

OPEN SECRETS: THE WIDESPREAD AVAILABILITY OF INFORMATION ABOUT THE HEALTH AND ENVIRONMENTAL EFFECTS OF CHEMICALS

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I

INTRODUCTION

The point of departure for this symposium¹ was the asserted conflict between (1) “the principles and practice of open science” and (2) “laws and policies that restrict access to results and ideas,” whether for reasons of individual privacy, national security, or the economic benefits derived from information.² The symposium proposal placed special emphasis on circumstances in either the regulatory or judicial arenas in which access to information relevant to protecting public health or safety may be restricted in order to prevent “financial harm to private parties.”³

This article represents the perspective of the chemical industry on these issues.⁴ For reasons of space and time, it focuses primarily on the regulatory

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1. The symposium was sponsored by the Project on Scientific Knowledge and Public Policy (SKAPP), based at the George Washington University School of Public Health and Health Science. The articles are derived from papers presented at SKAPP's 2004 Coronado Conference II: “Sequestered Science: The Consequences of Undisclosed Knowledge.” See Project on Scientific Knowledge and Public Policy, Coronado Conference Papers, http://www.defendingscience.org/coronado_conference_papers/Coronado-Conference-Papers.cfm (last visited June 6, 2006) (providing information about SKAPP and the Coronado conferences, and promising to publish forthcoming papers from the conference online); see also discussion *infra* Part IV. This article was solicited after the conference.

2. David Michaels and Neil Vidmar, Sequestered Science: The Consequences of Undisclosed Knowledge (Oct. 19, 2004) (unpublished symposium proposal, on file with Law & Contemporary Problems).

3. *Id.*

4. Another article in this issue conveys the perspective of the pharmaceutical industry in the regulatory setting, so this article does not discuss that aspect. See Scott M. Lassman, *Transparency and Innuendo: An Alternative to Reactive Over-Disclosure*, 69 LAW & CONTEMP. PROBS. 69 (Summer 2006).

system. In short, it contends that this symposium's premise—that economic considerations result in concealment by industry of health or safety data—is faulty, especially as regards toxicological data on health or the environment in the regulatory arena.

Part II of the article addresses when and how access to health effects information may be affected by financial interests. (It does not consider individual privacy or national security because far less conflict is apparent in those cases.)⁵ Part II begins by discussing the numerous federal laws that (1) require information regarding the hazards of chemicals to be reported to the U.S. Environmental Protection Agency (EPA) or otherwise to be made public, or (2) enable EPA to gather or require the creation of this information. These laws generally do not allow public access to the information to be restricted based on commercial considerations. Other federal statutes create significant disincentives to nondisclosure, as do the potentially ruinous consequences of civil liability. In addition, the chemical industry is voluntarily generating and releasing an enormous volume of information relevant to chemical risk assessment—both chemical-specific hazard data and more general methodological research.

Part III argues that no qualitative distinction can be drawn between the financial and other incentives that might affect disclosure by for-profit entities and the incentives that might affect disclosure by other entities that may conduct, sponsor, or opine on scientific research.

Turning briefly to the judicial arena, Part IV explores some of the implications for open (and meritorious) science arising from lawyers' being not only advocates, but also for-profit entities.

II

THE GREAT EXTENT TO WHICH CHEMICAL HAZARD INFORMATION IS ALREADY PUBLIC

Numerous mechanisms already exist to ensure the disclosure of information about chemical hazards to the public: Some federal laws drive the disclosure of information regarding hazards that chemicals may pose to health or the environment. Other federal laws and the tort law system create substantial liabilities for entities that conceal chemical hazard information. And several major voluntary initiatives of the global chemical industry are making vast quantities of information about chemicals available to the public.

5. The author is unaware of controversy over restrictions on access to health or safety information premised on privacy reasons. Some debate has emerged about whether and how the government might use concepts like "for official use only" and "sensitive but unclassified" to restrict access to government-funded research. See Leslie Jacobs, *A Troubling Equation in Contracts for Government Funded Scientific Research: "Sensitive But Unclassified" = Secret But Unconstitutional*, 1 J. NAT'L SECURITY L. & POL'Y 113, 113–17 (2005) (discussing how secrecy clauses and government-contracted research by private scientists connect to influence the content and flow of scientific information, and under what circumstances the use of such clauses is constitutional in view of the First Amendment).

A. Federal Statutes Requiring Disclosure

1. The Toxic Substances Control Act (TSCA)⁶

a. The TSCA regulatory regime. Any discussion of chemical hazard regulation must begin with TSCA, which comprehensively governs the subject.⁷ Section 5 of TSCA requires manufacturers and importers to notify EPA⁸ prior to bringing any newly developed chemicals to market.⁹ Such a “premanufacture notice” (PMN) must include available test data on the chemical.¹⁰ Under section 4 of TSCA, EPA has broad power to issue rules ordering persons manufacturing, processing, or importing a chemical to conduct further tests regarding the chemical’s effects on health or the environment whenever EPA has insufficient data to determine or predict those effects and certain risk or exposure criteria are met.¹¹ EPA frequently works out enforceable consent agreements with these parties to perform such tests.

For any test that EPA requires, or for test results to be considered as part of a voluntary submission to EPA, the tests must be conducted following EPA guidelines for test protocols designed or approved by EPA to ensure that those results will provide reproducible, reliable, and relevant information suitable for regulatory decisionmaking.¹² These protocols are part of the EPA Good Laboratory Practice Standards (GLP Standards), which, among other things,

6. 15 U.S.C. § § 2601–2692 (2000).

7. *See id.* “[TSCA] covers all chemicals planned for production, manufactured in, imported to, or exported from the United States.” U.S. ENVTL. PROTECTION AGENCY, OVERVIEW: OFFICE OF POLLUTION PREVENTION AND TOXICS PROGRAMS 2 (Draft Version 2.0, 2003), <http://www.epa.gov/opptintr/oppt101c2.pdf> [hereinafter EPA OVERVIEW]. The only “[s]ubstances not covered under TSCA are pesticides; tobacco (or tobacco products); firearms and ammunition; source material by-products or special nuclear material defined by the Atomic Energy Act; and food, food additives, drugs, or cosmetics covered under the Federal Food, Drug and Cosmetic Act.” *Id.* at 2 n.3.

8. The EPA program office tasked with implementing TSCA is called the Office of Pollution, Prevention and Toxics, sometimes referred to as “OPPT.” EPA OVERVIEW, *supra* note 7, at 1. For simplicity, this article refers to EPA as a whole.

9. 15 U.S.C. § 2604(a). “When TSCA was passed in 1976, it was not known how many chemicals were in commerce in the U.S., in what quantities or where they were produced and/or imported.” EPA OVERVIEW, *supra* note 7, at 2. TSCA therefore required persons manufacturing, importing or processing chemicals to notify EPA. *Id.* at 5. This resulted in the initial TSCA Chemical Substance Inventory of “existing” chemicals in 1979. *Id.* at 5–6. As persons notify EPA of “new” chemicals they propose to manufacture or import, these are added to the inventory. *Id.*

10. 15 U.S.C. § 2604(d)(1). “Test data” is defined broadly to include data that is “related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health of the environment.” *Id.* § 2604(d)(1)(B). As a result of the PMN requirement, EPA has reviewed every new chemical prior to its commercialization, or a total of about 36,600 PMNs from 1979 through 2003. EPA OVERVIEW, *supra* note 7, at 8–10. Only about half of such new chemicals were ever commercialized. *Id.* at 11. About ten percent of PMNs reviewed between 1979 through 2003 have resulted in EPA requiring testing or submission of additional information, agreements by companies to limit the uses of production volume of a chemical, restrictions on uses of a chemical, or withdrawal of the submission. *Id.* at 9–11.

11. *Id.* § 2603(a).

12. *See* 40 C.F.R. § 792.120 (2004) (listing fifteen nonexclusive guidelines and requiring that any variation from the guidelines be documented and explained).

require that EPA have access to complete, quality-assured data sets documenting that experimenters (1) adhered to the experimental protocol employed, (2) took all of the steps and measurements claimed to have been taken during the study, and (3) accurately reported the test results.¹³

Beyond tests that EPA may require, TSCA section 8(d) authorizes EPA to compel, by rule, manufacturers and importers of a given chemical to submit lists and copies of unpublished health and safety studies for the chemical.¹⁴ Such reporting can be required of any company that made or imported the chemical in the ten years before the effective date of the EPA rule¹⁵ and extends for a period of sixty days following publication of the rule.¹⁶

Since TSCA was enacted in 1976, EPA has used its legislative authority to require (1) testing on approximately two hundred chemicals, (2) reporting of specific information for approximately eleven hundred chemicals, and (3) submission of health and safety studies for approximately one thousand chemicals. These mandates have resulted in “more than 50,000 studies covering a broad range of health and ecological endpoints.”¹⁷ These information collection activities continue: in early 2005, EPA announced plans to issue rules requiring health effects data for high production volume chemicals not “adopted” as part of the High Production Volume Challenge Program, which is discussed below.¹⁸

Finally, TSCA includes two important provisions regarding observed adverse effects in humans or the environment. First, TSCA section 8(c) requires persons manufacturing, importing, processing, or distributing a

13. *Id.* Part 792. See also William L. Anderson et al., *Daubert's Backwash: Litigation-Generated Science*, 34 U. MICH. J. L. REFORM 619, 632–33, 675 (2001) (noting that “[GLP Standards] offer evidence that the study was rigorously conducted” for both regulatory review and purposes of litigation). Anderson et al. wrote:

Laboratories performing work for regulatory purposes . . . are required to conform to strict laboratory protocols The regulators will reject studies that do not meet these criteria Because of the financial implications of poorly documented studies, company laboratories are generally careful about the [Good Laboratory Practice] quality of their work.

