (as opposed to chemical identity); however, it notes throughout the report that there was a significant incidence of these claims,<sup>96</sup> despite the fact that the agency's own general counsel concedes that "health and safety stud[ies]" should never or rarely be protected from disclosure by trade secret claims.<sup>97</sup> Even industry representatives openly admit that they claim CBI protection when the claim is inappropriate.<sup>98</sup>

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The General Accounting Office ("GAO") reports that the Hampshire Study also found that firms claimed as CBI under TSCA information that had already been disseminated publicly. "For example, information contained elsewhere in newspaper articles and corporate annual reports was submitted as CBI was publicly available information from EPA's Toxics Release Inventory, a system that contains nationwide information on toxic chemicals emitted into the air, ground, and water by manufacturing facilities." TOXIC SUBSTANCES CONTROL ACT, *supra* note 68, at 56.

<sup>91</sup> See, e.g., *In re Hercules, Inc.*, No. TSCA-III-416, 1990 WL 303887 (Apr. 26, 1990).

<sup>92</sup> TOXIC SUBSTANCES CONTROL ACT, *supra* note 70, at 5:2. EPA's limited resources make this approach available only in the short-term, however. *Id.* EPA also reviewed CBI claims on health and safety studies and found that over one-fifth of the claims had no merit. *Id.*

<sup>93</sup> See, e.g., HAMPSHIRE STUDY, *supra* note 61, at figs. 2, 6. Under TSCA, premanufacture notification CBI claims do not require upfront substantiation whereas section 8(e) adverse effects reports do require substantiation.

<sup>94</sup> See *id.* at 44-45 (referencing figures 1 and 2).

<sup>95</sup> See *id.* at 53-54 (referring to figures 9 and 10).

<sup>96</sup> See, e.g., *id.* at 12 (observing that "[s]ubstantial numbers of CBI claims were asserted for 'toxicity, exposure, and environmental release data' except for the year 1986"); *id.* at 18-19 (recounting specific unjustified instances where industry asserted CBI claims on health and safety studies for reasons that did not relate to trade-secret concerns).

<sup>97</sup> See, e.g., 15 U.S.C. § 2613(b) (2000); HAMPSHIRE STUDY, *supra* note 61, at 23-24; see also Thomas O. McGarity & Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 874 (1980) (arguing that TSCA "specifically exempt[s] health and safety studies from the protections otherwise afforded to proprietary information").

The Hampshire Study reaches strong conclusions with regard to the frequency of unjustified CBI claims, noting that:

In those cases where EPA has had the resources to evaluate individual CBI claims, it has determined that a significant fraction of the submissions (up to 50 percent or more of Section 8(e) filings) contained invalid CBI claims. When submitters of these claims were challenged, EPA prevailed in every case.

HAMPSHIRE STUDY, *supra* note 61, at 41.

<sup>98</sup> In the GAO's 1994 study, industry commentators who were interviewed "accepted the [GAO's] basic finding that the chemical industry does make improper confidentiality claims and needs to address such claims." TOXIC SUBSTANCES CONTROL ACT, *supra* note 68, at 5:2. They defended their practice of overclaiming under TSCA, however, by arguing that "the purpose of TSCA information is to provide EPA with a factual basis for chemical regulation, not to provide a basis for disseminating data on the chemicals to other interested organizations." *Id.*

From the standpoint of ensuring the quality of industry research used for regulation, broad CBI protections are very problematic. The only parties able to review the scientific information are a few "cleared" agency officials, and the rigor and assumptions made in their review are effectively unreviewable by others inside and outside the agency. As a result, a few agency officials will decide whether the study's design and report passes muster, and these decisions themselves will be completely insulated from public view, leaving the agency officials with reduced incentives for making wise or aggressive decisions. The lack of oversight of research quality might also lead some manufacturers who are particularly inclined to conduct research of poor quality to take undue advantage of this reduced scientific oversight and accountability. As a result, the underlying quality of this large set of regulatory research may be compromised because it is insulated from searching review. In opposing the government's use of proprietary models to predict harm, industry has in fact conceded these serious problems that can attend classified information.<sup>99</sup>

Yet it comes as no surprise that the EPA's concerted efforts to reform the program have consistently failed given the multi-faceted advantages that accrue to firms from classifying information, and the lack of documentation of the adverse effects that generous CBI policies have on the quality and dissemination of scientific research.<sup>100</sup> Indeed, industry representatives not only vigorously oppose regulatory reform, but they argue that existing protections are inadequate to ensure that competitive secrets are safe from disclosure when information is submitted to regulators.<sup>101</sup>

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<sup>99</sup> The Vice President of CropLife (the trade association of the nation's pesticide manufacturers), for example, has observed:

When public access to data and methods is not possible, such as when EPA must rely on proprietary models to perform risk assessments, the Agency must be able to establish, as a matter of public record, that the "robustness checks" being applied are scientifically sound and that reproducibility is being verified through meaningful, independent validations. [Absent such a showing,] [t]he Agency's decisions will continually be subject to challenge as "black box" exercises, unless adequate demonstration of the quality, utility, integrity, and objectivity of the information produced by such proprietary models for use in regulation.

Letter from Ray S. McAllister, Vice President, Science & Regulatory Affairs, CropLife America, to Evangeline Tsibris Cummings, Office of Environmental Information, EPA (June 21, 2002) available at <http://www.pestlaw.com/x/comments/2002/EPA-20020621A.html>; see also Letter from Jim Tozzi, Member CRE Board of Advisors, to Evangeline Tsibris Cummings, Officer of Environmental Information, EPA (Mar. 22, 2002), available at [http://thecre.com/quality/20020319\\_cre-epa\\_dq-comments.html](http://thecre.com/quality/20020319_cre-epa_dq-comments.html).

<sup>100</sup> Over the past decade, EPA has twice attempted to reform the problem of overbroad CBI protections without success. See 65 Fed. Reg. 80,394 (Dec. 21, 2000); 59 Fed. Reg. 60,446 (Nov. 23, 1994); Letter from Warren E. Stickle & Bill Balek to EPA, *supra* note 67; GAO, ENVIRONMENTAL INFORMATION: EPA COULD BETTER ADDRESS CONCERNS ABOUT DISSEMINATING SENSITIVE BUSINESS INFORMATION (June 1999) [hereinafter ENVIRONMENTAL INFORMATION]; TOXIC SUBSTANCES CONTROL ACT, *supra* note 68; HAMPSHIRE STUDY, *supra* note 61; see also Yang, *supra* note 60, at 229-37 (discussing EPA's failed effort to reform CBI under TSCA in 1994); *Confidential Business Information Rule on Hold as Regulatory Negotiation Eyed*, 26 ENVTL. REP. (BNA) 17 (1995).

EPA has also suggested that firms provide materials accounting to strengthen EPCRA reporting, which would include information on toxic chemicals that enter, are used, and leave the facility. These reforms were similarly opposed and ultimately terminated by industry. See, e.g., ENVIRONMENTAL INFORMATION, *supra* note 100, at 11, 12 (discussing how industry opposition based on CBI grounds led to the abandonment of this proposal).

<sup>101</sup> Industry argues that even more trade-secret protections are needed given the "mosaic" effect—the ability of competitors to piece together information about their operations from bits of

## B. THE INSULATION OF PRIVATE RESEARCH FROM OTHER QUALITY ASSURANCES APPLIED TO PUBLIC RESEARCH

The confidential business information protections afforded private research might be the largest source of reduced oversight and quality control over private, regulation-relevant research. But even if there were no CBI and all research were publicly available, under the current legislated and regulatory approaches, publicly sponsored research still receives much more vigorous scrutiny than private research. A number of mandated quality controls apply only to federally funded research and exempt most private research, even when it is used in making decisions about public safety or environmental protection.<sup>102</sup> This skewed oversight is discussed, after first outlining the existing scientific scrutiny of private research used in regulation.

### 1. Scientific Review of Private Research Used in Regulation

Although private research is subject to considerably less public scrutiny than public research, there is some oversight of the quality of the research. For routine private studies submitted in support of an application to market a product or to obtain a permit to discharge pollution, the agency does review the information provided and, particularly in the case of pesticides, may review the original research and even the original data through the use of a working group.<sup>103</sup> When the research is not classified as CBI, other parties, including competitors and public interest groups, might also scrutinize the research if they have the time and interest, and can file suit against the EPA if they believe that the grant of a license or registration is "arbitrary and capricious" because it is based on unreliable research.<sup>104</sup>

The main means of controlling the quality of private research and protecting against biases in study design and reporting is through the specification of testing protocols.<sup>105</sup> These protocols set forth cookbook-like requirements for conducting specific types of toxicity and related studies. Although rigid protocols cannot

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publicly available data. *See, e.g.*, 59 Fed. Reg. at 80,396 (discussing how the regulated community "has made the argument that multiple pieces of data which may not qualify individually to be treated as CBI and are made publicly available can be pieced together to reveal a trade secret."); Letter from Warren E. Stickle & Bill Balek to EPA, *supra* note 67, at 5 (same). In 1998, the law firm of Ropes and Gray prepared a report for the Chemical Manufacturers Association that advocated adoption of a uniform statute that would make it easier for its members to assert confidentiality claims based on the 'mosaic' argument. PROTECTION, *supra* note 57. Yet their support for the 'mosaic' effect problem was based on a Chemical Manufacturer Association commissioned study that hired someone to recreate one (not clearly random) industry based on the publicly available information. *Id.*

They also convened a working group to generally discuss the "mosaic effect," a discussion that is devoid of concrete examples or evidence. *See id.* at 97-98. The extent and pervasiveness of the mosaic effect, then is weakly supported at best. Also unclear are the competitive harms that flow from this intelligence gathering. The voluminous report on the mosaic effect does not provide a single example or argument about the potential types of harms resulting from intelligence-gathering-consultant groups carefully piecing together publicly available information on competitor firms. *Id.*

In its arguments, moreover, industry ignores the scientific benefits of disclosure and assumes that the only social value to disclosure is the "public's right to know" the risks to which they are exposed. *See id.* at 107 (observing EPA's lack of CBI protection for some data cannot be justified by its "'right to know' mission"). *See generally id.* at § 5.

