LAW AND CONTEMPORARY PROBLEMS

Volume 69 Summer 2006 Number 3

# FOREWORD: SARBANES-OXLEY FOR SCIENCE

DAVID MICHAELS*

## I
## INTRODUCTION

Science is built on the sharing of information. Scientists generate knowledge to explain the workings of the natural world, building on the information produced and shared by other scientists. Some scientists see this construction in moral or ethical terms;[1] according to Albert Einstein, for example, "The right to search for truth implies also a duty: one must not conceal any part of what one has recognized to be true."[2]

Science flourishes best in conditions of the open and public exchange of ideas, methods, findings, and interpretations. Openness facilitates vetting new findings and new theories through continued study and analysis. The open

Copyright © 2006 by David Michaels

This article is also available online at http://www.law.duke.edu/journals/lcp.

* Research Professor and Acting Chairman, Department of Environmental and Occupational Health, the George Washington University School of Public Health and Health Services; Assistant Secretary of Energy for Environment, Safety and Health, 1998-2001; Director of the Project on Scientific Knowledge and Public Policy (SKAPP).

Acknowledgements: I am very grateful to Molly Jacobs and Celeste Monforton for their work coordinating the "Sequestered Science" conference and Rebecca Jensen-Bruhl and Christina Morgan for their help in putting this issue together. Eula Bingham, Les Boden, Richard Clapp, Polly Hoppin, Sheldon Krimsky, David Ozonoff, and Anthony Robbins—my fellow SKAPP planning committee members—also contributed greatly to formulating the ideas underpinning the conference and this paper.

1. *See, e.g.*, *A Duty to Publish*, 4 NATURE MED. 1089, 1089 (1998) (listing recent instances in which drug companies tried to suppress the unfavorable results of studies they helped to fund, but the researchers, "acting in the interests of the public," resisted the pressure and published their findings).

2. *Id.*

exchange of ideas is valued not only because it facilitates the advancement of science, but also because it is concordant with the ideals of a democratic society.

The principles and practice of open science can come into conflict with individual or corporate actions intended to limit public access to information, or with government laws and policies that restrict access to results and ideas. Sometimes these restrictions are needed to preserve important values, such as individual privacy, or to further certain policy objectives, such as protecting national security or the economic benefits derived from innovation. However, there are also potential costs to restricting certain kinds of information; for example, when such suppression limits public knowledge about health risks, it can prevent people and their government from protecting public health.

The best known and most tragic examples of data sequestration contributing to public health disasters are tobacco and asbestos. The tobacco industry developed extensive structures and policies to hide scientific studies whose results were detrimental to the industry's health.[3] The confidentiality that accompanies the attorney–client relationship was a particularly important tool to sequester data on the powerful, terrible effects of cigarette smoke on the health of smokers.[4] Similarly, an untold portion of the worldwide epidemic of asbestos-related disease—currently estimated at 100,000 deaths each year—might have been prevented had the manufacturers of asbestos products not systematically hidden the results of inhalation studies linking asbestos with lung cancer, performed in the 1940s.[5]

Of course, the concealment of scientific evidence has not been limited to the tobacco and asbestos contexts, and less well-known episodes of data sequestration have occurred in relation to several industrial chemicals.[6] More recently, instances in which drug manufacturers withheld study results unfavorable to their product but clearly important in terms of patient treatment[7]

---

3. *See generally* STANTON A. GLANZ ET AL., THE CIGARETTE PAPERS 235–87 (1996).

4. *See, e.g.*, Lisa Bero et al., *Lawyer Control of the Tobacco Industry's External Research Program: The Brown and Williamson Documents,* 274 JAMA 241-47 (1995); Stanton A Glantz et al., *Looking Through a Keyhole at the Tobacco Industry: The Brown and Williamson Documents,* 274 JAMA 219–24 (1995); Peter Hanauer et al., *Lawyer Control of Internal Scientific Research to Protect Against Products Liability Lawsuits: The Brown and Williamson Documents*, 274 JAMA 234–40 (1995). *See also* Glanz, *supra* note 3, at 235–87.

5. Press Release, International Labour Organization (ILO) & World Health Organization (WHO), Number of Work Related Accidents and Illnesses Continues to Increase: ILO and WHO Join in Call for Prevention Strategies (Apr. 28, 2005), *available at* http://www.ilo.org/public/english/bureau/inf/pr/2005/21.htm. *See also* BARRY I. CASTLEMAN, ASBESTOS: MEDICAL AND LEGAL ASPECTS 41–132 (2005).

6. *See* Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research,* 30 AM. J.L. & MED. 119, 121–28 (2004).

7. *See, e.g.*, D. Blumenthal et al., *Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty*, 277 JAMA 1224–28 (1997); B. Psaty & D. Rennie, *Stopping Medical Research to Save Money: A Broken Pact with Researchers and Patients*, 289 JAMA 2128, 2128–31 (2003); D. Rennie, *Thyroid Storm*, 277 JAMA 1238–43 (1997); S.A. Rosenberg, *Secrecy in Medical Research*, 334 N. ENG. J. MED. 392, 392–94 (1996).

have been the impetus to major changes in the registration and reporting of clinical trials in biomedical literature.

Concerned about these issues, the Planning Committee of the Project on Scientific Knowledge and Public Policy (SKAPP)[8] convened a symposium to explore the scientific and social consequences of failure to disclose scientific knowledge. The symposium placed special emphasis on the tension between the imperative to protect public health and safety and provisions restricting access to documents whose publication or dissemination might result in financial harm. The second Coronado Conference,[9] *Sequestered Science: The Consequences of Undisclosed Knowledge* (Coronado II), brought leading scholars and practitioners from the fields of philosophy of science, law, ethics, business, and public health to New York City on October 14–15, 2004, to discuss these issues. This issue of *Law and Contemporary Problems* includes papers presented at Coronado II and others solicited for inclusion in this publication.