Id. at 632–33.

14. 15 U.S.C. § 2607(d).

15. 40 C.F.R. § 716.5(a)(1) (2004).

16. 40 C.F.R. § 716.65 (2004). The reporting period after the rule is published may be extended, but in no event may it exceed two years. *Id.* See also 40 C.F.R. § 716.120 (2004) (listing chemicals for which reporting is required, including the effective date of such requirement).

17. EPA OVERVIEW, *supra* note 7, at 17. To put these numbers into context, only 9000 organic chemicals were reported as being produced or imported in annual quantities of 10,000 pounds or more when the TSCA inventory of chemicals was updated in 2002. *Id.* at 14 n.9; see also U.S. Env'tl. Protection Agency, Inventory Update Rule, <http://www.epa.gov/opptintr/iur/tools/iur02/index.htm> (last visited Apr. 17, 2006) (providing certain information on chemicals updated every two years). EPA estimates that today there could be as many as 6000 additional chemicals currently in commerce, a figure that presumably includes inorganic chemicals and chemicals produced or imported in quantities less than 10,000 pounds. EPA OVERVIEW, *supra* note 7, at 14 n.9.

18. See discussion *infra* Part II.C.1; see also U.S. ENVTL. PROTECTION AGENCY, POLICY REGARDING ACCEPTANCE OF NEW COMMITMENTS TO THE HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM 1–3 (June 2005), <http://www.epa.gov/chemrtk/hpvpolcy.pdf> (providing an overview of the program).

chemical to maintain records of significant adverse reactions for five years (thirty years, in the case of reactions among employees) and to make this information available to EPA upon request.¹⁹ Second, TSCA section 8(e) requires the same persons to “immediately inform” EPA of any “information which reasonably supports the conclusion that [a chemical] presents a substantial risk of injury to health or the environment,” unless the person has “actual knowledge that [EPA] has been adequately informed of such information.”²⁰

Section 8(e) has generated a tremendous volume of reporting. Since 1977, when such reporting began, EPA has received over 15,500 section 8(e) submissions, not including any follow-up information requested.²¹ Although questionable in the view of many, the recent high-profile EPA administrative enforcement case against DuPont regarding a chemical used in manufacturing the nonstick surface Teflon® has certainly generated renewed attention to section 8(e) requirements.²² Law firms have warned clients that additional section 8(e) enforcement cases may be initiated,²³ and the convening of a grand jury to examine possible criminal violations in the DuPont case—an even more dubious claim—has also attracted wide attention.²⁴

19. 15 U.S.C. § 2607(c) (2000). Records to be maintained include “records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source.” *Id.*

20. *Id.* § 2607(e).

21. U.S. Env'tl. Protection Agency, Substantial Risk Information: TSCA Section 8(e), <http://www.epa.gov/oppt/itc/pubs/sect8e.htm> (last visited Apr. 17, 2006). Section 8(e) submissions are publicly available at U.S. Env'tl. Protection Agency, Chemical Testing Overview, <http://www.epa.gov/opptintr/chemtest/view.htm> (last visited Apr. 17, 2006).

22. EPA alleged that in 1981 DuPont failed to report the results of a blood test showing that trace amounts of perfluorooctanoic acid from drinking water may cross from a mother's blood through the placenta to a fetus. Answer and Request for Hearing at 1-3, *In re Matter of E.I. du Pont de Nemours and Co.*, Nos. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016 (filed Aug. 11, 2004), available at http://www2.dupont.com/PFOA/en_US/pdf/answer_and_request_for_hearing.pdf. DuPont and others believe that this information, in and of itself, does not demonstrate a “substantial risk.” See Press Release, I.E. du Pont de Nemours and Co., Dupont Responds to EPA Complaint on Alleged PFOA Reporting Violations, (Aug. 12, 2004), <http://www.dupont.com/> (follow “Media Center” hyperlink; follow “News Releases” hyperlink; then follow “2005 Archives” hyperlink)(explaining the company response to three EPA claims). For the resolution of this administrative case via settlement, see generally Juliet Eilperin, *DuPont, EPA Settle Chemical Complaint*, WASHINGTON POST, Dec. 15, 2005, at D3 (reporting DuPont paid a multimillion dollar administrative penalty without any admission that it deliberately withheld information from EPA).

23. See, e.g., Latham & Watkins Env't, Land and Resources Dep't, *EPA Steps Up Enforcement of TSCA Section 8(e) “Substantial Risk” Reporting Requirements*, CLIENT ALERT 3, Apr. 11, 2005, http://www.lw.com/resource/Publications/_pdf/pub1236_1.pdf (last visited Apr. 17 2006) (suggesting that advances making it more feasible to collect biomonitoring data, such as measuring trace amounts of chemicals in the human body, will raise additional questions about when TSCA section 8(e) reporting obligations arise).

24. Press release, I.E. du Pont de Nemours and Co., DuPont Receives Department of Justice Subpoena for Information on PFOA (May 19, 2005), <http://www.dupont.com/> (follow “Media Center” hyperlink; follow “News Releases” hyperlink; then follow “2005 Archives” hyperlink). The company announced that the Environmental Crimes Section of the Environment and Natural Resources Division of the U.S. Department of Justice served the company with a grand jury subpoena from the U.S. District Court for the District of Columbia in connection with three named chemicals. *Id.* Given

There is inherent uncertainty about exactly what the phrase “substantial risk of injury to health or the environment” means in any given context, especially in the case of environmental data.²⁵ Given the substantial penalties for noncompliance, it is likely that the ambiguity of the requirement has actually encouraged over-reporting. Equally important, the difficulty experienced by EPA and companies in determining what constitutes a reportable “substantial risk of injury to health” illustrates the profound challenge of attempting to put into narrative form a single, agreed-upon standard for when health effects or other risk data are so significant that EPA should be made aware of it. Any alternative formulation is bound to face the same challenge. In fact, as the *DuPont* case shows, a summary and general standard such as that in section 8(e) has the virtue—or vice, depending upon one’s perspective—of sliding readily to become a very low threshold for disclosure.

b. Public disclosure under TSCA. As can be seen, EPA’s implementation of TSCA has resulted in the submission of huge amounts of chemical hazard information to EPA. TSCA does not provide business confidentiality protection to health and safety studies of any chemical that has been offered for commercial distribution and that is the subject of a PMN or a 4 test rule, nor to any data reported to or otherwise obtained by EPA regarding such a chemical.²⁶ The phrase “health and safety study,” moreover, is expressly defined “broadly” in corresponding EPA regulations, which further inhibits confidentiality claims.²⁷

Under some circumstances, TSCA does allow submissions of other information, such as precise production volume, producer identity, and chemical uses, to be claimed confidential for legitimate reasons.²⁸ However,

the uncertainty regarding whether the facts in this case presented a “substantial risk,” it seems a stretch to argue that DuPont knowingly failed to report a substantial risk.

25. Questions regarding what is reportable under section 8(e) led EPA to initiate a one-time, voluntary Compliance Audit Program (CAP) under which companies could submit information that arguably should previously have been submitted under section 8(e) and pay stipulated penalties of up to \$1,000,000. See U.S. Env’tl. Protection Agency, Registration and Agreement for TSCA Section 8(e) Compliance Audit Program, 56 Fed. Reg. 4128 (Feb. 1, 1991). EPA spent from 1991 to 2003 reconsidering what sorts of environmental data were reportable under section 8(e). See U.S. Env’tl. Protection Agency, Notice: Registration and Agreement for TSCA Section 8(e) Compliance Audit Program Modification, 56 Fed. Reg. 28458, 28459 (June 20, 1991) (extending the time to file under the CAP and providing for further clarification of reporting environmental data under section 8(e)); U.S. Env’tl. Protection Agency, Notice: TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33129, 33130 (June 2, 2003) (revising and clarifying provisions of the TSCA section 8(e) policy statement issued in 1978; all guidance is now in the current document, obviating the need to refer back to older documents).

26. 15 U.S.C. § 2613(b)(1)(2000).