<sup>102</sup> *See infra* Section III.B.2.

<sup>103</sup> *See, e.g.*, ATRAZINE, *supra* note 13.

<sup>104</sup> Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A) (2000).

<sup>105</sup> *See supra* note 12 and accompanying text. *Cf.* EPA's Good Laboratory Practices, 40 C.F.R. pt. 160 (providing general requirements for "good lab" practices for research submitted to EPA; these requirements still leave researchers with considerable research discretion in the design and reporting of most individual research projects).

protect against the suppression of adverse results or data falsification, they do provide important protections against bias in the design of studies or in the reporting of results. Yet this protection is still incomplete. For example, if the protocols do not specify precise categories of adverse effects (or endpoints) for animals exposed to toxins, then there is remaining discretion in what to count as an adverse effect or what unexpected effects to notice and report. These types of inevitabilities in most toxicity studies, except perhaps for the most routine, thus leave room for bias. Some of the tests can also be altered or designed in ways that favor sponsor interests if the agency has not specified restrictive protocols in advance. There has been no systematic inventory of the toxicity tests typically used by sponsors or attempts to rank private research studies according to the remaining researcher discretion in design and reporting, so the extent of this problem remains unspecified. It is evident, however, that this discretion exists in some research and that it can lead to the underreporting of adverse effects.

2. Disproportionately Greater Oversight of Public Relative to Private Research

In contrast to the more limited scientific review applied to private research, a number of separate, overlapping checks are applied to ensure the quality of public research. The greater scrutiny applied to public as compared with private research is summarized in Table 1 below and discussed in more detail in the subsections that follow.

**Table 1: Federal Quality Controls Governing Research Used for Regulation**

Types of Federally-Mandated Requirements Governing Research	External review	Internal agency review	Scientific misconduct requirements	Public DQA complaint process	Public access to underlying data
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**Federally Funded Research**

All facets of research	√	√	√	√	√
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**Privately Sponsored Research**

Study methods and results	*	√		**	
Disclosure of nature of sponsor influence					
Suppression of adverse results	*	√			

√ Denotes complete requirement

\* Denotes partial requirement which exempts confidential business information (CBI)

\*\* Denotes partial requirement which exempts CBI, public filings, and information submitted for an adjudication.

a. *Data Access Act*

The Data Access Act, passed as an appropriations rider in 1999, requires that all "data needed to validate a federally funded study" be made available to requesting parties through the Freedom of Information Act.<sup>106</sup> Regulatory firms can obtain data from all federally funded studies and can review and reanalyze the data, often using electronic data supplied by the original researcher.<sup>107</sup> However, studies conducted by industry or others without the benefit of public funds are not covered by the legislation's data sharing requirements.<sup>108</sup> As a result, the data underlying private research used in regulation need not be publicly available, even when access to this data is necessary for the public to comment meaningfully on a regulation that relies on this private research.<sup>109</sup> Indeed, the data might not even be available to the agency itself, unless an official explicitly insists on the data as a condition to granting a license or permit.<sup>110</sup>

The explicit exemption of private research from the Data Access Act not only leads to lopsided public oversight of regulation-relevant research, but seems directly at odds with the purported intent of the Act. The rider's congressional sponsor, Richard Shelby, justified the Act on the need for greater public access to regulatory science. As Shelby observes, "[p]ublic confidence in the accuracy and reliability of information being used to drive public policy ultimately is in the best interest of scientific research. Increasing access to such data promotes the transparency and accountability that is essential to building public trust in government actions and decision-making."<sup>111</sup>

b. *Data Quality Act*

A second law passed in 2001, also as a rider to an appropriations bill, the Data Quality Act, provides mechanisms for interested parties to file complaints about the quality of regulatory science, but again this Act focuses predominantly on publicly

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<sup>106</sup> See Shelby Amendment, Pub. L. No. 105-277, 112 Stat. 2681-495 (1998).

<sup>107</sup> See OMB Circular A-1110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, 64 Fed. Reg. 54,926, 54,927 (Oct. 8, 1999) ("[I]n response to a Freedom of Information Act (FOIA) request for data relating to published research findings produced under an award that were used by the Federal Government in developing policy or rules, the Federal awarding agency shall, within a reasonable time, obtain the requested data so that they can be made available to the public through the procedures established under the FOIA.").

<sup>108</sup> See OMB, Final Revision, OMB Circular A-110, 64 Fed. Reg. at 54,929 (requiring research findings to be produced if they were "produced under an award that [was] used by the Federal Government in developing an agency action that has the force and effect of law").

<sup>109</sup> See, e.g., NATIONAL RESEARCH COUNCIL, ACCESS TO RESEARCH DATA IN THE 21ST CENTURY: AN ONGOING DIALOGUE AMONG INTERESTED PARTIES: REPORT OF A WORKSHOP 27 (2002) (the chair of the National Academy of Science committee, Richard Merrill, expressed concern over the fact that the Shelby Amendment "is not bilateral in its application" since it does not apply "to data that [is] generated by private dollars that [is] submitted to support agency decisions."); *id.* at 16 (reporting that panelist David Hawkins, representative of a public interest advocacy group, criticized the Shelby Amendment for being "'one-sided' because it applies only to federally funded research" and not to "industry-supported studies that have been submitted on a confidential basis").

<sup>110</sup> But see CENTER FOR REGULATORY EFFECTIVENESS, RELATIONSHIPS WITH PRIVATE FUNDING SOURCES, at <http://www.thecre.com/access/comments/2-9-7.html> (last visited July 20, 2003) ("As part of the award process, federal awardees should be required to provide notice to private research partners that sharing data with federally funded researches may subject that data to possible public disclosure.").

<sup>111</sup> Richard Shelby, *Accountability and Transparency: Public Access to Federally Funded Research Data*, 37 HARV. J. LEGIS. 369, 379 (2000).

funded research. The Data Quality Act requires agencies to develop formal procedures "for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies" through a formal complaint process.<sup>112</sup> The implementing regulations, however, exempt most industry-sponsored science from these new processes. Specifically, the Data Quality Act requirements apply only to science that is "disseminated" by an agency,<sup>113</sup> but exempts "adjudications," which has been interpreted to include studies produced by a company to support an application for licensing a product or obtaining a pollution permit.<sup>114</sup> OMB has also interpreted the term "dissemination" to exempt "public filings," which would seem to include industries' documentation of compliance, as well as the basis for their Toxic Release Inventory estimates submitted under the Emergency Planning and Community Right-to-Know Act ("EPCRA").<sup>115</sup> Finally, OMB exempts from the Data Quality Act all information classified as confidential business information.<sup>116</sup> Together these Data Quality Act exemptions insulate from the "sound science" requirements virtually all mandated industry research. Subsequent "data quality" regulations passed by the agencies themselves leave OMB's broad exemptions of private research in place. Most striking is EPA's recent promulgation of guidelines intended specifically for the oversight of "third-party" research submitted to the

<sup>112</sup> Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, Stat 5658 (2000).

<sup>113</sup> See *id.* §§ 515(a), (b) (stating requirements apply only to information "disseminated by Federal agencies").

<sup>114</sup> See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 369, 377-78 (Jan. 3, 2003) (defining "dissemination" as "agency initiated or sponsored distribution of information to the public . . . [but] does not include[] distribution limited to correspondence with individuals or persons, . . . public filings, . . . or adjudicative processes"); NATIONAL ACADEMY OF SCIENCE, ENSURING THE QUALITY OF DATA DISSEMINATED BY THE FEDERAL GOVERNMENT 60 (Mar. 21, 2002), available at [http://www7.nationalacademies.org/stl/4-21-02\\_Transcript.doc](http://www7.nationalacademies.org/stl/4-21-02_Transcript.doc) [hereinafter NAS DATA QUALITY TRANSCRIPT] (observing that the issuance of a permit constitutes an adjudication under the APA). National Academy of Science, Ensuring the Quality of Data Disseminated by the Federal Government, available at [http://www7.nationalacademies.org/stl/4-22-02\\_Transcript.doc](http://www7.nationalacademies.org/stl/4-22-02_Transcript.doc) (Mar. 22, 2002) [hereinafter NAS DATA QUALITY TRANSCRIPT DAY 2] (expressing concern that the agency "reach[es] into the open literature for information that it will use in making a pesticide decision and that though that literature may be peer reviewed, . . . we believe [it] complies with a much lower quality of standards in terms of transparency and reproducibility to trump the data produced under higher quality standards by manufacturers in making a pesticide decision").