Science has the connotation of openness; the phrase "sequestered science" is intentionally discordant. An objective of this collection of articles is to examine that discordance. Several articles discuss the tradeoffs involved in the decision to sequester science. Who participates in weighing cost against benefits? Which and whose values are considered? Is this process of deciding what is to be sequestered open to public scrutiny—or is it likewise sequestered? A further objective is to explore incentives, such as laws and regulations, to enhance or limit the production of knowledge.[10]

The U.S. regulatory system faces a difficult challenge: safeguards are inadequate to ensure appropriate access to the results of scientific studies needed to protect public health and safety and the environment. Nevertheless,

---

8. SKAPP, based at the George Washington University School of Public Health, engages scientists in examinations of the nature of science and how it is used and misused in government decisionmaking and legal proceedings. Through empirical research, discussions among scholars, and publications, SKAPP aims to enhance understanding of how knowledge is generated and interpreted. Major funding for SKAPP, and support for this symposium, is provided by the Common Benefit Trust, a fund established pursuant to a court order in the Silicone Gel Breast Implant Products Liability litigation. The funding is unrestricted; we do not provide our funders the opportunity to review or approve our activities. For more information, see the SKAPP website at http://www.DefendingScience.org.

9. The first Coronado Conference hosted by SKAPP, *Scientific Evidence and Public Policy*, was held in March 2003. At the conference, the distinguished group of participants examined the use and misuse of scientific evidence in public policy and the implications of the 1993 Supreme Court decision in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). The participants focused on how these issues are worked out in the legal and regulatory arena, with topics that included the meaning of causation, how scientists reach judgments, and whether there is a scientific method. Additional information is available at http://www.DefendingScience.org. In addition, the papers and commentaries presented at the 2003 Coronado Conference have been published in a special supplement to the *American Journal of Public Health* and are available for downloading from the SKAPP website. *See* 95 AM. J. PUB. HEALTH 4 (2005).

10. In the public health arena, the Toxic Substances Control Act, 15 U.S.C. §§ 2601–2671 (1976), and the Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. § 768 (1906) (codified as amended at 21 U.S.C. 1-15 (1934)), are good examples of these types of legal incentives to create knowledge.

as several authors in this issue note, excessive transparency can have significant negative consequences to society.

In the early part of this decade, the nation grappled with a different set of issues relating to data integrity and transparency, namely, questionable accounting and reporting practices led to the bankruptcies of Enron and WorldCom, as well as the demise of the "Big Five" accounting firm Arthur Andersen. The economic and social impact of the scandals was substantial, including a huge reduction of shareholder assets and the disappearance or substantial reduction of the pensions of thousands of workers. In response, the U.S. Congress enacted the American Competitiveness and Corporate Accountability Act of 2002, commonly known as the Sarbanes-Oxley Act.[11]

Based on the findings and conclusions of the authors in this issue, this article ends with a call for another Sarbanes-Oxley initiative—one for science. Although the needs of science and accounting are quite different, the Sarbanes-Oxley Act inspires a need for legislation that would safeguard the integrity and transparency of scientific data vital to protecting the public, while recognizing the valid need for limited data sequestration in certain circumstances.

## II

## THE SEQUESTERED SCIENCE SYMPOSIUM PAPERS

The contours of the policy debate over data sequestration are lyrically described by Sheila Jasanoff in this issue's opening essay.[12] Jasanoff, one of the country's most insightful and important thinkers on the use of science in public policy,[13] explains that "[o]penness and transparency in science, then, cannot be treated as absolute goods. Rather, the degree of openness is context-specific and needs to be traded off against other important social values. The problem for contemporary law and policy is to develop principled approaches to maintaining the desired balance."[14]

Jasanoff looks at issues of transparency in both regulation and litigation. In what she describes as "public, or policy-relevant, science,"[15] she rejects the relatively superficial question of whether information should be transparent, recognizing the greater inquiry for whom such science should be transparent and for what purpose. As she notes, "Openness is a treasured attribute of science, but like most good things, even scientific openness has to be

11. Pub. L. No. 107-204, 116 Stat. 745 (2002) (codified as amended in scattered sections of 15 U.S.C.).

12. Sheila Jasanoff, *Transparency in Public Science: Purposes, Reasons, Limits*, 69 LAW & CONTEMP. PROBS. 21 (Summer 2006).

13. *See, e.g.*, SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICYMAKERS (1990); SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE AND TECHNOLOGY IN AMERICA (1995). Jasanoff is the Pforzheimer Professor of Science and Technology Studies at the John F. Kennedy School of Government of Harvard University.

14. Jasanoff, *supra* note 12, at 20.

15. *Id.* at 29.

purposefully cultivated and judiciously deployed in order to serve its intended functions well."[16]

Jasanoff then succeeds in refocusing the question at hand, from how to ensure the disclosure of useful information to how to transform the judicial system so that it contributes to the generation of knowledge for public good. She argues that "litigation is an indispensable aid to knowledge production," a fact that should lead to the design of "procedures aimed at increased transparency, such as enforced negotiation between parties," and that "some forms of external review, could be devised to improve the quality and reliability of the science that lawsuits help generate."[17]

The tradeoffs between data sequestration and disclosure discussed by Jasanoff are particularly acute in the production and marketing of drugs. The choices made in this arena have substantial implications, both for public health and for the financial health of the corporations involved. Three papers in this issue address these choices.[18]

First, noted philosopher of science Susan Haack[19] recounts the tale of the drug Remune, in which the drug's manufacturer hired scientists to conduct a clinical trial but subsequently blocked the scientists' efforts to reveal that the drug was ineffective in slowing the progression of HIV-related disease.[20] As recounted by Haack, the manufacturer encouraged investors to believe Remune was effective, at the same time litigating against the scientists for violating an agreement to keep certain information confidential—information that would have shown the drug actually to be ineffective.[21] Although for a few years the manufacturer was able to maintain the illusion that Remune was effective, the unfavorable findings from the clinical trial eventually came to light and forced the company to abandon the drug.[22] Nevertheless, over that period, the company gave out false information—along with false hope—to AIDS patients and investors alike.