27. See 40 C.F.R. § 716.3 (2004) (defining “health and safety study” and providing applicable examples). In particular, “[a]ny data that bear on the effects of a chemical substance on health or the environment would be included. Chemical identity is part of, or underlying data to, a health and safety study.” *Id.* § 716.3(1). EPA PMN rules use a different but comparable definition. See 40 C.F.R. § 720.3(k) (2004).

28. 15 U.S.C. § 2613(a)–(b) (2000). Such business information can be highly valuable to competitors, as evidenced by the fact that most Freedom of Information Act requests come from

even this information must—not may—be disclosed by the agency “if necessary to protect health or the environment against an unreasonable risk of injury.”²⁹

As exemplified by the DuPont case, TSCA contains civil and criminal penalties for violations of its provisions.³⁰ Also, the U.S. criminal code establishes substantial penalties for false statements.³¹

In summary, TSCA alone assures that a vast universe of chemical hazard information is, or can be required to be, provided to EPA and cannot be kept secret for financial reasons.

2. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)³²

Pesticides are regulated under FIFRA.³³ Any potential pesticide chemical must undergo more than one hundred scientific tests addressing chemistry, health effects, environmental effects, and residue chemistry to determine whether it can be used safely.³⁴ Only after the information has undergone a thorough and rigorous review by EPA can the product be “registered” by EPA for use to protect crops or public health.³⁵ According to an industry trade association, on average, only one in 139,000 potential pesticide products ever makes it from discovery to eventual commercial use.³⁶ Registered pesticides have to be reregistered unless EPA concludes that no outstanding data requirements remain and the pesticide meets all registration requirements.³⁷

FIFRA requirements regarding the conduct of testing, the reportability of adverse effect data, and the public availability of test and other risk-related data, generally track those of TSCA:

- (1) Pesticide tests must use EPA-approved test protocols and follow GLP Standards.³⁸

businesses or agents for undisclosed companies. See Heritage Foundation Center for Media & Public Policy, Special Report: Few Journalists Use the Federal Freedom of Information Act, <http://www.heritage.org/Press/MediaCenter/FOIA.cfm> (last visited Apr. 17, 2005) (reporting a study of such requests during the first half of 2001). See also discussion *infra* Part III.4.

29. 15 U.S.C. § 2613(a)(3) (2000).

30. *Id.* §§ 2615(a)–(b). See *supra* notes 22, 24 (discussing the civil and criminal aspects of the DuPont case).

31. See the False Identification Crime Control Act, 18 U.S.C. § 1001(a) (2004) (allowing for fines and imprisonment up to five years for intentional fraud or misrepresentation).

32. 7 U.S.C. §§ 136–136y (2000).

33. See *id.*

34. See U.S. Env'tl. Protection Agency, Pesticides: Regulating Pesticides, <http://www.epa.gov/pesticides/regulating/index.htm> (last visited on Apr. 17, 2006) (describing EPA pesticide regulation). The regulatory tests are described in greater detail at U.S. Env'tl. Protection Agency, Pesticides: Regulating Pesticides Data Requirements, <http://www.epa.gov/pesticides/regulating/data.htm> (last visited on Apr. 17, 2006).

35. 7 U.S.C. § 136a (2000).

36. See Crop Life America, Learn More About... Pesticide Regulation, http://www.croplifeamerica.org/learn_more/pesticide_reg.htm (last visited Apr. 17, 2006) (summarizing briefly pesticide regulation).

37. 7 U.S.C. § 136a-1(a) (2000).

38. See 40 C.F.R. § 160.120 (2004) (setting forth GLP Standards). See also discussion *supra* Part II.A.1.

(2) FIFRA Section 6(a)(2) requires pesticide registrants to submit to EPA any “factual information regarding unreasonable adverse effects on the environment of the pesticide.”³⁹ “Environment” includes humans.⁴⁰

(3) FIFRA requires EPA to make publicly available, notwithstanding any claim of business confidentiality,

the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment⁴¹

Under FIFRA, confidential information regarding “manufacturing or quality control processes” and certain information regarding inert pesticide ingredients can be released if EPA (or a court) determines that “disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.”⁴²

Confidential information regarding “production, distribution, sale or inventories of a pesticide” can be released if EPA (or a court) determines that, on balance, such disclosure is “necessary in the public interest” in connection with a public proceeding to determine whether a pesticide or one of its ingredients causes “unreasonable adverse effects.”⁴³ Thus, as with chemicals generally, information about pesticide hazards generally is publicly available without regard to its financial consequences for the registrant.⁴⁴

3. Material Safety Data Sheets (MSDSs)

Under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard, a chemical manufacturer or importer is required to develop (or obtain) an MSDS for each hazardous chemical it produces or imports.⁴⁵ MSDSs must be provided to distributors of such hazardous chemicals and to employers whenever those chemicals are used in the workplace;

39. 7 U.S.C. § 136d(a)(2) (2000) (requiring submission of such adverse effects information “at any time” after the pesticide is registered). EPA has issued a class determination under the Freedom of Information Act that adverse effects information is categorically not protected as confidential business information. See U.S. Env'tl. Protection Agency, Notice: Disclosure of Information Obtained Regarding Unreasonable Adverse Effects of Pesticides on the Environment; Class Determination, 64 Fed. Reg. 70019 (Dec. 1, 1999) (denying confidentiality to safety and efficacy information both currently in EPA possession or later acquired).

40. 7 U.S.C. § 136(j) (2000). “Environment” is defined to include “water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.” *Id.*

41. *Id.* § 136h(d)(1).

42. *Id.* § 136h(d)(1)–(d)(3).

43. *Id.* § 136h(d)(2)–(d)(3).

44. Under FIFRA Section 3(c)(1)(F), prospective registrants relying on another registrant’s data may be required to pay the original registrant to use that data. See 7 U.S.C. § 136a(c)(1)(F) (“The terms and amount of compensation may be fixed by agreement . . . [or] binding arbitration . . .”).

45. 29 C.F.R. § 1910.1200(g)(1) (2003).

employers in turn must make MSDSs readily available to workers.⁴⁶ An MSDS must identify the chemical and its hazardous ingredients (if it is a mixture) and must also list, among other things, the following:

- (1) Physical and chemical characteristics (for example, flash point),
- (2) Physical hazards (for example, potential for fire, explosion, and reactivity),
- (3) Health hazards (“including signs and symptoms of exposure, and any medical conditions . . . generally recognized as being aggravated by exposure to the chemical”),
- (4) Recognized or recommended exposure limits, and
- (5) Whether the hazardous chemical may cause cancer in the view of certain organizations.⁴⁷

The MSDS must “accurately [reflect] the scientific evidence used in making the hazard determination,” and the preparer must revise it within three months of becoming aware of “any significant new information regarding the hazards of a chemical, or ways to protect against the hazards.” MSDSs must be made readily available to OSHA and relevant unions upon request.⁴⁸

Under the Emergency Planning and Community Right-to-Know Act (EPCRA), every workplace that maintains one or more MSDSs for a chemical present on-site in an amount above a certain threshold (generally ten thousand pounds) must supply copies or a list of MSDSs to the State Emergency Response Commission, the Local Emergency Planning Committee (LEPC), and the local fire department.⁴⁹ LEPCs must in turn make these MSDSs available to the public upon request.⁵⁰

The only information that can be withheld from an MSDS on the basis of trade secrecy is the specific chemical identity, and even then, only when the properties and effects of the hazardous chemical are disclosed and the specific chemical identity is made available to health professionals, employees, and relevant unions pursuant to procedures and conditions spelled out in the OSHA rules.⁵¹

4. Limitations Imposed by Other Environmental Laws on the Ability to Claim Risk Information as Confidential

The Freedom of Information Act (FOIA) allows federal agencies to withhold from public disclosure “trade secrets and commercial or financial

46. *Id.* § 1910.1200(b).

47. *See* the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11021(a) (2000) (setting forth the basic requirements for submitting MSDSs or lists); *see also* 29 C.F.R. § 1910.1200(g) (detailing the contents of an MSDS).

48. 29 C.F.R. § 1910.1200(g)(11).

49. 42 U.S.C. § 11021(a)(1); 40 C.F.R. § 370.21 (2004). *See generally* 40 C.F.R. § 370.20 (2004) (discussing various threshold requirements triggering the obligation to make an MSDS available to certain parties).

50. 42 U.S.C. § 11021(c)(2).