<sup>115</sup> See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 369, 377-78 (Jan. 3, 2003) (defining "dissemination" as "agency initiated or sponsored distribution of information to the public . . . [but] does not include distribution limited to correspondence with individuals or persons, . . . public filings, . . . or adjudicative processes").

<sup>116</sup> See 67 Fed. Reg. 369, 374 (listing requirements that data and methods be made publicly available does not "override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections"); see also NAS, DATA QUALITY TRANSCRIPT, DAY 2, *supra* note 114, at 128-29 (noting Dr. Galson's statement that FDA approvals are largely based on industry generated data and that "much of this is considered confidential business information. It is closely held by the sponsors."). But see McGarity & Shapiro, *supra* note 97, at 887 (arguing that trade secret status should not extend to much of the health and safety testing information); see also Lyndon, *supra* note 67, at 22-35 (outlining the prominence of trade secrecy claims under major regulatory statutes and observing that because "[f]or a worker or neighbor seeking data from a company, trade secret information is, as a practical matter, simply unavailable" the employer lacks any incentive to disclose such information) (citations omitted).

agency.<sup>117</sup> Despite its title, these guidelines appear to keep the OMB exemptions of private research in place,<sup>118</sup> targeting instead state-produced research.

*c. Scientific Misconduct*

Aggressive provisions that penalize researchers who engage in scientific misconduct are targeted solely at federally funded research and do not apply to private research. To ensure that scientific research is conducted honestly, federal law provides the Office of Research Integrity with the authority to investigate federally funded researchers who are alleged to have engaged in "scientific misconduct," a term that includes fabrication, falsification, and plagiarism of data.<sup>119</sup> Any party can complain of this scientific misconduct, and there are anecdotes of industry using the misconduct provisions to harass and discredit scientists whose research is adverse to their interests.<sup>120</sup> Again the disparate oversight of the quality of public versus private research repeats itself. Publicly sponsored research is governed by scientific misconduct regulations that withdraw funding and stigmatize the offending researchers; private research is exempt from this form of regulatory oversight, even when private research forms the primary basis for federal health and safety regulation.

*d. Heightened Peer Review Requirements for Agency Research*

In contrast to its ad hoc review of private research, which varies by supervising staff official and the applicable regulatory program, EPA is employing increasingly rigorous and systematic peer review of research that is produced or funded by the EPA and the federal government.<sup>121</sup> Federally conducted research was criticized in

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<sup>117</sup> *But see* EPA Human Testing; Advance Notice of Proposed Rulemaking, 68 Fed. Reg. 24,410, 24,413 (May 7, 2003) ("In general, EPA cannot readily determine whether such policies are consistent with or as protective of human subjects as the Common Rule, nor the extent to which such policies or standards have been followed in the conduct of any particular study. Thus, even well-conducted third-party human studies may raise difficult questions for the Agency when it seeks to determine their acceptability for consideration.").

<sup>118</sup> *Id.*

<sup>119</sup> Scientific Misconduct Regulations, 40 C.F.R. pt. 50, subpt. A; *see generally* Robert M. Anderson, *The Federal Government's Role in Regulating Misconduct in Scientific and Technological Research*, 3 J. L. & TECH. 121 (1988).

<sup>120</sup> Herbert Needleman (whose research on child lead poisoning was pivotal in EPA's lead phase-out of gasoline) was alleged to have engaged in misconduct. The accusations of misconduct, brought by scientists who consulted with the lead industry, turned out to be meritless, and he was cleared of wrongdoing. *See, e.g.,* Herbert L. Needleman, *Salem Comes to the National Institute of Health: Notes from Inside the Crucible of Scientific Integrity*, 90 PEDIATRICS 977 (1992); Joseph Palca, *Lead Researcher Confronts Accusers in Public Hearing*, 256 SCIENCE 437 (1992); Gary Putka, *Professor's Data on Lead Levels Cleared by Panel*, WALL ST. J., May 27, 1992, at B5. Scientific misconduct allegations were also brought against researchers documenting how the "Joe Camel" logo appealed to young adolescents. The charges were brought by an academic affiliated with RJR Reynolds, the holder of the Joe Camel trademark. Paul M. Fischer, *Science and Subpoenas: When Do the Courts Become Instruments of Manipulation?*, 59 LAW & CONTEMP. PROBS. 159, 160 (1996).

<sup>121</sup> Some statutes like FIFRA even mandate rigorous peer review and scientific oversight for federal (but not private) research. *See, e.g.,* 7 U.S.C. §§ 136w(d)-(e) (2000) (requiring the scientific advisory panel established under the FIFRA to review the scientific basis for major regulatory proposals concerning pesticides and to adopt peer review procedures for scientific studies carried out by the government or under federal contract pursuant to FIFRA). Some of this elaborate peer review is mandated by Congress, and some is internally mandated. *See* NATIONAL ACADEMIES PRESS, STRENGTHENING SCIENCE AT THE U.S. ENVIRONMENTAL PROTECTION AGENCY: RESEARCH MANAGEMENT AND PEER REVIEW PRACTICES 102 (2000), available at <http://books.nap.edu/books/0309071275/html#pagetop> (listing the statutes that require peer review of "various scientific and

the past for the lack of reliable and standardized peer review.<sup>122</sup> In response to these criticisms, EPA has established an agency-wide peer review process that subjects a great deal of agency research, especially "significant work products," to external peer review.<sup>123</sup> Here again the emphasis is exclusively on agency "work products" for peer review.<sup>124</sup> While some private studies might be included in this peer review when that research is included within a larger agency risk assessment, it is not clear how rigorously the individual private studies will be reviewed at this later stage of review.<sup>125</sup>

*e. Limited Oversight of Research Ethics for Private Research*

Since we are concerned only with research quality, the ethical conduct of the research is secondary and not directly relevant. Nevertheless, it deserves mention that institutions receiving federal dollars must institute aggressive oversight processes to ensure human subject protection in research that uses human subjects.<sup>126</sup> These human subject protections can limit the types of research that can be done.<sup>127</sup> Again, however, human subject protections do not apply to privately sponsored research done outside of these institutions, even though an international treaty generally prohibits unethical research on human subjects.<sup>128</sup> The agencies have routinely applied this ethical requirement to private research so that both public and private research is conducted in ways that protect human subjects, although Congress has never legislated the requirement.<sup>129</sup> Private manufacturers have recently filed a petition challenging this equal treatment of private and public research, arguing that EPA is legally required to consider human subjects research regardless of whether it complies with federal requirements governing human subjects research.<sup>130</sup> The outcome of the petition is still pending.<sup>131</sup>

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technical practices, policies, and activities of the agency"); EPA, SCIENCE POLICY COUNCIL, PEER REVIEW HANDBOOK xi-xii (2d ed. 2000), available at <http://www.epa.gov/osp/spc/2peerrev.htm> [hereinafter PEER REVIEW HANDBOOK].

<sup>122</sup> See, e.g., NAS DATA QUALITY TRANSCRIPT, *supra* note 114, at 102-08, 144-46 (describing past and current weaknesses in EPA's peer review policies).

<sup>123</sup> See generally PEER REVIEW HANDBOOK, *supra* note 121.

<sup>124</sup> See, e.g., NAS DATA QUALITY TRANSCRIPT, *supra* note 114, at 105 (discussing the various federally supported research that should be peer reviewed, with lists that are often several lines long; but making no mention of industry-sponsored research used for regulation).

<sup>125</sup> See generally PEER REVIEW HANDBOOK, *supra* note 121.

<sup>126</sup> The Common Rule, 45 C.F.R. pt. 46 (2003).

<sup>127</sup> See *id.*

<sup>128</sup> 45 C.F.R. § 46.101; see THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH n.1 (1978) (discussing Nuremberg Code of 1947 and Helsinki Declaration of 1964 that are dedicated to protecting human subjects in research settings).

<sup>129</sup> See, e.g., Press Release, EPA, Agency Requests National Academy of Sciences Input on Consideration of Certain Human Toxicity Studies; Announces Interim Policy (Dec. 14, 2001), available at [http://www.epa.gov/epahome/headline2\\_121401.htm](http://www.epa.gov/epahome/headline2_121401.htm) (postponing consideration of private human subjects research pending a National Academy of Sciences review of "the complex scientific and ethical issues posed by EPA's possible use of third-party studies which intentionally dose human subjects with toxicants to identify or quantify their effects").

<sup>130</sup> See Letter from Jim J. Tozzi, Center for Regulatory Effectiveness Board of Advisors, to Stephen L. Johnson, Assistant Administrator (May 10, 2002), EPA, available at [http://thecre.com/pdf/20020510\\_cre-epa-letter.pdf](http://thecre.com/pdf/20020510_cre-epa-letter.pdf).