---

16. *Id.* at 40. Jasanoff further explains reasons for and methods to ensure such safeguards:

> [S]ome common pathologies of science-based decisionmaking [are] imperfect accountability, asymmetric standards, and excessive transparency. . . . All three affect the production of reliable scientific knowledge, but all reflect at bottom procedural deficiencies: withholding access from, or in some cases granting it to, the wrong people, at the wrong times, for the wrong purposes.

*Id.*

17. *Id.* at 42.

18. Susan Haack, *Scientific Secrecy and "Spin": The Sad, Sleazy Saga of the Trials of Remune,* 69 LAW & CONTEMP. PROBS. 47 (Summer 2006); Scott M. Lassman, *Transparency and Innuendo: An Alternative to Reactive Over-Disclosure,* 69 LAW & CONTEMP. PROBS. 69 (Summer 2006); Peter Lurie & Allison Zieve, *Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at FDA*, 69 LAW & CONTEMP. PROBS. 85 (Summer 2006).

19. Haack was included in PETER J. KING, 100 PHILOSOPHERS: THE LIFE AND WORK OF THE WORLD'S GREATEST THINKERS 180 (2004). She is the Cooper Senior Scholar in Arts and Science and Professor of Philosophy and Law at the University of Miami.

20. Haack, *supra* note 18, at 52–60.

21. *Id.*

22. *Id.* at 59.

Haack uses this case study to illustrate "how scientific inquiry can be hampered or perverted by pressure to transform it into boosterism for a product (or a policy)."[23] Haack concludes the "scientific ethos" is threatened when science becomes entangled with commercial interests and these types of relationships have significant consequences for the advancement of science.[24]

Many commentators have noted the recent, rapid demise of the barriers between commerce and science, particularly in medicine.[25] Aided by the passage of the Bayh-Dole Act,[26] universities are forming lucrative collaborations with private corporations.[27] In the medical sphere, much of this cooperation has focused on the development and testing of new drugs. Remune was only one of several recent episodes of data sequestration in which the sponsors of research used their financial control to the detriment of public health.[28] In response to this trend, a group of editors of the world's leading biomedical journals declared they would no longer publish articles based on studies conducted under contracts in which the investigators did not have the unfettered right to publish their findings.[29] They asserted that such contractual arrangements

> 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.[30]

Although the opprobrium of these editors undoubtedly focused the attention of the biomedical community on the sequestration of unfavorable clinical trial results, the intervention of New York Attorney General Eliot Spitzer has fundamentally altered the debate. In June 2004, Spitzer filed suit against GlaxoSmithKline (GSK), charging that the pharmaceutical company concealed unfavorable scientific studies on the efficacy and safety for children of the antidepressant Paxil.[31] Specifically, Spitzer alleged that GSK had withheld data that adolescents taking Paxil were at increased risk of suicidal thoughts and acts[32]—meaning the sequestration of this information might have prevented

---

23. *Id.* at 60.

24. *See id.* (noting that this pressure "damages the fragile social mechanisms that sustain the scientific ethos of honest investigation and encourage free exchange of ideas and information").

25. *See id.* at 47 (referencing the works of several commentators that discuss the potential problems of commercially sponsored scientific research).

26. 35 U.S.C. §§ 200–212 (1980). This legislation allows small businesses and universities to elect ownership of patents over inventions created with federal funding and to become directly involved in the process of commercialization; it has the "policy and objective" of "promot[ing] collaboration between commercial concerns and nonprofit organizations, including universities." *Id.* at § 200.

27. SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED THE VIRTUE OF BIOMEDICAL RESEARCH? (2003).

28. *See* Haack, *supra* note 18, at 60–61.

29. Frank Davidoff et al., *Sponsorship, Authorship and Accountability*, 286 JAMA 1232, 1233 (2001). The statement was jointly issued by the editors of thirteen leading journals.

30. *Id.*

31. *See* Complaint, State v. GlaxoSmithKline (N.Y. Sup. Ct. June 2, 2004), *available at* http://files.findlaw.com/news.findlaw.com/cnn/docs/glaxo/nyagglaxo60204cmp.pdf.

32. *See, e.g.*, Eliot Marshall, *Buried Data Can Be Hazardous to a Company's Health,* 304 SCIENCE 1576, 1576–77 (2004); Editorial, *Is GSK guilty of fraud?*, 363 LANCET 1919, 1919 (2004).

doctors treating children with mood disorders from considering all of the relevant scientific information necessary to make informed decisions with patients and their families. Less than a month after the suit was filed, GSK announced it would release the clinical data on Paxil's safety and effectiveness;[33] later that year, another pharmaceutical manufacturer agreed to create a public registry of clinical trials data for its antidepressant medications.[34]

These scandals, accompanied by empirical research showing they were not isolated instances but symptomatic of a larger problem,[35] have contributed to a change in the relationship between the pharmaceutical industry and the editors of the medical journals in which clinical trial results are published. Several physicians who have served as editors of the most important biomedical journals have written scathing critiques of drug company practices, focusing particularly on the publication and interpretation of clinical trial results.[36] In fact, the culture of drug testing has changed sufficiently that it is now widely recognized that pharmaceutical manufacturers have an obligation to report the existence and results of all clinical trials,[37] although this is often not done satisfactorily.[38]

---

33. *See* Press Release, Office of New York State Attorney General Eliot Spitzer, Statement Regarding Decision by GlaxoSmithKline to Post Summaries of Clinical Trial Result (June 18, 2004)(on file with author). Spitzer stated that it was "unacceptable for companies like GSK to divulge favorable results while hiding negative data when the health of patients is at stake." *Id.*

34. Press Release, Office of New York State Attorney General Eliot Spitzer, Forest Labs to Establish Clinical Trials Registry (Sept. 7, 2004)(on file with author).