51. 29 C.F.R. §§ 1910.1200(g)(i), 1200(i).

information [that is] privileged or confidential,”⁵² customarily referred to as “confidential business information” or “CBI.” The Trade Secrets Act makes disclosure of “trade secrets”—interpreted by courts to be coextensive with the CBI protected by FOIA—a crime.⁵³ As noted above, although both TSCA and FIFRA provide for the protection of CBI, they generally do not allow CBI claims to be made regarding health or environmental hazard data.⁵⁴ Most other environmental statutes require all records, reports, and other information obtained by EPA in the course of implementing the laws to be made publicly available unless the information is covered by the Trade Secrets Act,⁵⁵ and several exclude important risk data from trade-secret coverage. For example,

- (1) EPCRA protects only specific chemical identities, so long as several restrictive conditions can be met; even then, however, information regarding the adverse effects of such chemicals must be made available to any person requesting that information.⁵⁶
- (2) The Comprehensive Environmental Response, Compensation, and Liability Act, or “Superfund,” requires the release of names of chemical substances, their physical properties, and hazards posed to health and the environment, “including physical hazards (such as an explosion) and potential acute and chronic health hazards,” potential routes of human exposure, and monitoring data pertaining to disposal activities.⁵⁷
- (3) The Clean Air Act requires “emission data” to be made public.⁵⁸
- (4) The Clean Water Act requires “effluent data” to be made public.⁵⁹

52. 5 U.S.C. § 552(b)(4) (2000).

53. See 18 U.S.C. § 1905 (2000) (regarding disclosure of confidential information). See also generally U.S. DEPARTMENT OF JUSTICE OFFICE OF INFORMATION AND PRIVACY, FREEDOM OF INFORMATION ACT GUIDE (May 2004), <http://www.usdoj.gov/oip/foi-act.htm> (discussing cases and Department of Justice policy on coextensive definitions of trade secrets).

54. See discussion *supra* Part II.A.1.b, Part II.A.2.

55. See, e.g., Clean Water Act, 33 U.S.C. § 1318(b) (2000); Resource Conservation and Recovery Act, 42 U.S.C. § 6927(b)(1) (2000); Clean Air Act, 42 U.S.C. § 7414(c) (2000); Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. § 9604(e)(7)(2000); Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11042(f) (2000).

56. 42 U.S.C. § 11042(a), 11042(h) (2000). For example, information claimed as a “trade secret” must meet four factors, including chemical identity not being “readily discoverable through reverse engineering.” *Id.* at § 11042(b)(4).

57. *Id.* § 9604(e)(7)(F).

58. *Id.* § 7414(c). EPA rules define “emission data” to include “[i]nformation necessary to determine the identity, amount, frequency, concentration, or other characteristics (to the extent related to air quality) of any emission which has been emitted by the source” 40 C.F.R. § 2.301(a)(2)(i)(A) (2004).

59. 33 U.S.C. § 1318(b) (2000). EPA rules define “effluent data” to include “[i]nformation necessary to determine the identity, amount, frequency, concentration, temperature, or other characteristics (to the extent related to water quality) of any pollutant which has been discharged by the source” 40 C.F.R. § 2.302(a)(2)(i)(A) (2004).

5. Securities Laws

A public company's possession or control of health or safety risk information that could cause financial harm to the company if disclosed could well be reportable under Securities and Exchange Commission (SEC) Regulation S-K, requiring disclosure of "known trends or uncertainties that have had or that the registrant reasonably expects will have a material . . . unfavorable impact" on company operations.⁶⁰ The requirements of the Sarbanes-Oxley Act that corporate chief executive officers and chief financial officers certify the completeness of company financial reports filed with the SEC,⁶¹ and the significant criminal penalties for false certifications,⁶² further reduce the chance that senior management would accede to the suppression of such information.

B. Legal Disincentives to Concealment

All the foregoing legal authorities that require disclosure of health and safety information to an agency or the public also function to discourage nondisclosure because of the potential for civil or criminal liability for noncompliance. Several other federal laws also serve as a substantial disincentive to concealing such information, as does state tort law.

1. Whistleblower Protections

Virtually all major federal environmental statutes contain "employee protection" provisions that prevent a private employer from firing or otherwise discriminating against an employee in retaliation for whistleblower actions.⁶³ In general, these protected actions include commencing, testifying in, or "assist[ing] or participat[ing] . . . in any manner," in an enforcement action "or any other action to carry out the purposes of" the law—or being about to do any of these things.⁶⁴ Beyond reinstatement and back pay, remedies available in whistleblower proceedings (conducted by the Secretary of Labor) typically include compensatory damages and attorneys' fees.⁶⁵ Thus, employees are federally protected if they blow the whistle on a company that has violated a law by not reporting chemical risk information. Perhaps more importantly, company managers thinking of not disclosing such information would have to be concerned that a disgruntled employee who believes he or she might be fired or disciplined for some unrelated matter may decide to reveal their

60. 17 C.F.R. § 229.303(a)(3)(ii) (2005).

61. 18 U.S.C.S. § 1350(a), (b) (2000).

62. *Id.* § 1350(c). Penalties for willful violation can reach a maximum of \$5,000,000 and imprisonment for twenty years, or both. *Id.*

63. *See, e.g.*, Clean Water Act, 33 U.S.C. § 1367(a) (2000); Resource Conservation and Recovery Act, 42 U.S.C. § 6971(a) (2000); Clean Air Act, 42 U.S.C. § 7622(a) (2000); Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. § 9610(a) (2000).

64. *See, e.g.*, 42 U.S.C. § 7622(a) (2000).

65. *Id.* § 7622(b).

nondisclosure as a means of turning the tables on the employer under these provisions.

2. The False Claims Act (FCA)⁶⁶

The FCA establishes a qui tam or bounty-hunter incentive for plaintiffs to sue over risk information allegedly concealed from the U.S. government.⁶⁷ Dating back to the Civil War, and originally enacted to help assure the honesty of the federal procurement system, the law enables private citizens, called “relators,” to sue, on behalf of the federal government, anyone who the relator believes has made a false claim for payment to the United States, for civil penalties and treble damages.⁶⁸ The United States can intervene and take over the litigation; otherwise, the private party can pursue the suit.⁶⁹ In any event, if successful, the relator is entitled to between ten and thirty percent of the amount the defendant is ordered to pay, based on judicial discretion, plus reasonable expenses, attorneys’ fees, and costs.⁷⁰ The FCA also allows for so-called “reverse false claims” actions, premised on the notion that the defendant has used a false statement or record to avoid liability to the government.⁷¹ Enterprising plaintiffs have argued that the failure to report required information to the government—such as a release of a toxic substance—constitutes a reverse false claim because it allows the defendant to avoid paying a penalty for noncompliance.⁷² Although this approach does not always succeed, some precedent supports it.⁷³ The FCA is thus one more reason for businesses to be chary about not disclosing information that could reveal a violation of law, or where failure to disclose might itself be illegal.

3. The Effect of Potential Civil Liability

Finally, state tort law provides powerful incentives for a company to take action once it possesses information that its products or operations may pose significant risks to others or to the environment. The precise standards differ from state to state, but as a general rule, if a company is aware of such information and does not take reasonable steps to reduce those risks, it could face very significant liability for negligence if a plaintiff were harmed as the

66. 31 U.S.C. §§ 3729–3733 (2000).

67. *Id.* § 3730(d).

68. *Id.* § 3730(b).

69. *Id.* § 3730(b)(4).

70. *Id.* § 3730(d)(2).

71. *Id.* § 3729(a)(7) (establishing liability for one who “knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government”).

72. *See, e.g., United States ex rel. Bain v. Georgia Gulf Corp.*, 386 F.3d 648, 657–58 (5th Cir. 2004) (reversing and remanding the denial of a motion to dismiss for the relator’s failure to state a cognizable claim; no relationship, economic or otherwise, existed between the government and defendant that would give rise to a financial transfer or payment upon which to base a reverse false claim).

73. *See, e.g., United States ex rel. Sequoia Orange Co. v. Oxnard Lemon Co.*, 1992 WL 795477, at 7–11 (E.D. Cal. May 4, 1992) (unreported opinion) (denying motion to dismiss reverse false claim).

proximate result of that failure to act.⁷⁴ Alternatively, or in addition, if such a company did not alert foreseeable victims to those risks, and a warning would have prevented such persons from being harmed, the company could be liable for negligent failure to warn if those persons were in fact harmed.⁷⁵ Liability either for negligence or negligent failure to warn could be heightened by documents tending to show that the company was aware of its duties but did not take action required by them.

Any well-advised company will be aware of these duties and would not be likely to actively suppress significant risk information. Although some businesses in prior decades may have thought it economically wise to conceal clear hazards, the experiences of the tobacco and asbestos industries today serve as a sobering warning. In fact, the duty of due care and the duty to warn, as well as the prospect of strict products liability,⁷⁶ provide incentives not only to act on risk information, but to affirmatively design products and services to minimize or avoid such risks in the first place. Risk evaluation is not only, or even mostly, a retrospective activity among responsible companies. Indeed, among members of the American Chemistry Council, one of the ten Guiding Principles of the Council's Responsible Care® Management System, which is binding on members, is "[t]o make health, safety, the environment and resource conservation critical considerations for all new and existing products and processes."⁷⁷

C. The Chemical Industry Voluntarily Publishes Enormous Amounts of Risk Information

Chemical safety investigations are routine for chemical manufacturers, so large amounts of information on those chemicals in commerce exist in company files. Because adverse effects information must be submitted under section 8 of TSCA, industry "private" data is generally thought to show a lack of adverse effects. However, that such information exists does not necessarily mean it is in the public domain, particularly in a form that is subject to electronic searches. Three major chemical industry initiatives, two operating in partnership with EPA, are designed to address this shortcoming. A fourth initiative produces other important, publicly available information relevant to assessing the risks of chemicals.