<sup>131</sup> See *id.*

### C. POTENTIAL DEFICIENCIES IN PRIVATE RESEARCH ARE GENERALLY IGNORED IN REGULATORY OVERSIGHT OF THE RESEARCH

The ways that conflicts of interest and suppression of adverse information have historically afflicted private research used in regulation, especially in relation to its public research counterpart, were discussed in Part II. In this section, we discuss the incomplete ways that the regulatory system has come to terms with these two problems inherent in sponsor-controlled research.

#### 1. Agencies Do Not Require Private Research to be Independent from the Sponsor or to Provide Conflict Disclosures

Despite growing insistence by biomedical journal editors that the scientific research they publish is "free of commercial influence,"<sup>132</sup> agencies continue to accept all private research without any disclosure of research independence. Most federal agencies, including the EPA, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, the Consumer Product Safety Commission, and the National Highway Traffic Safety Administration, have no formal mechanisms to identify potential conflicts of interest and promote research integrity.<sup>133</sup> The EPA, for example, does not require any conflict disclosures for research submitted in support of a license to market a pesticide or toxic substance or in support of a license to emit pollutants or handle hazardous wastes.<sup>134</sup> The Food and Drug Administration ("FDA") is one of the few agencies that has instituted a conflict policy that requires financial disclosures for safety research conducted by private parties in support of a license to market a drug or food additive.<sup>135</sup> The required FDA disclosures do not, however, discriminate between sponsored research where the sponsor controls the design or reporting of the research and research where the sponsor relinquishes control over the research process.<sup>136</sup> Thus, an important mechanism for encouraging greater freedom among researchers is lost.

#### 2. Penalizing Suppression of Research

Several of the major environmental laws anticipate the possibility that regulated actors will conceal adverse information and research results, and to counteract this tendency, the laws require the disclosure of adverse information under threat of both civil and criminal sanctions.<sup>137</sup> Two statutes play a particularly significant role in

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<sup>132</sup> See, e.g., Catherine D. DeAngelis et al., *Reporting Financial Conflicts of Interest and Relationships Between Investigators and Research Sponsors*, 286 JAMA 89 (2001); Jeffrey M. Drazen & Gregory D. Curfman, *Financial Associations of Authors*, 346 NEW ENG. J. MED. 1901 (2002).

<sup>133</sup> Cf. Jennifer A. Henderson & John J. Smith, *Financial Conflict of Interest in Medical Research: Overview and Analysis of Federal and State Controls*, 57 FOOD & DRUG L.J. 445, 455 (2002) (noticing in the area of biomedical research that "both federal and state controls provide a relative lack of prospective guidance as to what constitutes acceptable institutional conflict policy.").

<sup>134</sup> See, e.g., 7 U.S.C. § 136a(c)(1)(F) (2000) (outlining test reporting required for registration of pesticides under FIFRA); 15 U.S.C. § 2603 (2000) (outlining test reporting required for registration of substances of substances under TSCA).

<sup>135</sup> Financial Disclosure by Clinical Investigators, 21 C.F.R. § 54 (2003).

<sup>136</sup> See *id.* (making no distinction between sponsor-controlled research and research where the sponsor relinquishes control).

<sup>137</sup> See generally Arnold W. Reitze, Jr. & Lee D. Hoffman, *Self-Reporting and Self-Monitoring Requirements Under Environmental Laws*, 1 ENVTL. LAWYER 681, 681, 739-41 (1995) (discussing

dictating the applicable requirements governing the disclosure of information on adverse effects (as opposed to environmental releases): the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act.<sup>138</sup> Yet, despite Congress's hope that agencies could deter the suppression of research through strong sanctions and aggressive enforcement, these provisions appear only partly effective.

Compliance with these adverse effects reporting requirements is generally a function of two features of the regulatory program. First, the requirements must be clear enough to be enforceable. Second, the sanctions and resources dedicated to enforcement must present a credible risk of enforcement to the manufacturer and other covered parties.

With respect to the first criterion, TSCA and FIFRA differ considerably with regard to the clarity and enforceability of their requirements. Under FIFRA, EPA's regulations governing "adverse effects" reporting are lengthy, specific, and leave little discretion or room for argumentation with regard to reporting requirements.<sup>139</sup> For example, "opinion" evidence by reliable experts;<sup>140</sup> discontinued studies;<sup>141</sup> and a lengthy list of effects, including minor effects, are identified as reportable.<sup>142</sup> EPA further warns that while registrants might doubt the validity or significance of an adverse effect, they must still report it and can simply provide their own qualifications, disagreements, or other commentary in the report.<sup>143</sup>

By contrast, EPA has still not promulgated regulations interpreting the similar "substantial risk" reporting requirement of TSCA. Instead EPA has published only "policy statements" that appear to be getting progressively weaker in terms of the specificity they provide regarding compliance.<sup>144</sup> EPA in fact goes to great lengths to remind regulated parties that since the guidelines are not rules, they are not officially binding.<sup>145</sup> Even as guidance, EPA's directions are generally unhelpful. In stark contrast to the several-page list of specific adverse effects that must be

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civil and criminal penalties for violating reporting requirements, including criminal enforcement of false reporting and fraud).

<sup>138</sup> See FIFRA, 7 U.S.C. § 136d(a)(2) (2000) ("If at any time after the re-registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the regulator."); TSCA, 15 U.S.C. §§ 2607(c), (e) (2000) (stating that manufacturers and processors must maintain records of "significant adverse reactions to health or the environment . . . alleged to have been caused by the substance or mixture . . . [and must immediately report] information which reasonably supports the conclusion that such substances or mixture presents a substantial risk of injury to health or the environment").

<sup>139</sup> See generally 40 C.F.R. pt 159 (2003) (outlining reporting requirements for risk/benefit information); EPA, Reporting Requirements For Risk/Benefit Information, 62 Fed. Reg. 49,370 (Sept. 19, 1997) (codified at 40 C.F.R. pt. 159).

<sup>140</sup> 40 C.F.R. § 159.158(a) (2003).

<sup>141</sup> *Id.* § 159.167.

<sup>142</sup> See *id.* § 159.184.

<sup>143</sup> See, e.g., 62 Fed. Reg. at 49,372 ("Registrants are free to submit information challenging the validity of section 6(a)(2) information either at the time of, or after submission of the information to the Agency.").

<sup>144</sup> For example, in its 2003 guidance, EPA created a number of new exemptions and lengthened the reporting time from fifteen working days to thirty calendar days. See TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33,129, 33,130 (June 3, 2003).

<sup>145</sup> See, e.g., *id.* ("Although these preferences could be codified in procedural rules . . . , EPA is not at this time adopting them as rules. While submitters of section 8(e) notices are not therefore obligated to comply with the preferences articulated in this document, EPA encourages submitters to consider and follow them . . .").

reported under FIFRA, EPA's TSCA guidance provides a very vague and generally narrow set of "risks" that necessitate reporting.<sup>146</sup> A "substantial risk," for example, occurs when evidence "reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects, or toxic effects resulting in death, or serious or prolonged incapacitation."<sup>147</sup> This means that only the most serious incidents are identified as within the scope of TSCA.<sup>148</sup> Also in contrast to the FIFRA reporting requirements, EPA does not advise manufacturers and other covered parties to err on the side of reporting, but provides manufacturers with discretion to decide when evidence "reasonably supports" a conclusion of "substantial risk"—opinion evidence is not required to be reported.<sup>149</sup> Finally, a series of confusing exemptions for reports made to other federal offices further buffer manufacturers from the threat of enforcement given the extra steps enforcement officials must take to learn of violations.<sup>150</sup> As a result, manufacturers have many plausible arguments for not disclosing adverse information in a timely or informative way under TSCA.

Second, to identify and penalize the suppression of adverse information, the agency must learn about it; yet the enforcement resources EPA dedicates to the statutes that require adverse reporting of research results—FIFRA and TSCA—are the lowest in comparison to other statutory programs.<sup>151</sup> Moreover, the testing and information disclosure requirements of TSCA and FIFRA programs are not delegated to the states, and thus EPA remains the sole agency overseeing enforcement of these programs.<sup>152</sup> This makes the probability of catching noncompliance with adverse reporting requirements lower still, despite EPA's undocumented assurances that since 1977 it has "initiated a number of formal enforcement actions relating to Section 8(e) of TSCA," most of which concern "the

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<sup>146</sup> See, e.g., *id.* at 33,138 (stating what the EPA considers "substantial risks").

<sup>147</sup> *Id.*

<sup>148</sup> "Substantial risks" to ecosystems, for example, occur in relatively rare and worrisome settings. The EPA, for example, identifies substantial risks in non-emergency situations where there are "[e]cologically significant changes in species' interrelationships; that is, changes in population behavior, growth, survival, etc. that in turn affect other species' behavior, growth, or survival." *Id.* at 33,138.

<sup>149</sup> At most, EPA warns on its section 8(e) fact sheet that "[l]imited studies (e.g., range finding studies), preliminary results and draft reports may constitute sufficient evidence for Section 8(e) reporting." EPA, TSCA SECTION 8(E) FACT SHEET, at <http://www.epa.gov/opptintr/tscas8e/doc/facts8e.htm> (last updated Apr. 12, 2004) (emphasis added). EPA also warns that the manufacturer need not wait for corroborating evidence, but implies that not reporting if a manufacturer believes the information is low quality is a valid basis for withholding reports. TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. at 33,138-39.