35. *See* An-Wen Chan et al., *Empirical Evidence for Selective Reporting of Outcomes in Randomized Trials: Comparison of Protocols to Published Articles.* 291 JAMA 2457, 2457–65 (2004) ("The reporting of trial outcomes is not only frequently incomplete but also biased and inconsistent with protocols."). This research arose out of the uproar around incomplete reporting of clinical trial results, which led investigators to study the conduct and reporting of research itself. One of the challenges in conducting this research was to identify either a representative or complete sample of clinical trials that have been initiated in order to see when and how the results were provided to the public. An ingenious group of European researchers was able to take this on, utilizing the records of the Scientific-Ethical Committees for Copenhagen and Frederiksberg, Denmark, the Institutional Review Board (IRB) through which all clinical trials conducted in that region must be registered and approved. There were 102 trials approved in 1994–1995 that eventually were completed and published, resulting in 122 journal articles. The researchers found that half the efficacy outcomes and sixty-five percent of harm outcomes were incompletely reported. More than sixty percent of the trials had at least one primary outcome that was changed, introduced after the protocol was approved, or omitted. Eighty-six percent of survey responders (forty-two out of forty-nine) denied the existence of unreported outcomes despite clear evidence to the contrary. *Id.* at 2457.

36. *See, e.g.*, MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES (2004); JEROME P. KASSIRER, ON THE TAKE: HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH (2005); Richard Smith, *Medical Journals are an Extension of the Marketing Arm of Pharmaceutical Companies*, 2 PUB. LIBR. SCI. MED. 364, 364–66 (2005).

37. *See* C. DeAngelis et al., *Is this Clinical Trial Fully Registered? A Statement from the International Committee of Medical Journal Editors*, 352 N. ENG. J. MED. 2436, 2436–38 (2005) "In September 2004, the members of the International Committee of Medical Journal Editors (ICMJE) published a joint editorial aimed at promoting registration of all clinical trials." The members of the ICMJE will consider a trial for publication only if it is registered for the purpose of providing a "comprehensive, publicly available database of clinical trials."

38. *See* C. Rowland, *Drug Firms Lagging on Openness*, BOSTON GLOBE, Jan. 9, 2005, at A1. Despite increased levels of voluntary disclosure by drug firms, "[a] *Globe* review of websites indicates that the voluntary approach has produced limited disclosures thus far." *Id.*

Another aspect of the movement for increased disclosure or transparency is the Food and Drug Administration's (FDA) new "Drug Safety Initiative," which seeks to increase the access of patients, health care providers, and consumers to drug safety information.[39] A component of this initiative would be a proposed "Drug Watch" website, intended to enable FDA to "communicate emerging safety information to the public" while it is under evaluation by the agency.[40]

Scott Lassman asserts in his paper that although this FDA goal of "prompt communication of important and useful safety information about drug products to physicians and patients" is a laudable one, the FDA's planned website could actually have an adverse impact on public health.[41] Specifically, Lassman projects that the use of the website "would (1) disseminate unverified and potentially misleading safety information; (2) prompt physicians and patients to make healthcare decisions based on little more than scientific innuendo; and, (3) undercut well-established methods of risk communication, such as the approved drug label."[42] Lassman's preference would be to use the website "as part of an accelerated labeling revision process, which would provide valid and useful safety information in a more timely manner."[43]

Although much of Lassman's paper focuses on the Pharmaceutical Research and Manufacturers of America's (PhRMA) detailed concerns about this current FDA proposal,[44] it also raises fundamental issues that transcend the specifics of the proposed Drug Watch website. At its heart, Lassman's paper addresses a common dispute in public health: when and how the public should be informed about possible health risks. Proponents of a broad "right to know" argue that information should not be kept from the public, even if its implications are not yet clear.[45] They argue that freedom of choice is hampered if relevant (if imperfect) information is withheld.[46] Finally, even if dissemination of research results should be limited in some cases, they question whether manufacturers of

39. Press Release, Food and Drug Administration, New Drug Safety Initiative (May 5, 2005), *available at* http://www.fda.gov/cder/drugSafety.htm.

40. Draft Guidance for the Industry on the Food and Drug Administration's "Drug Watch" for Emerging Drug Safety Information; Availability, 70 Fed. Reg. 24,606 (May 10, 2005).

41. Lassman, *supra* note 18, at 69. Lassman is Assistant General Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA).

42. *Id.*

43. *Id.*

44. *See also* Scott Lassman & Alan Goldhammer, *RE: Docket No. 2005D-0062, FDA Request for Comments on the Draft Guidance entitled, "FDA's 'Drug Watch' for Emerging Drug Safety Information,"* 70 Fed. Reg. 24,606 (May 10, 2005), (PhrMA), Aug. 8, 2005, *available at* http://www.fda.gov/ohrms/dockets/dockets/05d0062/05d-0062-c000013-vol1.pdf.

45. *See* John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261 (1991); Mary Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data,* 87 MICH. L. REV. 1795 (1989); David Roe, *Barking up the Right Tree: Recent Progress in Focusing the Toxics Issue*, 13 COLUM. J. ENVTL. L. 275 (1988).

46. *Id.*

potentially harmful substances should be making decisions about when risk information is reliable enough to release to the public.[47]

In this context, Lassman's paper raises the issue of the control of dissemination of vital information about product safety. As Lassman notes, the primary and current mechanism for communicating about risks associated with taking a particular pharmaceutical is the label.[48] This label generally refers not to something affixed to the package but to the lengthy enclosure provided to purchasers and published in advertisements extolling the efficacy of a medicine. Currently, drug labels are often the product of extensive negotiation between FDA and a drug's manufacturer.[49] Opposing FDA's efforts to establish a mechanism independent of the drug manufacturers to communicate data on drug safety, Lassman's paper argues for maintaining the role of the manufacturer in interpreting data on risks associated with drugs and in shaping how this information is conveyed to physicians and consumers.[50]

The Public Citizen's Health Research Group (HRG) has been closely monitoring the new FDA drug approval process for several decades, starting long before the recent, highly publicized episodes of data sequestration cited above.[51] The HRG provides the public with an independent appraisal of the data that manufacturers provide to FDA, then continues to examine the safety and efficacy of drugs after they have been approved by the agency.[52] According to the HRG, the organization has filed twenty-seven petitions since 1971 requesting FDA to withdraw drugs from the market, contending that the drugs were not efficacious or that their risks outweighed their benefits.[53] For the most part, FDA eventually