74. See generally RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL HARM (BASIC PRINCIPLES) § 7 (Tentative Draft No. 1, 2001) (discussing duty as a qualification for liability for negligence).

75. See generally *id.* at § 18 (discussing negligent failure to warn).

76. See generally RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (1998) (establishing separate standards of liability for manufacturing defects, design defects, and defects based on inadequate instructions or warnings). "The rule for manufacturing defects . . . imposes liability whether or not the manufacturer's quality control efforts satisfy standards of reasonableness." *Id.* at § 2 cmt. a.

77. American Chemistry Council, Overview: Guiding Principles, http://www.rctoolkit.com/overview_principles.asp (last visited April 13, 2006). Responsible Care® is the chemical industry's global initiative to improve health, safety, environmental, and security performance. *Id.*

1. High Production Volume (HPV) Challenge Program and Extended HPV Challenge Program

In 1998, the chemical industry, working with EPA, the Environmental Defense Fund (now known as Environmental Defense) and other organizations, developed the HPV Challenge Program, an unprecedented voluntary initiative with a goal of making uniform health and environmental screening information on HPV chemicals publicly available by the end of 2005.⁷⁸ Collectively, HPV chemicals, defined by EPA as those produced or imported in the United States in quantities greater than one million pounds annually,⁷⁹ represent more than ninety percent of current U.S. chemical production and use by volume.⁸⁰

Through the HPV Challenge Program, more than four hundred sponsoring manufacturers have volunteered to provide hazard-screening information for approximately 2200 HPV chemicals.⁸¹ Sponsoring manufacturers commit to providing complete Screening Information Data Sets (SIDS) for one or more chemicals.⁸² The SIDS standards were established in 1987 by the thirty nations of the Organization for Economic Co-operation and Development to secure uniform sets of hazard-screening information on HPV chemicals worldwide.⁸³ The standards comprise a series of data sets, tests, testing protocols, and information formats for conducting basic hazard assessments of HPV chemicals, and cover seventeen endpoints in four categories: (1) physical and chemical

78. See Letter from Carol M. Browner, Former Administrator, U.S. Env'tl. Protection Agency, to Manufacturers/Importers (Oct. 9, 1998), available at <http://www.epa.gov/chemrtk/ceoltr1.htm> (announcing the launch of the HPV Challenge Program in correspondence to the chief executive officers of more than 900 chemical companies); see also U.S. Env'tl. Protection Agency, High Production Volume (HPV) Challenge Program, available at <http://www.epa.gov/chemrtk/volchall.htm> (last visited Apr. 13, 2006) (providing information about the program, chemicals, and program participants); see generally EPA OVERVIEW, *supra* note 7, at 31–34 (describing the HPV Challenge Program). The HPV Challenge Program grew out of an Environmental Defense Fund report and similar evaluations asserting a lack of publicly available hazard information for various subsets of HPV chemicals. See, e.g., U.S. Env'tl. Protection Agency, Office of Pollution Prevention and Toxics, Chemical Hazard Data Availability Study: What Do We Really Know About the Safety of High Production Volume Chemicals? (Apr. 1998), available at <http://www.epa.gov/chemrtk/hazchem.pdf> ("EPA's 1998 Baseline of Hazard Information that is Readily Available to the Public"). All of these evaluations were limited to publicly available, electronically searchable information sources, and only identified chemical-specific studies, rather than all relevant information. These limitations resulted in a profound underestimation of the available information.

79. EPA OVERVIEW, *supra* note 7, at 32.

80. News Release, Chemical and Consumer Product Makers Promise More Public Information on Chemical Safety 1 (Mar. 15, 2005), http://www.americanchemistry.com/s_acc/bin.asp?CID=206&DID=829&DOC=FILE.PDF (announcing the start of the Extended HPV Program and summarizing the impact of the preceding HPV Challenge Program).

81. *Id.* at 1–2.

82. See generally U.S. Env'tl. Protection Agency, Office of Pollution Prevention and Toxics, Guidance for Meeting the SIDS Requirements (Nov. 3, 1998), <http://www.epa.gov/chemrtk/sidsappb.pdf> [hereinafter EPA Guidance for Meeting the SIDS Requirements].

83. See generally Organization for Economic Co-operation and Development, Description of OECD Work on Investigation of High Production Volume Chemicals, http://www.oecd.org/document/21/0,2340,en_2649_34379_1939669_1_1_1_1,00.html (last visited Apr. 13, 2006) (describing how SIDS fit within international investigation of HPV chemicals).

properties, (2) ecological toxicity, (3) environmental fate, and (4) human toxicity.⁸⁴ In the minority of cases in which data did not already exist to complete a data set, test plans to develop that data were developed and have been posted for public comment on the EPA Home Page.⁸⁵ So far, data sets have been submitted for more than 2200 chemicals: 1371 via the U.S. HPV Challenge Program, which will conclude in 2005, and roughly 851 via its international counterpart, operating on a longer time horizon.⁸⁶ All HPV Challenge Program data is publicly available on the EPA Home Page.⁸⁷

Earlier this year, the chemical industry announced the Extended HPV (EHPV) Program, which broadens the current initiative in two ways.⁸⁸ First, companies are being asked to provide health and environmental information on five hundred “new” chemicals that have met the HPV threshold since start of the original HPV Challenge Program.⁸⁹ Second, the EHPV Program increases the scope of information being collected for *all* HPV chemicals to include a screening level set of information on use and exposure.⁹⁰ As with the HPV Challenge, all information collected through the EHPV Program will be posted on the EPA website by the end of 2010.⁹¹

2. CHEMSTAR® Activities

For many years, the American Chemistry Council has operated a host of self-funded panels and councils composed of chemical industry companies and addressing chemical-specific issues that are significant to chemical manufacturers and downstream users.⁹² Scientific research is a substantial focus of these “Chemical Self-funded Technical Advocacy and Research Team” (CHEMSTAR®) organizations. In 2004, CHEMSTAR® panels funded \$4.6 million in research studies. As a matter of policy, CHEMSTAR® entities make

84. EPA Guidance for Meeting the SIDS Requirements, *supra* note 82.

85. See U.S. Env'tl. Protection Agency, Determining the Adequacy of Data, Appendix C (Feb. 10, 1999 Draft), <http://www.epa.gov/chemrtk/datadfin.htm> (explaining test plans in further detail). The test plans are posted at U.S. Env'tl. Protection Agency, Robust Summaries and Test Plans, <http://www.epa.gov/chemrtk/hpvrstp.htm> (last visited Apr. 13, 2006).

86. News Release, *supra* note 80, at 2.

87. See U.S. Env'tl. Protection Agency, Robust Summaries and Test Plans, <http://www.epa.gov/chemrtk/hpvrstp.htm> (last visited Apr. 17, 2006) for results for the U.S. HPV Challenge Program. Results from its international counterparts are available at Organization for Economic Cooperation and Development, OECD Integrated HPV Database, <http://cs3-hq.oecd.org/scripts/hpv/> (last visited Apr. 13, 2006).

88. News Release, *supra* note 80, at 1; see also American Chemistry Council et al., Questions and Answers on the Extended HPV Program (Mar. 15, 2005), http://www.americanchemistry.com/s_acc/bin.asp?CID=199&DID=536&DOC=FILE.PDF (explaining the similarities and differences between the HPV Challenge Program and its subsequent counterpart).

89. News Release, *supra* note 80, at 1.

90. *Id.* at 4.

91. *Id.* at 2.

92. See generally American Chemistry Council Home Page, http://www.americanchemistry.com/s_acc/sec_initiatives.asp?CID=157&DID=202 (last visited Apr. 17, 2006) (stating that seventy-three panels and two councils have addressed chemistry- or product-related issues).

available to the public and appropriate government agencies validated final results of all environmental, health, and safety research that they manage.⁹³

3. Voluntary Children's Chemical Evaluation Program (VCCEP)

In December 2000, EPA announced the VCCEP, designed to help the public understand the potential health risks to children associated with certain chemical exposures.⁹⁴ EPA developed a list of twenty-three chemicals that have been found in various biomonitoring or environmental databases and asked companies that manufacture or import these chemicals to volunteer to sponsor their evaluation in the first tier of a pilot of the VCCEP.⁹⁵ Afterwards, "[t]hirty-five companies and ten consortia responded and volunteered to sponsor twenty chemicals."⁹⁶ These companies are collecting or developing health effects and exposure information on the chemicals and are preparing both a risk assessment and a "data needs assessment."⁹⁷ After a "peer consultation" (a review by scientific experts in the field), EPA will determine whether higher tier information is needed.⁹⁸ If needed, sponsors will again be asked to volunteer to provide it; otherwise, EPA and the sponsors plan to "cooperate to conduct appropriate risk communication and, if necessary, risk management."⁹⁹ All risk assessments and peer consultation documents are publicly available.¹⁰⁰

4. ACC Long-Range Research Initiative

In 1999, ACC initiated its Long-Range Research Initiative (LRI) to generate research focused on the three health and environmental issue areas of "highest priority to society and the chemical industry".¹⁰¹

- (1) improving risk assessment methods,
- (2) identifying vulnerable groups and characterizing factors that may place them at greater risk, and
- (3) understanding the fate and transport of chemicals in the environment.¹⁰²

93. Final reports are sent routinely to eight agencies: the Agency for Toxic Substances & Disease Registry, the Consumer Product Safety Commission, EPA, the Food and Drug Administration, the National Cancer Institute, the National Institute of Environmental Health Sciences, the National Institute for Occupational Safety and Health, and OSHA.