<sup>150</sup> *Id.* at 33,139-40.

<sup>151</sup> Information on EPA's enforcement resources under FIFRA was not readily available; in terms of the number of inspections conducted by EPA regional offices, this statute fared the worst, accounting for only one percent of all inspections conducted in 1998 (a decline from roughly 3% in 1995). ARNOLD W. REITZ, JR., AIR POLLUTION CONTROL LAW: COMPLIANCE & ENFORCEMENT 491 (2001). Some dated information on the staffing and resources of EPA's TSCA program, which primarily involves the review of pre-manufacture notifications under TSCA, suggests that the program is badly understaffed. A Bureau of National Affairs article reports that from 1990 to 1994 EPA experienced a 33% drop in staff and a 60% drop in funding dedicated to the review of new chemicals. See *Testing: Screening Studies for Evaluating Chemicals on TSCA Inventory Suggested at OTA Workshop*, 19 CHEM. REG. REP. (BNA) 105 (1997). An Office of Technology Assessment project commenced in the mid-1990s found that in the nineteen-year history of TSCA implementation, EPA had reviewed only "about two percent of the 70,000 chemicals in commerce." *Id.*

<sup>152</sup> See 7 U.S.C. § 136v (2000); 15 U.S.C. § 2627 (2000) (stating that the EPA's authority under FIFRA is not delegated to the states).

late reporting of animal study findings."<sup>153</sup> In addition, the penalties for violating adverse effects reporting requirements are generally the same under both FIFRA and TSCA—roughly a \$5,000 to \$15,000 penalty for each unreported incident with the “possibility” of criminal penalties if the knowledge of the information was reckless,<sup>154</sup> although for FIFRA, the penalties also include a risk that EPA might cancel the pesticide.<sup>155</sup> In comparing the costs of the penalties (and the low probability of being caught in violation of the regulations) against the economic benefits of withholding adverse information, rational companies may find it in their interest to violate the adverse reporting requirements when the chance of detection is especially low.<sup>156</sup> By contrast, since greater regulatory activity is a reasonable worry as a result of adverse effects reporting, not to mention potential tort liability, manufacturers, and related parties might perceive great benefits from resisting reporting.

As a result, there is reason for skepticism about the effectiveness of the adverse reporting requirements, especially under TSCA, given the strong incentives that regulated parties have for suppressing this information. Armed with ambiguous and narrow criteria for reporting under TSCA, coupled with low sanctions and a low probability of enforcement, one would expect rational manufacturers and other covered parties to report adverse discoveries only when the records of these adverse effects are likely to be discovered. In fact, the primary information that is reported as “substantial risk” information under TSCA is standard toxicity studies.<sup>157</sup> “Incidents” and other unexpected adverse effects are rarely, if ever, reported.<sup>158</sup> This is rational to the extent that planned, in-house research would be much more easily discovered after the fact by EPA. Second, firms historically did not report any “substantial risks” under TSCA until EPA threatened more aggressive enforcement action and simultaneously offered reduced penalties for the submission of

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<sup>153</sup> See EPA, TSCA 8(e) REPORTING GUIDE JUNE 1991, at <http://www.epa.gov/opptintr/tsca8e/doc/rguide.htm> (last updated May 13, 2004).

<sup>154</sup> See, e.g., Reporting Requirements for Risk/Benefit Information, 62 Fed. Reg. 49,370, 49,372 (Sept. 19, 1997) (to be codified at 40 C.F.R. pt. 159) (noting that violations of the FIFRA reporting requirements “could result in actions for civil and/or criminal penalties under FIFRA section 14”); TSCA Section 8(e): Notification of Substantial Risk, Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33,129, 33,140 (June 3, 2003) (noting that violations of the TSCA reporting requirement can lead to civil and possible criminal liability).

<sup>155</sup> Reporting Requirements for Risk/Benefit Information, 62 Fed. Reg. 49,370, 49,372 (Sept. 19, 1997) (to be codified at 40 C.F.R. pt. 159) (“EPA does not intend to pursue cancellation every time section 6(a)(2) may have been violated, but egregious or repeated violations may warrant cancellation rather than, or in addition to, monetary fines.”).

<sup>156</sup> See, e.g., Steven Shavell, *The Optimal Structure of Law Enforcement*, 36 J.L. & ECON. 255, 261-62 (1993) (observing that firms will find it financially imprudent to comply with legal requirements when the benefits of noncompliance outweigh the probability of being caught multiplied by the penalty for the violation).

<sup>157</sup> 15 U.S.C. § 2607e (2000) (requiring reporting to the EPA of substances that present a “substantial risk of health or injury of the environment”); see, e.g., EPA, TSCA8(E) AND FYI SUBMISSIONS RECEIVED FROM 10/21/03 TO 10/31/03, at [http://www.epa.gov/opptintr/tsca8e/doc/8esub/2003/8e1020\\_103103.htm](http://www.epa.gov/opptintr/tsca8e/doc/8esub/2003/8e1020_103103.htm) (last updated Apr. 23, 2004) (providing a recent sample of EPA section 8(e) submissions where the majority of section 8(e) submissions report results from formal toxicity studies).

<sup>158</sup> It appears that nearly all of the “substantial risk” and “for your information” (“FYI”) submissions are designed toxicity studies. See, e.g., EPA, PREVIOUS TSCA 8(E) AND FOR YOUR INFORMATION (FYI) SUBMISSIONS LIST, at [http://www.epa.gov/opptintr/tsca8e/doc/previous8\(e\).htm](http://www.epa.gov/opptintr/tsca8e/doc/previous8(e).htm) (last updated July 14, 2003).

information.<sup>159</sup> In response, the companies volunteered 11,000 studies of their products—four times the number of studies submitted in the prior fifteen years since passage of the statute!<sup>160</sup> Finally, it appears that industry has developed a compliance strategy under TSCA that routinely involves sending toxicity research to the EPA even when the outcome is inconclusive or not suggestive of a “substantial risk.” These are called “for your information” (“FYI”) submissions.<sup>161</sup> This might also be a rational compliance strategy for industry because they can avoid damaging admissions of “substantial risk” by labeling all reports as FYI.

Equally relevant to the instant analysis, it is not clear how useable the information that is reported under these adverse reporting requirements is, or whether it is even intended to be useable when the manufacturer or other party reports it. The data reported under both FIFRA and TSCA is not available except at EPA offices, although an Internet list is available for TSCA “substantial risk” reports arranged by date of the report (but not searchable with other queries).<sup>162</sup> The data is sometimes protected as confidential business information, although EPA does require upfront substantiation for the “substantial risk” reporting under TSCA.<sup>163</sup> Even though the rates of CBI claims are far lower for 8(e) submissions, presumably because of this substantiation requirement,<sup>164</sup> CBI claims still lead to the classification of either the chemical identity or the submitter for about 20-25% of the “adverse effects” reports. Even when the adverse effects reports are accessible and publicly available, they appear to be incomplete. In a 1994 report, a nonprofit examined more than 13,000 section 8(e) submissions and concluded, among other weaknesses, that “[s]ome notices did not provide enough information about the nature of the risk, or the research method used, to assess the significance of the results.”<sup>165</sup>

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<sup>159</sup> Press Release, EPA, TSCA Enforcement Action Secures New Chemical Risk Data (Apr. 25, 1997), at <http://yosemite.epa.gov/opa/admpress.nsf>.

<sup>160</sup> See Agency Watch, *EPA's "Voluntary" Data; FAA Curbs the Bar*, NAT'L L.J., Nov. 4, 1996, at A10.

<sup>161</sup> See, e.g., HAMPSHIRE STUDY, *supra* note 61, at 10 (describing FYI filings and the dramatic increase in section 8(e) filings after EPA announced a reporting incentives program).

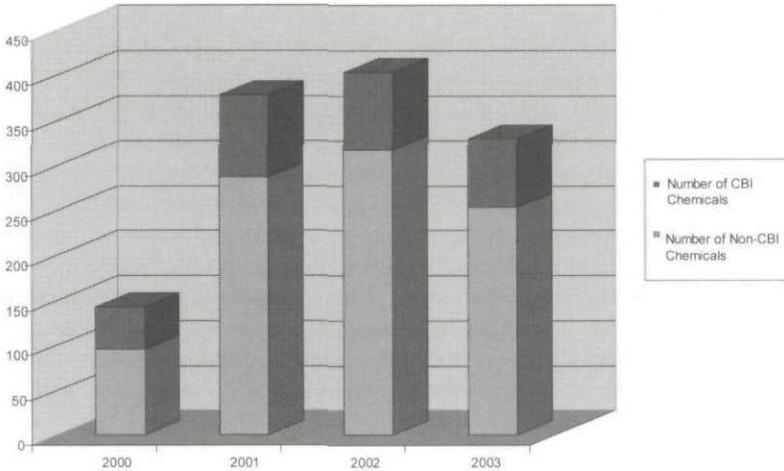
<sup>162</sup> See, e.g., EPA, TSCA 8(E) AND FYI SUBMISSIONS RECEIVED FROM 01/02/03 TO 01/15/03, at [http://www.epa.gov/opptintr/tscas8e/doc/8esub/2003/8e0102\\_011503.htm](http://www.epa.gov/opptintr/tscas8e/doc/8esub/2003/8e0102_011503.htm) (last updated Apr. 23, 2004) [hereinafter 01/02/03 TO 01/15/03 FYI SUBMISSIONS].