---

47. *Id.*

48. Lassman, *supra* note 18, at 76–78.

49. *See* Gardiner Harris, *F.D.A. Official Admits 'Lapses' on Vioxx,* N.Y. TIMES, Mar. 2, 2005, at A15 (quoting an FDA official that the agency "[doesn't] have the authority to tell a company, 'this is how your label has to look'. . . . We have to negotiate with the company the specific language of how things should be worked, the placement, those kinds of things, after talking to them."). This statement came in testimony at a 2004 U.S. Senate hearing investigating FDA's approval of Vioxx (rofecoxib), a situation that illustrates the public health consequences of FDA's inability to specify the content of warning labels. It took more than a year for information about the cardiovascular risks of Vioxx identified by an FDA advisory panel to be added to the drug's label. According to at least one account, FDA and Merck "battled over the label." Anna Wilde Mathews, *Did FDA Staff Minimize Vioxx's Red Flags?*, WALL ST. J., Nov. 10, 2004, at B1. *See also* Anna Wilde Mathews & Barbara Martinez, *E-mails Suggest Merck Knew Vioxx's Dangers at Early Stage*, WALL ST. J., Nov. 1, 2004, at A1.

50. Notwithstanding Lassman's conclusions, the recent history of the marketing and withdrawal of Vioxx (rofecoxib), discussed *infra* in Part III, is an illustration of the problems associated with that type of reliance on the interpretation of data by scientists with financial conflicts of interest.

51. For more information about Public Citizen's Health Research Group, see http://www.citizen.org/hrg.

52. *Id.*

53. Sidney Wolfe, *Is the FDA Adequately Assuring Drug Safety?,* Power Point Presentation at the Food and Drug Law Institute (FDLI) 48th Annual Conference, *Preparing for the Next Century of Drug Regulation*, April 7, 2005.

agreed with the HRG's independent assessments, indicating that the HRG's interventions have made a significant contribution to public health.[54]

The paper by Peter Lurie and Allison Zieve is an analytical examination of the HRG's attempts to monitor the workings of FDA's drug approval process through disclosure mechanisms provided by two important sunshine statutes:[55] the Freedom of Information Act (FOIA)[56] and the Federal Advisory Committee Act (FACA).[57] New drug applications are reviewed by FDA advisory committees, whose recommendations are generally accepted by the agency.[58] As a result of a successful HRG lawsuit, FDA initiated a policy to place the materials already provided to advisory committee members on the FDA website twenty-four hours prior to each advisory committee meeting,[59] enabling members of the public to have adequate information to participate meaningfully in the meeting.

Lurie and Zieve also describe how, despite this success in fighting for greater transparency, FDA has withheld other information that the HRG believes would be beneficial to public health. Lurie and Zieve conclude

> [a]t each step of the drug approval process, a variety of documents of potential relevance to the public health are generated. To date, numerous contentious legal battles have been waged to obtain access to information generated during various stages in this process, with FDA typically weighing in alongside the manufacturer and favoring nondisclosure. Obstacles to the release of information at each of these stages must be addressed if optimal transparency in the drug approval process is to be assured.[60]

FOIA and FACA, two of the basic tools used by the public to monitor the activities of the government, are also a major focus of the paper by Sidney A. Shapiro and Rena I. Steinzor.[61] These authors assert that the administration of President George W. Bush has invoked the "war on terrorism" to justify withholding information that was routinely disclosed by past Presidents;[62] moreover, they argue that recent "[j]udicial interpretations and executive

---

54. Of the drugs implicated in the twenty-seven petitions, eighteen (sixty-seven percent) were eventually withdrawn from the market, and the use of an additional four (fifteen percent) has been severely limited. *Id.*

55. Lurie & Zieve, *supra* note 18, at 87–95. Lurie is a physician and Deputy Director of HRG; Zieve is Senior Attorney of HRG.

56. 5 U.S.C. § 552 (2000). FOIA requires that, upon request by any person, an agency must disclose documents that do not fall into one of nine specific exemptions from disclosure. *Id.*

57. 5 U.S.C. App. II §§ 1–15 (2000). Federal advisory committees constituted under FACA are subject to disclosure requirements, including an advance notice of upcoming meetings and opportunities for public attendance and input. *Id.* at § 10.

58. Kenneth I. Kaitin, et al., *FDA Advisory Committees and the New Drug Approval Process*, 29 J. CLINICAL PHARMACOLOGY 886 (1989).

59. Lurie & Zieve, *supra* note 18, at 90.

60. *Id.* at 93.

61. Sidney A. Shapiro & Rena I. Steinzor, *The People's Agent: Executive Branch Secrecy and Accountability in an Age of Terrorism,* 69 LAW & CONTEMP. PROBS. 99, (Summer 2006). Shapiro is Distinguished Chair in Law at Wake Forest University, and Steinzor is Professor of Law at University of Maryland School of Law. Both authors are among the founders of the Center for Progressive Reform, a nonprofit research and educational organization that focuses on the government's role in protecting health, safety, and the environment.

62. *Id.* at 97.

branch hostility have narrowed the application of both FOIA and FACA."[63] The authors further describe the Critical Infrastructure Information Act (CIIA), enacted as part of the Homeland Security Act of 2002,[64] and its implications on the public's ability to learn more about the functioning of the U.S. government.