94. See generally U.S. Env'tl. Protection Agency, Voluntary Children's Chemical Evaluation Program (VCCEP), <http://www.epa.gov/chemrtk/vccep> (last visited Apr. 13, 2006) (providing program overview) [hereinafter VCCEP].

95. *Id.*

96. *Id.* The companies and consortia are listed at U.S. Env'tl. Protection Agency, Who's Participating?, <http://www.epa.gov/chemrtk/vccep/whospon.htm> (last visited Apr. 17, 2006).

97. VCCEP, *supra* note 94.

98. *Id.*

99. *Id.*

100. See U.S. Env'tl. Protection Agency, How to Access Assessments/Reports/Decisions, http://www.epa.gov/_chemrtk/vccep/access.htm (last visited Apr. 17, 2006).

101. AMERICAN CHEMISTRY COUNCIL, LONG-RANGE RESEARCH INITIATIVE 2004 ANNUAL REPORT, 1 http://www.uslri.org/documents/cat_14/doc_437.pdf, (last visited Apr. 13, 2006) [hereinafter LRI ANNUAL REPORT]. See generally American Chemistry Council, Long-Range Research Initiative Home Page, <http://www.uslri.org> (last visited Apr. 13, 2006).

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Research is supported by grants to the CIIT Centers for Health Research, collaborative funding efforts with government agencies, and competitive grants issued to other organizations and academic institutions through a peer-reviewed “Request for Proposal” process.¹⁰³ Through 2004, approximately \$128 million had been awarded in support of 164 research projects, ninety-nine of which had been completed.¹⁰⁴

The LRI consciously operates to maximize researcher independence and scientific openness. By contract, LRI-funded investigators own and retain intellectual property rights in the data they generate.¹⁰⁵ The LRI program has no approval authority over publications.¹⁰⁶ Investigators are strongly encouraged to publish their work in the peer-reviewed literature.¹⁰⁷ If they do not, the LRI reserves the right to make the final report public.¹⁰⁸ Through 2004, LRI-funded research had generated a total of 335 peer-reviewed articles and 102 other scientific publications such as books, final reports, and newsletter articles, with fifty-six peer-reviewed articles published in 2004.¹⁰⁹ In addition, 1121 presentations on this research have been made over the course of the first six years of the LRI program, with 132 presentations in 2004.¹¹⁰

III

INCENTIVES ARE EVERYWHERE

The organizers of this symposium highlighted the economic incentives that manufacturers and other for-profit entities have not to disclose scientific information that shows their products or operations to be risky. But as shown above, acting upon such incentives is broadly illegal, and substantial, countervailing incentives operate against them. Moreover, for-profit businesses are not the only entities affected by incentives to manipulate or conceal information. As emphasized in the recent bestseller *Freakonomics*,¹¹¹ all actors are affected by incentives that tend to shape behavior. This principle holds true in the area of scientific research as well.

To be clear, this article does not assert that particular scientific research is invalid because of the source of its funding or the motivation of the

102. LRI ANNUAL REPORT, *supra* note 101, at 7.

103. *Id.* at 1.

104. *Id.*

105. American Chemistry Council, Long-Range Research Initiative Home Page, Funding Opportunities, <http://www.uslri.org/home.cfm?id=funding> (last visited Apr. 13, 2006).

106. *Id.*

107. *Id.*

108. *Id.*

109. LRI ANNUAL REPORT, *supra* note 101, at 32.

110. *Id.*

111. Steven D. Levitt & Stephen J. Dubner, *FREAKONOMICS: A ROGUE ECONOMIST EXPLORES THE HIDDEN SIDE OF EVERYTHING* 13 (2005) (“*Incentives are the cornerstone of modern life. And understanding them—or, often, ferreting them out—is the key to solving just about any riddle, from violent crime to sports cheating to online dating.*”) (emphasis in original).

experimenter. Rather, the point is only that *everyone* faces potentially multiple incentives regarding disclosure, most of which are directly or indirectly financial. Besides affecting for-profit businesses, these incentives can also affect whether, when, and how governmental or nonprofit entities—or scientists funded by them—disclose data they generate, or challenge data others generate.

Most simply, but perhaps most importantly, all researchers face endemic questions about guarding the results of their work to ensure they are the first to publish the results. This dynamic affects not only whether and how much of their data and methods to disclose in the initial publication, but how much to maintain confidential thereafter so as to enable additional publications based on the same data set. Recently, the National Heart, Lung and Blood Institute (NHLBI) refused to release data from a study it funded on the effects of dietary salt on blood pressure. Even as the NHLBI was issuing press releases and other recommendations trumpeting the results of the study, it did not release underlying data and methods—until the Salt Institute and the U.S. Chamber of Commerce filed a lawsuit to compel its release.¹¹² It is unclear why the agency was initially unwilling to release the data, but one possible answer is that the researchers were waiting for publication of a journal article based on the data, which appeared shortly before the government filed its reply brief in support of its motion to dismiss.¹¹³ Credentials based on first publication and volume of publications are key to career advancement in academia, but they are important in the career of any scientist, regardless of where he or she is employed. Because the credential incentive is so widespread and fundamental, it poses a profound and difficult question for the academic and scientific communities, one that warrants inclusion in any assessment of scientific sequestration.

Economic as well as credential incentives affect a researcher's interest in sharing unpublished data. All scientific researchers without unlimited personal wealth need funding to conduct research and will therefore inevitably be conscious of where the next grant or contract is coming from. Thus, even academic researchers are likely at least to think about the effect on their current or future sources of funding when determining whether, when, and how to disclose their results and the data underlying them.

112. *Salt Inst. v. Thompson*, 345 F. Supp. 2d 589, 592–93, 603 (E.D. Va. 2004) (granting motion to dismiss claims, *inter alia*, for lack of standing), *appeal docketed*, No. 05-1097 (4th Cir. Jan. 25, 2005). The NHLBI is part of the Department of Health and Human Services. *Id.* This research was funded before the effective date (April 17, 2000) of the so-called “Shelby Amendment,” which requires government agencies to publicly disclose the results of federally funded research, subject to personal privacy protections. *Id.* at 595. For the text of the Shelby Amendment, see Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, 112 Stat. 2681. The two-sentence Shelby Amendment required the Office of Management and Budget to revise its Circular A-110 to ensure that all data from federally funded research be made publicly available pursuant to the Freedom of Information Act. Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations, 65 Fed. Reg. 14406 (Mar. 16, 2000) (to be codified at 7 C.F.R. pt. 3019).

113. *See Thompson*, 345 F. Supp. 2d at 597–98.

Economic incentives affect the behavior of nonprofit professional associations, as well. The American Chemical Society (ACS)¹¹⁴ recently secured congressional assistance in protecting its fee-based Chemical Abstracts Service (CAS) Registry—historically *the* reference database for information on the structure and property of chemicals—from possible competition by “PubChem,” a free database operated by the National Institutes of Health (NIH).¹¹⁵ ACS is understandably concerned that PubChem may—at taxpayer expense—replicate portions of the CAS generated at substantial expense by ACS, this example confirms that economic incentives can lead even nonprofit professional associations to take actions at least facially inconsistent with “free” science.¹¹⁶

Mission-oriented entities such as regulatory agencies and nongovernmental advocacy organizations are subject to programmatic, as well as financial, incentives that inescapably color whether, when, and how to disclose or characterize scientific research results. On the financial side, the size of a regulatory agency’s budget is generally proportional to the perceived size of the problems it is attempting to address. Looking beyond financial incentives, in the case of environmental hazards, the relevant federal statutes are generally oriented toward restrictive or negative goals—identification of toxic or hazardous substances, prevention of harm, and forcing technology beyond its current capabilities.¹¹⁷ Most statutes administered by EPA do not embody a competing, positive statutory impetus to allow any particular substance or activity (unlike the Food, Drug and Cosmetic Act, for example), or to promote a sector of the economy or employment.¹¹⁸ Institutional dynamics operating upon and within agencies not surprisingly push the same way. Therefore, agencies are hailed for banning or restricting bad substances, but criticized if

114. The American Chemical Society is unrelated to the American Chemistry Council.

115. See Susan R. Morrissey, *NIH and ACS Spar over PubChem: Agency’s New Chemical Database Draws Concern From ACS for Similarities to CAS Registry*, 83 CHEM. & ENGINEERING NEWS 23–25 (2005) (discussing the creation, content, and scope of the private CAS Registry and “unfair competition” arguments against the government-sponsored rival database, PubChem). The free PubChem database is available at National Center for Biotechnology Information, PubChem Text Search, <http://pubchem.ncbi.nlm.nih.gov> (last visited Apr. 13, 2006). The CAS Registry is accessible on a fee basis through SciFinder, Product Overview, <http://www.cas.org/SCIFINDER> (last visited Apr. 13, 2006).