<sup>163</sup> See EPA, SUPPORT INFORMATION FOR CONFIDENTIALITY CLAIMS, at <http://www.epa.gov/opptintr/tscas8e/doc/cbi.htm> (last updated Apr. 12, 2004).

<sup>164</sup> See HAMPSHIRE STUDY, *supra* note 61.

<sup>165</sup> See, e.g., CAROLYN A. NUNLEY, RISK ON RECORD: AN OVERVIEW OF TSCA'S SUBSTANTIAL RISK REPORTING SYSTEM WITH BULLETINS ON SELECTED CHEMICALS (1996), available at [http://informinc.org/xsum\\_risks.php](http://informinc.org/xsum_risks.php) (providing summary of work).

**Figure 1: Number of CBI Claims in “Adverse Effects” Reports Submitted under 8(e) of TSCA from 2000 to 2003<sup>166</sup>**



(2000 Submissions are from Aug. 28 to End of Year; 2003 Submissions are through Oct. 27)

#### IV. REFORM

The insulation and limited scrutiny of private research used in regulation, especially in contrast to the scrutiny afforded public research, is problematic from the standpoint of “sound science” and sound regulation. It is impossible to empirically determine the costs of the current, weak quality controls governing private research, because so much of this research is classified or otherwise exempted from meaningful oversight. Yet as discussed in Part II, one can expect the quality of private research to be potentially biased in ways that under-state risks. Additionally, the absence of incentives to conduct independent research (in contrast to the obvious benefits of retaining sponsor control over the design and reporting of research) raise still more reason to worry that much of private research submitted to regulators may not in fact be free of conflicts, or at least is not as unbiased as is possible under the circumstances.

In this final Part, we offer three sets of reforms to correct the quality problems that may plague private research used for regulation, especially in relation to public research. We start with what we consider to be the most obvious and easy to implement reforms and move incrementally to more vigorous reforms.<sup>167</sup>

<sup>166</sup> Figure 1 was prepared using EPA’s section 8(e) database. See 01/02/03 TO 01/15/03 FYI SUBMISSIONS, *supra* note 162. For each submission that included at least one CBI claim, the chemical that was the basis for the submission is identified as a CBI chemical. The larger column provides the total number of non-redundant 8(e) submissions for each year (note that two of the years are incomplete). For access to the underlying worksheets used to prepare this figure, please contact Wendy Wagner at [WWagner@mail.law.utexas.edu](mailto:WWagner@mail.law.utexas.edu).

<sup>167</sup> These reform proposals are also advanced in Wagner, *supra* note 16, to combat the overlapping problem of inadequate environmental and public health research that results, in part, from regulated parties’ superior information over the effects of their products and activities.

#### A. EQUALIZING THE TREATMENT OF PRIVATE AND PUBLIC RESEARCH

A regulatory system that provides considerably greater scrutiny for publicly funded research than private research cannot be justified. Since regulatory decisions have a direct impact on the public health and environmental protection, research that is demonstrably afflicted with bias should be afforded at least the same level of scrutiny as research that is more disinterested.

To that end, we recommend that whatever oversight is given to public research (and the appropriate level is certainly open to question) should also be applied to private research. The Data Access Act, the Data Quality Act, internal peer review requirements, scientific misconduct, and even human subject protections should apply with the same force to private research as they apply to public research. To the extent that research is protected as confidential business information, the agency should develop oversight mechanisms to offset the lack of oversight by outside parties. Formal peer review requirements and random validation of research, with hefty fines for research that is incompletely reported or not accurate, are among the possible approaches to ensure equivalent oversight of the quality of confidential research.<sup>168</sup> In order to deter parties from overclaiming CBI for health and safety research, moreover, the expense of additional peer review and random validation should be borne by the parties claiming CBI protections.<sup>169</sup> If research is ultimately found to be biased or incomplete, the manufacturer-sponsor would be "red-flagged" and all of their studies would require validation until the agency is satisfied that they are once again conducting quality, independent research.

#### B. CORRECTING BIAS AND SUPPRESSION IN PRIVATE RESEARCH

Private research runs the risk of being biased by financial conflicts of interest. Private research that is adverse is also capable of being suppressed. Reforms should be implemented to directly address these two problems.

##### 1. Discourage Conflicted Research

Under the current system, research with complete sponsor control enjoys potentially the same credibility as research produced by scientists with no financial interest in the outcome and no sponsor control. EPA does not require conflict disclosures for private information submitted for regulatory purposes and makes no apparent distinction between private research produced by academics under contracts that grant them complete independence and research funded and controlled by a regulated party.<sup>170</sup>

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<sup>168</sup> See, e.g., ENERGY INFORMATION ADMINISTRATION, DEPARTMENT OF ENERGY, ENERGY INFORMATION STANDARD 2002-28 (recommending the information that should be available to maximize the third-party review of proprietary models).

<sup>169</sup> See HAMPSHIRE STUDY, *supra* note 61.

<sup>170</sup> As discussed, moreover, a significant portion of industry-sponsored research used in these regulatory efforts is protected from external scientific review through trade secret and confidential business privileges. See *supra* Part III.A. In fact, even in spite of its promise of requiring agencies to use and publicize only "quality," "objective" science, the Data Quality Act requirements omit any disclosure requirements for conflicts of interest. By ignoring these disclosure requirements, the Data Quality Act seems to provide the public with misleadingly incomplete information for evaluating the integrity of research used for regulatory decisions. See Consolidated Appropriations (Information (or Data) Quality) Act, § 515, Pub. L. No. 106-554, 114 Stat. 2763 (2000).

As discussed earlier, EPA's willingness to treat "all science as equal" has been flatly rejected by the scientific community.<sup>171</sup> The biomedical community's concern about potential conflicts of interest has been codified in the widespread,<sup>172</sup> although not uniformly applied,<sup>173</sup> policy of journals to require that the authors of submitted articles disclose any financial relationships and sources of influence so that editors and readers can judge whether the results reported are influenced by those financial ties.<sup>174</sup> The academic community has endorsed this commitment to independent research, as have several policy nonprofits.<sup>175</sup> It is worth noting, moreover, that the scientific community relies heavily on researchers' disclosure of conflicts of interest despite the fact that, as part of the peer review process, scientific editors and peer reviewers are far better situated to identify biased research than regulators, the public, or political officials.

EPA's laissez faire approach to research could be reformed simply by adopting conflict disclosures similar to those used by the biomedical journals.<sup>176</sup> Under such a reform, researchers and scientists providing critiques, comments, and research submitted to or used by an agency would be required to sign a conflict form

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<sup>171</sup> See *supra* Part III.C.

<sup>172</sup> See, e.g., INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS, UNIFORM REQUIREMENTS FOR MANUSCRIPTS SUBMITTED TO BIOMEDICAL JOURNALS, at <http://www.icmje.org> (last updated Nov. 2003).

<sup>173</sup> See, e.g., Sheldon Krinsky & L.S. Rothenberg, *Conflict of Interest Policies in Science and Medical Journals: Editorial Practices and Author Disclosures*, 7 SCI. & ENGINEERING ETHICS 205, 217-18 (2001) (listing survey).

<sup>174</sup> The form of conflict disclosures used by biomedical journals has grown more sophisticated over the years, and the editors of a group of the world's leading biomedical journals recently declared that they will no longer publish articles based on studies done under contracts in which the investigators did not have the unfettered right to publish the findings. In a joint statement the editors of thirteen journals asserted that contractual arrangements that allow sponsor-control of publication "not only erode the fabric of intellectual inquiry that has fostered so much high-quality clinical research but also make medical journals party to potential misrepresentation, since the published manuscript may not reveal the extent to which the authors were powerless to control the conduct of a study that bears their names." Frank Davidoff et al., *Sponsorship, Authorship and Accountability*, 286 JAMA 1232, 1233 (2001).

<sup>175</sup> With the increased involvement of universities in commercial enterprises and collaborations, many academic institutions have developed policies or guidelines that attempt to ensure this independence. The guidelines of the University of California, for example, assert that research is a component and outcome of an academic environment characterized by the free and open exchange of ideas. UNIVERSITY OF CALIFORNIA OFFICE OF THE PRESIDENT, GUIDELINES ON UNIVERSITY-INDUSTRY RELATIONS, available at <http://www.ucop.edu/ott/unindrel.html> (May 17, 1989) ("[F]reedom to publish is fundamental to the University and is a major criterion of the appropriateness of a research project."). Universities see the need to protect the independence of their research with formal policy. The Johns Hopkins University School of Public Health, for example, requires that faculty members who enter into contractual agreements for sponsored research retain full rights to publish and otherwise disclose information developed in the research. JOHNS HOPKINS SCHOOL OF PUBLIC HEALTH, OFFICE OF RESEARCH ADMINISTRATION, INTELLECTUAL PROPERTY POLICY, at <http://www.jhsph.edu/ora/IPG/nspolicy.htm#C.%20Publication> (Oct. 27, 1992).