Shapiro and Steinzor call on Congress to reverse the judicial interpretations that have weakened FOIA and FACA and to restore the open government requirements that Congress originally intended in these sunshine laws. Echoing other papers in this collection, Shapiro and Steinzor recognize that "wise policymaking requires a balancing of competing interests in secrecy and openness."[65] It is of particular importance, therefore, that "such decisions . . . be made by dispassionate and authoritative officials who have no personal stake in whether the information is ultimately disclosed."[66]

These calls for developing principled approaches to maintaining the desired balance between openness and sequestration are underscored by Daniel J. Givelber and Anthony Robbins, who examine the potential impact on public health of information uncovered in litigation.[67] Givelber and Robbins call attention to "[p]rotective orders and other secrecy agreements [that] have shielded many patterns of injury and disease associated with dozens of materials, products, and processes."[68] While recognizing there are valid reasons for secrecy, the authors ask, "Should courts, as public entities devoted to dispute resolution, tolerate, endorse, or protect secrecy when the sequestered information might help protect the public health?"[69]

Not all courts uniformly protect the ability of plaintiff and defense counsels to sequester information whose disclosure may benefit the public.[70] For

---

63. *Id.* at 99. Evidently this antipathy to open-government statutes has deep roots. Two prominent members of the Bush Administration were opposed to legislation expanding FOIA when it was passed by Congress in 1977; at that time, current Secretary of Defense Donald Rumsfeld was Chief of Staff to President Gerald Ford, and now-Vice President Richard Cheney was his deputy. *See id.* at 126. ("Presumably acting under [Rumsfeld's and Cheney's] advice, President Ford vetoed amendments expanding the FOIA, only to have his veto overridden by Congress.").

64. 6 U.S.C. § 131 (2002).

65. Shapiro & Steinzor, *supra* note 61, at 99.

66. *Id.*

67. Daniel J. Givelber & Anthony Robbins, *Public Health vs. Court-sponsored Secrecy,* 69 LAW & CONTEMP. PROBS. 131 (Summer 2006). Givelber's and Robbins's work is itself a collaboration of law and public health; Givelber, Professor of Law at Northeastern School of Law, served as that school's dean from 1984 until 1993. Robbins is a national figure in public health, having directed the Vermont State Health Department, the Colorado Department of Health, the U.S. National Institute for Occupational Safety and Health, and the U.S. National Vaccine Program. Currently he is Professor of Public Health at Tufts University School of Medicine, and a member of the SKAPP planning committee.

68. *Id.* at 131.

69. *Id.* at 129.

70. *See* Arthur R. Miller, *Confidentiality, Protective Orders, and Public Access to the Courts*, 105 HARV. L. REV. 427, 490–501 (1991). One important rationale often made for confidentiality agreements is efficiency; there is debate over a feared "chilling" impact of forced transparency on the willingness of parties to settle cases before trial. Some years ago, Arthur R. Miller wrote that restrictions on the use of mechanisms that sequester information uncovered in the course of litigation

example, judges in toxic tort cases must consider this issue specifically in approving secrecy agreements that encourage settlement and docket clearing.[71] Some have issued rules "disfavoring court-ordered secrecy in cases affecting public safety;"[72] others have suggested that "[p]erhaps existing rules of civil procedures and ethics should be altered to encourage attorneys as well as judges to more carefully consider the interests of scientists and the general public interest in publication of private information when resolving legal disputes."[73]

Givelber and Robbins contribute to this dialogue with an intriguing proposal to expand the nexus beyond the behavior of judges and attorneys. In cases in which the defendant has previously used confidentiality agreements to sequester information about products or practices implicated in subsequent injuries, the authors recommend allowing a jury to decide if the defendant's involvement in a secrecy agreement influences the defendant's punitive liability.[74]

While Givelber and Robbins focus on secrecy in court proceedings, James W. Conrad Jr. describes the requirements for transparency in regulation of chemicals and contends that economic considerations do not result in concealment of health or safety data.[75] He maintains that federal statutes requiring disclosure—such as the Toxic Substances Control Act (TSCA),[76] the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),[77] and Sarbanes-Oxley,[78] as well as legal disincentives to concealment, including fear of potential

---

would discourage settlements and result in further burdening the court system. *Id.* These restrictions are unnecessary, because judges currently have the discretion to ensure that information important to public welfare is provided to appropriate government agencies. *Id.* In response, James E. Rooks Jr. has recently pointed out that there is no empirical evidence of an increase in trial rates in jurisdictions imposing limits on secrecy in litigation. James E. Rooks Jr., *Settlements and Secrets: Is the Sunshine Chilly?*, 55 S.C. L. REV. 859, 870–75 (2004).

71. *See* Jack B. Weinstein, *Symposium: Panel II: Secrecy and the Civil Justice System, Secrecy in Civil Trials: Some Tentative Views*, 9 J. LAW & POL'Y 53, 65 (2000) (maintaining that while "each case is different," generally, "where there is doubt, secrecy [orders in litigation] should be rejected").

72. *See* Joseph S. Anderson, *Hidden from the Public by Order of the Court: The Case Against Government-Enforced Secrecy*, 55 S.C. L. REV. 711, 716–50 (2004) (discussing the actions taken in such cases by the judges of the U.S. District Court for the District of South Carolina).

73. Jack B. Weinstein & Catherine Wimberly, *Secrecy in Law and Science,* 23 CARDOZO L. REV. 1, 11 (2001). Judge Jack Weinstein is Senior Judge of the U.S. District Court for the Eastern District of New York and has presided over mass torts cases involving, among other toxins, asbestos, and agent orange.

74. Givelber & Robbins, *supra* note 67, at 136.

75. James W. Conrad, Jr., *Open Secrets: The Widespread Availability of Information about the Health & Environmental Effects of Chemicals,* 69 LAW & CONTEMP. PROBS. 141 (Summer 2006). Conrad is Assistant General Counsel of the American Chemistry Council, the trade association of U.S. chemical manufacturing companies.

76. 15 U.S.C. §§ 2601–2692 (2000).

77. 7 U.S.C. §§ 136–136y (2000).