116. The House Appropriations Committee report accompanying the Fiscal Year 2006 spending bill for NIH “urges NIH to work with private sector providers to avoid unnecessary duplication and competition with private sector databases.” See H.R. REP. NO. 109-143, at 112 (2005).

117. For example, the Clean Water Act directs EPA to identify “toxic” water pollutants, 33 U.S.C. § 1317(a)(1) (2000), to set effluent limitations for such pollutants that reflect “the best available technology economically achievable” for new sources discharging them, *id.* § 1317(a)(2), and to determine that such limitations provide “an ample margin of safety,” *id.* § 1317(a)(4).

118. Again, for example, the goals and policy of the Clean Water Act are expressed entirely in terms of “eliminat[ing]” and “prohibit[ing]” discharges of pollutants. See 33 U.S.C. § 1251(a). FIFRA is a rare, partial counterexample in that it requires EPA, when deciding whether to “register” a pesticide, to consider “the economic, social, and environmental costs and benefits” of its use. See 7 U.S.C. § 136a(a) (2000) (pesticide registrations are to include any limits needed to prevent “unreasonable adverse effects on the environment”; costs and benefits of pesticide use are relevant to determining such effects).

they fail to do so and allow one to enter the marketplace. Few cheer if a substance is reviewed, found to be safe, and left in commerce.

Commentators have noted how these dynamics can affect scientists employed or funded by agencies: “[I]t might be thought that that scientists employed or funded by an agency could feel pressured to support what they perceive to be the agency’s regulatory position, first in developing the science, and then in peer reviewing it.”¹¹⁹ “[M]ost money, even so-called government money, comes with some strings related to expected results.”¹²⁰ Some government agencies have refused to release critical data underlying their conclusions, generating significant controversies. A prime example is the Harvard “Six Cities” study that was the principal basis for the EPA “PM-2.5” rule regarding particulate air emissions.¹²¹ EPA’s nondisclosure ultimately led Congress to enact the “Shelby Amendment,” requiring all federally funded researchers to provide the funding agency with all information generated by the research so that it can be subject to FOIA.¹²² As noted earlier, the NHLBI also refused, until it was sued, to release data from a salt study it had funded.¹²³

In the case of nongovernmental organizations (NGOs), incentives are even more obvious. From the financial perspective, it is intuitive that fundraising appeals become more compelling as the evils they seek to combat increase. More programmatically, an NGO dedicated to advocacy faces all the same incentives as any other advocate in a controversy, and these incentives are bound to influence how NGOs present and characterize data. For example, Ralph Nader, the founder of Public Citizen, which advocated for mandatory air bags, trumpeted the virtues of air bags and derided the value of mandatory seat belt laws in the 1970s and 1980s.¹²⁴ Evidence now shows that mandatory seat belt laws are far more effective at saving lives than air bags and that air bags can actually pose significant risks.¹²⁵ During the same timeframe, auto companies

119. Office of Management and Budget, Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,023, 54,024 (Sept. 15, 2003).

120. Robert W. Hahn, *Disclosing Conflicts of Interest: Some Personal Reflections* 8 n.25 (AEI-Brookings Joint Ctr. for Regulatory Studies, Working Paper 02-2, 2002).

121. See C. Arden Pope, III et al., *Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults*, 151 AM. J. RESPIR. CRIT. CARE MED, 669 (1995). This study, which concluded that very small particles less than or equal to 2.5 microns were associated with significant public mortality, was influential in leading EPA to revise its national ambient air quality standards to include stringent limits on such particles. See National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652-01, 38655 n.7 (July 17, 1997) (to be codified at 40 C.F.R. pt. 50) (providing final PM-2.5 rule, citing Pope study).

122. See *supra* note 112.

123. See *supra* notes 112–113 and accompanying text.

124. Malcolm Gladwell, *Wrong Turn; How the Fight to Make America’s Highways Safer Went Off Course*, THE NEW YORKER, June 11, 2001, at 50, 56 (Ralph Nader was one of several high-profile advocates “consumed by the battle to force a reluctant Detroit to make the air bag mandatory equipment”). These advocates thought air bags would be more effective than seatbelts because air bags require no human action to work. *Id.*

125. See generally *id.* at 58–61. “[T]oday it is seatbelts, not air bags, that are providing the most important new safety advancements.” *Id.* at 58. A seatbelt alone cuts the chance of dying in an accident by forty-three percent, while an air bag alone only does so by thirteen percent. *Id.*

predicted that air bags would kill some number of children and small adults and raised these concerns with the National Highway Traffic and Safety Administration (NHTSA).¹²⁶ Joan Claybrook of Public Citizen, however, called their data “a little poop sheet,” and other “safety advocates” dismissed it as “manufactured” data.¹²⁷ Subsequently, the auto manufacturers’ predictions turned out to be correct.¹²⁸

As with industry-funded scientists, scientists allied with “public interest” groups have also been faulted for not disclosing the data on which they rely.¹²⁹ Such scientists have not been above outright falsification, as occurred with a widely publicized study that purported to show synergistic effects from pesticides; unfortunately, the falsification did not become known until after the study had played a major role in the enactment of the Food Quality Protection Act.¹³⁰

It is important to consider not only incentives for nondisclosure, but a range of other issues that could compromise the validity of what actually is disclosed, such as

- (1) drawing firm conclusions from novel results that have not been replicated,
- (2) making claims that data cannot support (due to sample size, etc.),
- (3) over-interpreting data,
- (4) editing data, and
- (5) falsification.

In fact, a recent commentary published in *Nature* provides empirical—and conservative—data that these kinds of problems are relatively widespread. The article, summarizing survey responses from 3247 scientists, found that while

126. See David B. Ottaway & Warren Brown, *From Life Saver to Fatal Threat: How the U.S., Automakers and a Safety Device Failed*, WASH. POST, June 1, 1997, at A01 (explaining that the federal government was expected to give drivers the option of deactivating air bags). NHTSA ultimately decided that persons within four “risk groups” can have their air bags turned off after securing approval from NHTSA. See 49 C.F.R. § 595.5 (2005) (setting forth requirements to have air bags turned off).

127. Ottaway & Brown, *supra* note 126. Claybrook became head of NHTSA in 1977 and went on to run Public Citizen in 1980. Gladwell, *supra* note 124, at 58–60.

128. Ottaway & Brown, *supra* note 126.

129. See NATIONAL TOXICOLOGY PROGRAM, REPORT OF THE ENDOCRINE DISRUPTORS LOW-DOSE PEER REVIEW, iv, 1–4 to 1–5 (August 2001), <http://ntp-server.niehs.nih.gov/ntp/htdocs/liason/LowDosePeerFinalRpt.pdf> (mouse colony in which low-dose endocrine effects—not reproduced elsewhere—were observed by Frederick vom Saal “is no longer available”; raw data supporting his oral presentation and two other papers was not provided to peer reviewers). Vom Saal is associated with non-governmental organizations supporting the notion that very low doses of some chemicals can cause adverse effects on the endocrine systems of organisms. See, e.g., Greenpeace Int’l, *Poisoning the Future: Impacts of Endocrine Disrupting Chemicals on Wildlife and Human Health* (Oct. 1997), <http://archive.greenpeace.org/toxics/reports/ptf/ptf.html> (citing multiple papers authored or coauthored by Vom Saal).

130. See John A. McLachlan, *Synergistic Effect of Environmental Estrogens: Report Withdrawn*, 227 SCIENCE 462, 462–63 (1997) (withdrawing earlier report on behalf of the author and coauthor Steven F. Arnold). See also Case Summaries, NEWSLETTERS, (U.S. Dep’t of Health and Human Services Office of Research Integrity), Dec. 2001, http://permanent.access.gpo.gov/lps17396/ori.dhhs.gov/html/publications/newsletters_vol10no1.asp.htm#CASE%20SUMMARIES (follow “Case Summaries” hyperlink) (detailing Arnold’s admission of scientific misconduct).

only three-tenths of one percent had not properly disclosed involvement in firms whose products were based on a scientist's own research, such as pharmaceutical companies, over ten percent had withheld the details of a methodology or result in a paper or proposal, and six percent had failed to present data contradicting the scientist's own research.¹³¹

In sum, a welter of financial and other incentives affect the disclosure practices of all players in the scientific process, particularly as it becomes relevant to regulation.