The Center for Science in the Public Interest advocates for the voluntary disclosure of funding sources. See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, INTEGRITY IN SCIENCE, at <http://www.espinet.org/integrity> (last visited July 14, 2004).

<sup>176</sup> David Michaels & Wendy Wagner, *Disclosure in Regulatory Science*, 302 SCIENCE 2073 (2003). An industry organization, the American Chemistry Council ("ACC"), concedes that such disclosures are a positive step, Carol J. Henry et al., Letter, *Questions About Disclosures*, 304 SCIENCE 1447 (2004), while disputing that there are bias and suppression problems with most industry-sponsored research. ACC's specific disagreements are refuted in detail at Part III, *supra*.

specifying the extent of financial and sponsor influence on the research.<sup>177</sup> Researchers, for example, would be required to disclose financial and other conflicts of interest that might bias their work, and they would also be required to disclose whether they had the contractual right to publish their findings without influence and without obtaining consent of the sponsor. If their work was reviewed by a party affected by the regulation prior to publication or submission, that review would need to be disclosed as well. Sponsors would also be required to provide this disclosure for all information they submit to the agency.

By mandating disclosures, sponsors who do relinquish control over the design and reporting of their sponsored research will be rewarded for their restraint and openness.<sup>178</sup> Requiring disclosure of the extent of sponsor influence on a project thus ensures that sponsors who fund research will not be tarred with the same brush as sponsors who work closely with researchers to control the design, methods, and reporting of the results. Rewards for disinterested research, in turn, should generate incentives for doing more of it. In addition, requiring mandatory conflict of interest disclosures will benefit the public, policy-makers, and the media by making it easier for them to assess the objectivity of individual research projects, especially when a "scientific controversy" arises.<sup>179</sup> Requiring standardized disclosures even assists journal editors and fellow scientists in evaluating studies when they serve on scientific advisory boards or are otherwise involved in reviewing regulatory science.

## 2. Discourage Suppression of Research

To limit the opportunities for actors to conceal adverse information through nondisclosure contracts, EPA should clarify and strengthen its adverse reporting requirements to leave fewer ambiguities regarding the compliance requirements, at least for the TSCA reporting requirements. By providing more specific requirements for reporting under these provisions, EPA could minimize opportunities for actors to dodge or delay adverse information reporting.<sup>180</sup> The

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<sup>177</sup> See, e.g., AMERICAN MEDICAL ASSOCIATION, AUTHORSHIP CRITERIA AND RESPONSIBILITY, FINANCIAL DISCLOSURE, COPYRIGHT TRANSFER, AND ACKNOWLEDGMENT FORM, available at <http://jama.ama-assn.org/cgi/data/290/1/125/DC1/1> (last visited July 20, 2004).

<sup>178</sup> Currently, since these positive attributes of researcher independence cannot be advertised or validated, actors cannot gain reputational advantages or esteem norms from relinquishing control over research studies. Cf. George Akerloff, *The Market for 'Lemons': Qualitative Uncertainty and the Market Mechanism*, 84 Q. J. ECON. 488 (1970) (observing in general that establishing a strong reputation is one of the primary means to avoid the downward forces of adverse selection); Richard H. McAdams, *The Origin, Development, and Regulation of Norms*, 96 MICH. L. REV. 338, 369-72 (1992) (arguing that norms work only when others can observe the good behavior).

<sup>179</sup> See, e.g., Cornelia Dean, *Editing Science*, Address at the Center for Science in the Public Interest Conference on Conflicted Science (July 11, 2003) (discussing the challenges to journalists reporting the status of research accurately and "learning and reporting the financial ties of those [scientists] who make the news"). With such a reform in place, EPA could post all research conducted on any given chemical or environmental issue, along with the "objectivity" status of each of the studies, based on the extent of sponsor control over the research. See, e.g., EPA, INTEGRATED RISK INFORMATION SYSTEM, at <http://www.epa.gov/iris/> (last updated July 9, 2004) (providing risk estimates on a chemical by chemical basis, with a reference list at the end of each chemical-specific report that currently does not, but could provide information about the independence of each study). This would provide valuable information for scientists, regulators, and the public. If, for example, the only positive studies on a new pesticide registration application were conducted by the pesticide manufacturers or users, this information would help in weighing all of the information, particularly if the adverse studies were produced by parties that were free of sponsor control.

<sup>180</sup> For example, under the Clean Water Act and Comprehensive Environmental Response, Compensation, and Liability Act, reporting requirements could be revised to require the reporting of

information that is reported, moreover, could be posted on the Internet and could be searched using a variety of queries, including chemical name and manufacturer. EPA might also select the most salient and important "adverse effects" information to counteract firms' natural inclination to dilute damaging information with routine "data dumps" of all in-house toxicity studies. Finally, EPA should institute a focused enforcement campaign to increase the probability that noncompliant firms will be caught. Since the information most likely to be suppressed will be less susceptible to documentation, EPA could offer bounties and added whistleblower protections for the disclosure of this reportable information, as well as educating informants of the types of information that should legally be disclosed.

Congress could also amend the reporting requirements to make them more effective. Most of the changes would include broadening the category of persons responsible for reporting and increasing the sanctions for violation of the reporting requirements. Initially, EPA attempted to include pesticide manufacturers' agents, including research scientists, among the groups responsible for reporting under FIFRA.<sup>181</sup> EPA concluded ultimately that it lacked legislative authority to broaden the category of responsible parties,<sup>182</sup> but Congress could amend the law to explicitly include these agents.<sup>183</sup> Scientists and others, who are often contractually barred from reporting adverse effects, will then have an overriding legal obligation to report adverse effects or else risk civil and criminal personal sanctions. Congress could also impose more significant civil and criminal penalties for the failure of a firm or any person to report adverse information, perhaps by including explicit causes of action for any victims that suffered from the suppression of information. Increasing the sanctions will increase the incentives for compliance. Finally, EPA must be provided with greater resources to oversee and enforce against the suppression of research. These lapses are difficult to catch, but with greater financial resources and stronger regulatory reporting requirements, EPA officials will be able to identify more violations or at least present a credible threat to counteract some of the incentives for noncompliance.

### C. REFORMING CONFIDENTIAL BUSINESS INFORMATION

Although its reform is controverted, the existence of a problem with current CBI protections is beyond question. EPA, the General Accounting Office ("GAO"), and

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any non-de-minimis releases. Legal authority exists for EPA to make this change because Congress clearly delegates the decision about setting reportable quantities or threshold levels to the EPA. *See* Clean Water Act, 33 U.S.C. § 1321(b)(4) (2000); CERCLA, 42 U.S.C. § 9602(b) (2000).

<sup>181</sup> *See* EPA Reporting Requirements for Risk/Benefit Information, 62 Fed. Reg. 49,388 (Sept. 19, 1997) (originally defining "registrant" to include "any employee or agent of such a person; provided that any employee or agent who is not expected to perform any activities related to the development, testing, sale or registration of a pesticide, and who could not reasonably be expected to come into possession of information that is otherwise reportable under this part, shall not be considered a registrant for purposes of this part; and provided further that information possessed by an agent shall only be considered to be possessed by a registrant if the agent acquired such information while acting for the registrant").

<sup>182</sup> *See* Reporting Requirement for Risk/Benefit Information; Amendment and Correction, 62 Fed. Reg. 49,388 (Sept. 19, 1997) (codified at 40 C.F.R. pt. 159) (omitting "agents" from definition of registrants).

<sup>183</sup> TSCA appears to already have broadened the scope of responsible parties for reporting. Under TSCA, "any person who has possession of a study" is among those required to report relevant health and safety studies on a toxic substance to the EPA. 15 U.S.C. § 2607(d) (2000). A clearer definition of what constitutes a "study" and the reporting requirements could impose substantially greater demands on both researchers and sponsors.

independent research consultants have each concluded that overbroad claims for trade secrets are not legitimate, justified, or economically optimal.<sup>184</sup> A 1999 GAO report on CBI claims of health and safety information, for example, found only weak support for industry claims that the confidential information is useful to competitors and that this classified information could not otherwise be obtained by competitors.<sup>185</sup> Recent technological developments and other changes in the competitive environment further suggest that whatever legitimate benefits industry may have derived from trade secret protections in the past are rapidly becoming obsolete.<sup>186</sup>

There is a rich body of literature suggesting remedies for problems that arise at the intersection of trade secret and environmental and public health regulation. Two reform proposals offer particularly promising approaches for combating the abuse of trade secret protections.<sup>187</sup> The first option is for regulators to exempt any health and safety data or information needed to assess health risks from trade secret protection. For those actors who can demonstrate competitive losses from the disclosure of the information, a cost-sharing mechanism could be devised to provide compensation.<sup>188</sup> Under such a scheme, competitors benefiting from the disclosure would be required to reimburse the initial firm for its costs and competitive losses (modeled roughly on the data compensation schemes required for pesticide

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<sup>184</sup> See, e.g., EPA OFFICE OF POLLUTION PREVENTION AND TOXICS, FINAL ACTION PLAN: TSCA CONFIDENTIAL BUSINESS INFORMATION REFORM (June 20, 1994); HAMPSHIRE STUDY, *supra* note 61, at 41 (concluding based on review of CBI claims from 1977 through 1990 that "all available evidence supports the proposition that much of the information covered by CBI claims is not legitimately entitled to protection as TSCA CBI."); TOXIC SUBSTANCES CONTROL ACT, *supra* note 68; ENVIRONMENTAL INFORMATION, *supra* note 100.