78. Pub. L. No. 107-204, 116 Stat. 745 (2002) (codified as amended in scattered sections of 15 U.S.C.).

civil liability—are adequate to ensure the full disclosure of relevant health and safety data.[79]

Conrad enumerates and describes a variety of health, safety, and environmental laws that involve the production of information about chemical toxicity, but he does not evaluate the factors that encourage or discourage the disclosure of that information.[80] For example, the classification of data submitted by chemical manufacturers to the U.S. Environmental Protection Agency (EPA) as "confidential business information" (CBI) provides a useful illustration of the gap between statute and practice. In a recent evaluation of EPA ability to assess health risks and manage its chemical review program, the U.S. Government Accountability Office (GAO) found that chemical manufacturers make CBI claims in ninety-five percent of the new chemical premanufacture notices.[81] The burden of evaluating the validity of all of these CBI claims falls on a resource-poor EPA, which rarely attempts to do so.[82]

Similarly, Conrad provides a useful listing of incentives for disclosure, including the effect of potential civil liability. He acknowledges the important role of toxic tort suits in encouraging manufacturers "not only to act on risk information, but to affirmatively design products and services to minimize or avoid creating such risks in the first place." Missing from his discussion, though, are the disincentives—the factors that discourage transparency. Returning to CBI, for example, there is in fact a strong incentive for chemical manufacturers to apply the CBI label in a most expansive manner, and little disincentive for them not to do so.[83]

---

79. Conrad, *supra* note 75, at 163.

80. *Id.* at 140–55.

81. U.S. GEN. ACCOUNTING OFFICE, REP. 05-458, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 5 (2005).

> TSCA generally prohibits disclosing to nonfederal officials trade secrets and privileged or confidential information protected under the Freedom of Information Act. In addition, TSCA authorizes chemical companies to claim data as confidential business information. According to EPA officials, about 95 percent of the premanufacture notices for new chemicals submitted by chemical companies contain some information that is claimed as confidential. . . . While TSCA confidential business information can be provided to federal officials and contractors, it generally cannot be provided to other organizations responsible for assessing chemical risks, enforcing chemical control laws, and performing other environmental activities, including state regulatory agencies and foreign governments.

82. *See id.* ("While EPA has the authority to evaluate the appropriateness of confidentiality claims and can deny companies' claims of confidentiality if they are found to be illegitimate, these efforts are time[-] and resource-intensive, and the agency does not have the resources to challenge a significant[ly] large number of claims.").

83. *See* Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research,* 30 AM. J.L. & MED. 119, 130 (2004) ("Under most existing regulations, the CBI claims require no substantiation—a manufacturer has only to stamp the documents "confidential" for the privilege to apply."). In fact, no official from the company need take responsibility for asserting the claim; there are no penalties for asserting the claim when it is facially frivolous; and the firm is presumed to waive the privilege, or at least must justify it later, if they do not stamp this information as confidential when first submitting it to the agency. Once the information is publicly disseminated, the company loses its right to claim misappropriation of a trade secret. Based on this regulatory structure, firms openly concede that it is

Conrad also raises important concerns about the relationship of funding to the outcome of scientific studies. In particular, he asserts that skepticism about the integrity of research, often focused on studies funded by industry, should be applied equally to studies that are funded by plaintiffs' attorneys for use in litigation.[84] He points out that conflict-of-interest concerns apply to all science whose sponsors have a financial interest in the outcome.[85]

Indeed, there has been extensive discussion in the biomedical literature on this so-called funding effect, a term used to describe the correlation between the results of a study desired by a study's sponsors and the reported results of that study.[86] Several recent reviews have reported that pharmaceutical industry sponsorship was strongly associated with conclusions favorable to the sponsor.[87] Investigators have recently begun to explore whether a funding effect has tainted studies of the toxicity of industrial chemicals.[88] Still, it is important to note that plaintiff attorneys sponsor little scientific research. In contrast, the chemical industry currently employs thousands of scientists and supports a substantial proportion of the research in toxicology and related fields. The sheer number of such studies and the magnitude of potential exposure to the

---

more cost-effective for them to routinely stamp much internal information as CBI when no substantiation is required.

Studies show that firms take full advantage of this generous approach to trade secrets and make the claim for information even when doing so is clearly without merit. In 1990, for example, EPA reviewed CBI claims under the Toxic Substances Control Act and challenged some nonmeritorious claims. By 1992, "industry had voluntarily amended and withdrawn over 600 claims after EPA's inquiries." 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. *Id.* at 130–34.

84. Conrad, *supra* note 75, at 160–62.

85. *Id*.

86. SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED THE VIRTUE OF BIOMEDICAL RESEARCH? (2003).

87. J.E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review*, 289 JAMA 454, 454–65 (2003); Sheldon Krimsky, *The Funding Effect in Science and its Implications for the Judiciary*, 13 J. LAW & POL'Y 43 (2005); Joel Lexchin et al., *Pharmaceutical Industry Sponsorship and Research Outcome and Quality*, 326 BRIT. MED. J. 1167 (2003); Richard Smith, *Medical Journals are an Extension of the Marketing Arm of Pharmaceutical Companies*, 2 PUB. LIBR. SCI. MED. 364, 364-66 (2005).

88. *See* F.S. Vom Saal & C. Hughes, *An Extensive New Literature Concerning Low-dose Effects of Bisphenol A Shows the Need for a New Risk Assessment*, 113 ENVTL. HEALTH PERSP. 926 (2005) (discussing a possible funding effect in research on low-dose exposure to bisphenol A (BPA), an environmental estrogen used in the manufacture of polycarbonate plastic, a resin widely used in food cans and dental sealants). As recounted by the authors, exposure to BPA had been found in some studies to alter endocrine function at very low doses. In response, the American Plastics Council hired the Harvard Center for Risk Analysis (HCRA) to conduct a "weight of the evidence" review of the toxicology; the HCRA panel reviewed nineteen animal studies and reported that it found no consistent affirmative evidence of low-dose BPA effects. *Id.*

This conclusion was challenged by government-funded scientists who felt that HCRA had chosen to examine only a minority of the forty-seven studies available at the time. These scientists reviewed the 115 published studies available in December 2004 and found results that differed markedly from the HCRA analysis. They determined that ninety percent (94 of 104) of the studies paid for with government funds reported an effect associated with BPA exposure; however, not a single one of the eleven corporate-funded studies found an effect.

studied substances make it particularly important that these studies be available for public scrutiny and evaluation.