IV

PLAINTIFFS' LAWYERS AND SCIENCE

Many of the articles in this symposium are principally concerned about the distorting influence that money in the hands of businesses can have on science and about the financial incentives for businesses to shape or manufacture science or to create scientific uncertainty. Besides manufacturers and users of products, the other major for-profit entities with an economic stake in the science related to chemical hazards are law firms who represent plaintiffs in toxic-tort litigation. Although the focus of their efforts is courtrooms, scientific evidence and methodologies that they promote can affect regulatory proceedings as well.

One of the consequences of the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*¹³² has been a greater emphasis on publication in peer-reviewed journals as an indication of scientific credibility and, hence, reliability. To help win judicial acceptance of their theories and studies, expert witnesses working for plaintiffs' lawyers have increasingly published articles in peer-reviewed journals. In many cases, the work was generated for litigation purposes and funded by law firms—but these facts have often not been disclosed in the articles.¹³³ Courts have also noted the “apparent obscurity”¹³⁴ of some of the journals that appear repeatedly in litigation and that are edited by regular expert witnesses for plaintiffs,¹³⁵ and have questioned whether they are

131. Brian Martinson et al., *Scientists Behaving Badly*, 435 NATURE 737 and Table 1 (2005).

132. 509 U.S. 579, 591–97 (1993) (establishing the trial judge as a gatekeeper for gauging the reliability of scientific evidence in federal courts). “The fact of publication (or lack thereof) in a peer reviewed journal [is] a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which the opinion is premised.” *Id.* at 593–94.

133. See Anderson et al., *supra* note 13, at 624–27, 660–62 (discussing, for example, *Nat'l Bank of Commerce v. Dow Chemical Co.*, 965 F. Supp. 1490 (E.D. Ark. 1996) and *Bourne v. E.I. DuPont de Nemours & Co.*, No. 2:97–0090 (S.D. W. Va. Dec. 31, 1996)).

134. See *Valentine v. Pioneer Chlor Alkali Co.*, 921 F. Supp. 2d 666, 670 n.3 (D. Nev. 1996) (questioning publication of an article in a journal apparently missing from the comprehensive Index Medicus of the National Library of Medicine, but weighing “apparent obscurity” with other factors in deciding the admissibility of plaintiff's expert testimony based on article).

135. For example, the *International Journal of Occupational Medicine and Toxicology* was relied on by plaintiffs in both *Valentine*, 921 F. Supp. 2d at 670 n.3, and *Nat'l Bank of Commerce*, 965 F. Supp. 2d at 1499. A second journal, the *Archives of Environmental Health*, was also relied on by the plaintiff's expert in *Nat'l Bank of Commerce*. *Id.* Kaye H. Kilburn, who is the president of his own consulting and expert firm (Kaye H. Kilburn, Curriculum Vitae, http://www.neuro-test.com/Khk_cv.htm, last

in fact “peer reviewed.”¹³⁶ Although this work is not automatically invalidated by its provenance, legitimate concerns can be raised about the reliability of research generated by law firms and witnesses with an obvious financial interest in the outcome, and about the effectiveness of peer review at some of the journals in which this work appears. Certainly, the failure to fully disclose that provenance impairs the practice of open science, whose validity ultimately depends on the integrity and authenticity of the scientists, institutions, and journals that are its major players.¹³⁷

Much concern has been expressed about the independence of scientists who are employed or funded by regulated businesses. Such concern should also logically apply to scientists who are paid by plaintiffs’ lawyers to serve as expert witnesses, many of whom also participate regularly in regulatory activities. In either case, the economic prospects of the sponsor are more or less dependent on decisions by government entities—be they courts or agencies—based on the work of the sponsored scientists. The point is not that scientists receiving funds from for-profit entities necessarily have a fatal conflict of interest, much less that their work is somehow less valid. Rather, the potential for conflict, or more likely bias, is present in both cases and justifies disclosure in order to allow adequate scientific assessment of the work.

Although much of the focus of the Coronado II papers is on sealing orders that prevent the public release of information generated in the course of a lawsuit,¹³⁸ it is important to note that such agreements require the consent not only of the defendant but also of the plaintiff. Thus, plaintiffs’ interests are also actively engaged in sequestering science. Moreover, although an individual plaintiff may be concerned only about winning justice for him or herself, the plaintiff’s lawyer could well benefit from a sealing order, as the lawyer will thereby avoid making it any easier for other lawyers to gain the subject matter expertise that the first lawyer has acquired and can use in subsequent cases.

One can also question—and indeed, someone should study—the degree to which, in the course of pretrial and trial proceedings, plaintiffs’ lawyers and experts in their employ are disclosing to public health officials the extent of occupational or other environmental injuries they assertedly are discovering and avenging in their litigation. In a remarkable opinion spanning over two hundred pages, a federal judge took to task the doctors working for the plaintiffs’ firms in a lawsuit that involved some nine thousand alleged silicosis cases:

visited Apr. 13, 2006), edits the latter journal and authored the relevant article in the former journal, whose “apparent obscurity” was noted by the court in *Valentine*, 921 F. Supp. 2d at 670 n.2, n.3. See *supra* note 122.

136. See *Nat’l Bank of Commerce*, 965 F. Supp. at 1499.

137. Anderson et al., *supra* note 13, provides a thoughtful and evenhanded analysis of how courts should address the challenges posed by “litigation science.”

138. E.g., Daniel J. Givelber & Anthony Robbins, *Public Health Versus Court-Sponsored Secrecy*, 69 LAW & CONTEMP. PROBS. 130 (Summer 2006).

And, finally, despite diagnosing a serious and completely preventable disease at unprecedented rates, not a single doctor even bothered to lift a telephone and notify any governmental agency, union, employer, hospital or even media outlet, all of whom conceivably could have taken steps to ensure recognition of currently undiagnosed silicosis cases and to prevent future cases from developing. One can imagine the outcry that would have resulted had these doctors kept silent after diagnosing thousands of new cases of avian flu or mad-cow disease.¹³⁹

The Project on Scientific Knowledge and Public Policy (SKAPP), which organized the conference giving rise to this symposium, is itself an indirect creation of the trial bar, as it is principally funded by the silicone-gel breast implant litigation settlement.¹⁴⁰ Indeed, it is not beyond the pale to view the overall thrust of work commissioned by SKAPP to date as seeking to tilt the balance in litigation and regulation away from science conducted or supported by regulated entities and defendants in lawsuits, and toward science conducted or supported by plaintiffs.¹⁴¹ This is unfortunate, because the scientific work conducted by regulated entities for submission to agencies is generally of the highest quality—and often of higher quality than that produced at universities. As discussed above, under laws like TSCA and FIFRA, research must use agency test protocols, must follow GLP Standards, and is subject to agency audit.¹⁴² The same frequently cannot be said of other research.¹⁴³

Based on the proceedings of the Coronado conferences, the first of which had no “counterpoint” papers such as those presented here,¹⁴⁴ one is moved to question whether the SKAPP agenda is any less self-interested than it claims those of “private parties” to be. Nothing is more “special” about the interests of profit-seeking manufacturers or their trade associations than about the interests of profit-seeking lawyers or their strategic allies.

V

CONCLUSION

Whatever the economic incentives facing businesses that make or use chemicals, numerous federal laws require them to make publicly available information regarding the health and environmental effects of chemicals. These and other laws also create substantial disincentives to concealment. Many of these businesses are also voluntarily disclosing enormous amounts of such data.

139. *In re Silica Products Liability Litigation*, MDL No. 1553 (S.D. Tex. June 30, 2005), slip op. at 149–50, available at <http://www.txs.uscourts.gov/notablecases/203md1553/203md1553-1902.pdf>. Of course, the judge also indicated her belief that the case involved not “an industrial disaster of unprecedented proportion”—20,479 silicosis cases were “identified” in Mississippi in three years, when twenty-four would have been expected—“[but] something else entirely.” *Id.* at 11–15.

140. SKAPP Self-description, *supra* note 1.

141. For example, review the articles from the first SKAPP Coronado Conference, compiled in Symposium, 95 AM. J. PUB. HEALTH, Supplement 1 (2005) (entitled “Scientific Evidence and Public Policy”).

142. See *supra* Part II.A.1, Part II.A.2.

143. See Anderson et al., *supra* note 13, at 632–33, 675.

144. The proceedings of the first Coronado conference were published in Symposium, *supra* note 140.

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Moreover, everyone who makes decisions regarding the disclosure of chemical effects data is subject to economic and other incentives that may affect whether, when, and how to disclose. Finally, the plaintiffs' bar and its expert witnesses face at least the same economic incentives that regulated businesses face, although their scientific work is less often produced under regulatory standards for rigor. Science is not more or less valid because of incentives affecting its creators, but those incentives should be identified and disclosed, so that all concerned can subject it to the desired degree of scrutiny. Ultimately, the methods and practices of open science—principally peer review, publication and replication—best determine the validity of scientific work.