<sup>185</sup> In the report, for example, GAO notes that "competitive intelligence professionals" and "industry representatives" disagreed on the value of environmental reporting to secure competitors' secrets. Industry representatives stated that the information "often contains valuable details about their competitors while other competitive intelligence professionals said that such information is neither sufficient or even necessary." ENVIRONMENTAL INFORMATION, *supra* note 100, at 15. GAO went on to note that "[r]egardless of their views on the usefulness of this information, industry officials acknowledged that they could do a better job in protecting their sensitive business information while still complying with EPA's and states' reporting requirements." *Id.*

In the report the GAO also provided other information that suggests industry might be inflating its claims that broad CBI protection in environmental regulation is needed to preserve their trade secrets. *Id.* First, GAO noted that in the two states that employ materials accounting, "fewer than two percent of the facilities . . . made confidentiality claims in 1996 [or thereafter]" even though both states (New Jersey and Massachusetts) have permissive CBI procedures. *Id.* at 18.

Industry itself seems to acknowledge the lack of competitor interest in the information, touting the infrequency of FOIA claims. See, e.g., Letter from Warren E. Stickle & Bill Balek to EPA, *supra* note 67 (arguing that the many thousands of products on the market few have or ever will be subject to a FOIA request and that the up-front substantiation requirement would be a waste of registrants' resources as well as harmful for the chemical manufacturers).

<sup>186</sup> See, e.g., O'Reilly, *supra* note 66, at 10203 (discussing the "obsolescence of industry's fixation on the physical security of regulatory submissions containing their chemical data" in the wake of the information age).

<sup>187</sup> See, e.g., Lyndon, *supra* note 67, at 50-55 (proposing multiple alternatives to trade secrets with varying levels of protection of an industry's competitive advantages); McGarity & Shapiro, *supra* note 97, at 882-87 (recommending exclusive-use periods for health and safety data that has trade-secret value, but requiring full disclosure); O'Reilly, *supra* note 66, at 10208-211 (proposing a narrower trade-secret protection for protecting information and more effective mechanisms for sharing information with the public); see also TOXIC SUBSTANCES CONTROL ACT, *supra* note 68, at 5:6 (suggesting specific TSCA legislative changes to reduce the problem of overbroad CBI protections).

<sup>188</sup> See, e.g., McGarity & Shapiro, *supra* note 97, at 880-81 (stating that although FIFRA does not suggest a cost apportioning method, TSCA directs the Administrator to consider various factors).

manufacturers under FIFRA).<sup>189</sup> Congress could also lengthen the time for reimbursement for data compensation under FIFRA.<sup>190</sup> In cases where the beneficiaries of the safety information are diffuse, public funds would provide the reimbursement. Prior to implementing such a reform, it would be advisable to conduct a follow-up to the GAO's 1999 study to better isolate areas where competitive harm is most likely and develop approaches that directly address those potential harms.<sup>191</sup> It is also important to explore the extent to which trade secret protections for chemical identity impair the use of health and safety research on that chemical by scientists and public health officials, a subject not addressed in any of the confidential business reports published to date.

A second, and more cumbersome, approach proposed by the EPA is to require firms to provide up-front substantiation for their CBI claims.<sup>192</sup> Although firms object to up-front substantiation as unduly burdensome, the requirement is used in some statutory programs such as EPCRA and has resulted in substantially fewer CBI claims.<sup>193</sup>

Finally, EPA could institute regulatory processes that provide oversight of the quality of manufacturer research, like random replication of the studies, and charge the costs through to all manufacturers as an administrative cost of claiming trade secret protection. Each CBI claim could be charged a review and classification fee that reflects the higher costs associated with securing the information and reviewing the claim.<sup>194</sup> EPA could also levy penalties for CBI claims found to be unjustified based either on an internal agency review or a review conducted following a FOIA request.<sup>195</sup> Such sanctions seem reasonable, especially in light of the significant penalties that can be levied against EPA officials who release trade secret-protected

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<sup>189</sup> Under FIFRA, subsequent manufacturers that benefit from data submitted previously by another manufacturer must compensate that manufacturer for part of the development costs if their application occurs within ten (plus) years after the original data production. See 7 U.S.C. § 136a(c)(1)(F) (2000) (providing original applicant a right to "exclusive data use" for registration of pesticides after 1978). The constitutionality of this provision has been upheld by the Supreme Court, including the use of binding arbitration to determine the amount of compensation. See *Thomas v. Union Carbide*, 473 U.S. 568 (1985); *Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984). Under the right circumstances, manufacturers may be able to copyright their studies. See, e.g., 17 U.S.C. § 102(a) (2000) (providing non-exclusive list of works meriting copyright protections, thereby allowing the copyright of studies in limited circumstances). But since the results of the study can be used by a regulator without having to pay copyright royalties (assuming that the manufacturer shares the study with an agency), then other manufacturers are still able to free-ride on the regulatory benefits of the information.

<sup>190</sup> The statutory time frame under FIFRA is ten years, which might not provide adequate time to ensure fair reimbursement for the originators of health and safety research. 7 U.S.C. § 136a(c)(1)(F) (2000).

<sup>191</sup> See, e.g., Lyndon, *supra* note 67, at 54 (discussing use of environmental patents to provide firms with mechanisms for seeking compensation for disclosure of competitively valuable information); McGarity & Shapiro, *supra* note 97, at 882-87 (recommending full disclosure, but allowing firms to claim "exclusive use").

<sup>192</sup> EPA underscores this in its 2000 effort at CBI reform. 65 Fed. Reg. 80,394, 80,395 (Dec. 21, 2000) (discussing proposal for up-front substantiation of CBI claims and stating that "[w]e believe this would help reduce the number of overly-broad or non-specific claims"); see also HAMPSHIRE STUDY, *supra* note 61, at 39-40 (recommending up-front substantiation and also sunset periods on CBI claims).

<sup>193</sup> See, e.g., HAMPSHIRE STUDY, *supra* note 61 at 39-40.

<sup>194</sup> See, e.g., *id.* at 26, 40 (discussing the direct and indirect out-of-pocket costs of CBI claims and recommending a filing fee for each CBI claim).

<sup>195</sup> See also *id.* at 38-39.

information without justification.<sup>196</sup> CBI claims could be tallied, much like EPA's Toxics Release Inventory Program data, to reveal the number and nature of CBI claims each industry files.<sup>197</sup> This may produce some accountability for the claims, and lead insurers, investors, and the public at large to decide how to evaluate specific industries in light of the secrecy related to the health risks that might be presented by their activities.

#### D. FINAL OBSERVATIONS

Ultimately, it might be preferable for all research to be done under the supervision of the EPA or state governments, with the costs charged back to the manufacturers.<sup>198</sup> Research required for regulation might be more expensive when done by the agency, but it will provide less risk of conflicts and a greater assurance of both consistency and reliability. Whether such a dramatic move is appropriate will depend on the extent of problems with private research and the cost increases that would result from EPA overseeing or conducting the research through its own facilities and contractors. To be effective, however, the research would need to be done in a "double-blind" fashion so that the manufacturer or regulated party has no way to trace the researcher or visa versa. Such a public research initiative would still require some protections for CBI and data compensation.

#### V. CONCLUSION

Private research produced by regulated parties under the pressure of future regulation is at significantly greater risk of underreporting harms than corresponding publicly sponsored research. Use of this compromised research for regulation could lead to protections that are not adequate to protect health and the environment. Yet despite these inherent problems with some sponsored science, current regulatory approaches continue to treat private research gingerly, often immunizing it from any external scrutiny at the behest of the regulated party. Even publicly accessible private research is not subjected to the quality control that applies to public research. In this Article, we argue that the playing field for these two types of regulatory research should be leveled. Private research should be subject to at least the same controls as public research. At the same time, other deficiencies specific to private research, such as sponsor-induced bias and suppression of adverse results, should be counteracted through more rigorous regulatory oversight.

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<sup>196</sup> 42 U.S.C. § 11042(c) (2000) (prescribing regulations "equivalent to comparable provisions in the Occupational Safety and Health Administration Hazard Communication Standard").

<sup>197</sup> See also HAMPSHIRE STUDY, *supra* note 61, at 39 (recommending report cards "indicating for each submitter the number of submissions, the number of CBI claims, and perhaps the number of challenges issued on these claims").

<sup>198</sup> An alternative approach would be the certification of private laboratories, with periodic quality audits, to ensure greater research independence from manufacturer and researcher. *Cf.* Shapiro & Charrow, *supra* note 18, at 2510 (suggesting similar certification requirements to reduce conflicts occurring in FDA required biomedical research).

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