In the final paper, Allen L. White explores the movement toward corporate transparency in the global economy.[89] According to White, increased disclosure is driven by, among other factors, the international regime of "soft law," comprised of dozens of codes, principles, standards, and guidelines whose implementation is dependent on voluntarism and moral persuasion, rather than legal enforceability.[90] An important manifestation of this movement is the Global Reporting Initiative, in which more than six hundred major corporations issue annual "sustainability reports" encompassing environmental, social, and economic indicators.[91]

White calls for global standards for corporate disclosure, arguing that higher standards of disclosure "build confidence and efficiency in capital markets" and contribute to the "quantity and quality of knowledge-based assets."[92] Optimistically, he suggests that "public policies that drive higher standards of nonfinancial disclosure, especially those that relate to knowledge-based assets, are likely to yield a range of social benefits that have yet to achieve rigorous measurement and full disclosure."[93]

## III

## A PROPOSAL: SARBANES-OXLEY FOR SCIENCE

The questions discussed by these authors—namely, the costs and benefits associated with transparency in scientific research—are only a first step; as has been said many times, where you stand depends on where you sit. There is only limited value in asking a beneficiary of a decision to evaluate its costs and benefits to others.

Where does this leave us? Although there is a basic societal preference for transparency and openness, there are situations and types of information that demand sequestration. The tension is real and unavoidable. There are no fast and easy rules for determining which data should be open and which held secret. Indeed, it is very much determined by the situation. The length of time information is held secret also depends on the situation; for example, the time needed to avoid giving competitors a technological advantage is likely to be far shorter than that necessary to protect national security.

Since so much is open to interpretation and the stakes are so high, greater consideration needs to be given to the process that leads to information-sequestration or disclosure. The processes used to maintain secrecy are easily

---

89. Allen L. White, *Why We Need Global Standards for Corporate Disclosure,* 69 LAW & CONTEMP. PROBS. 167 (Summer 2006). White is Vice President of the Tellus Institute and co-founder of the Global Reporting Initiative.

90. *Id.* at 167.

91. *Id.* at 175.

92. *Id*.

93. *Id*.

abused, and the institutional tools and imperatives that hide data are stronger than those that promote data sharing. Rather than focus on the types of data that should be disclosed or sequestered, or on the processes and principles invoked to manage the disclosure and sequestration itself, I would like to begin the discussion with looking at new statutes that could be called "Sarbanes-Oxley for Science."

When the Enron and WorldCom scandals were revealed, the executives of those firms claimed that they were unaware of the accounting misrepresentations in which their companies were engaged.[94] The Sarbanes-Oxley legislation was an attempt to ensure that the most senior managers of companies are held accountable for providing false or misleading financial data to regulators and to the public.[95] The papers in this issue have identified a fundamental dilemma that in some ways parallels the concerns that led to Sarbanes-Oxley. At present, there is virtually no oversight or independent review of corporate decisionmaking as it relates to the sequestration of scientific data. An important lesson of the accounting scandals is that responsibility must be linked with accountability; this should apply to scientific as well as financial data.

In the areas of public health and the environment, as long as the choice as to what scientific data are provided to regulators and the public rests in the hands of its corporate producers, it seems reasonable for the public to demand a modicum of accountability from those making the choices. A Sarbanes-Oxley for Science would require corporations to designate a person responsible for reporting the results of studies undertaken by the firm. He or she would have to certify that the information provided to the public and regulatory agencies, along with the methods used to obtain this information, was presented accurately and completely, and he or she would also be responsible for justifying designations of confidentiality. The current Sarbanes-Oxley statute is sufficiently broad to protect whistleblowers who disclose certain types of scientific information,[96] but the Sarbanes-Oxley for Science would further protect from discrimination those corporate epidemiologists, toxicologists, and other scientists who might choose to reveal information improperly hidden from regulators.

Science, of course, is not accounting, and there are obvious limits to the application of accounting reporting requirements to the disclosure of scientific research findings. For example, although conventions and guidelines for the application of certain scientific methods and techniques do exist, hypothesis-

---

94. *See* Lisa M. Fairfax, *Form Over Substance?: Officer Certification and Promise of Enhanced Personal Accountability under the Sarbanes-Oxley Act*, 55 RUTGERS L. REV. 1, 12 (2002) (citing how several executives of Enron and WorldCom claimed to be unaware of their respective company's wrongdoing).

95. *Id.* at 1–4.

96. Pub. L. No. 107-204, 116 Stat. 745 (2002) (codified as amended in scattered sections of 15 U.S.C.). *See also* Robert G. Vaughn, *America's First Comprehensive Statute Protecting Corporate Whistleblowers,* 57 ADMIN. L. REV. 1 (2005).

driven science, in which creativity is highly valued, is less amenable to practice and reporting standards than the practice of accounting. Beyond the actual conduct of studies, the scientific enterprise requires the interpretation of the results of these studies, and the synthesis of the results and interpretation of many studies. Although science, like accounting, assumes the existence of an underlying truth, the policy shaped by science is driven by these interpretations and syntheses, rather than by the data themselves.

The importance of ensuring that data interpretation is independent of conflicts of interest is tragically illustrated by the debate on the cardiovascular effects of Merck's painkiller Vioxx (rofecoxib). In early 2000, the results of a clinical trial showed that participants who took Vioxx for an average of nine months had a significantly higher risk of heart attack than those taking the comparison painkiller, naproxen (sold under the brand name Aleve).[97] Since the comparison was between two biologically active products, scientists could have interpreted these results to mean either that Vioxx increased heart-attack risk or that naproxen reduced it. Unfortunately, Merck's researchers chose to promote the latter interpretation, ignoring other evidence that supported the former.[98] Fortunately, among the clinical trials Merck had initiated was one in which Vioxx was compared to a placebo.[99] When participants who took the drug for more than eighteen months suffered twice as many heart attacks and strokes as those taking the placebo, the trial was halted, and Vioxx was removed from the market.[100] FDA scientists subsequently estimated that Vioxx was responsible for between 88,000 and 139,000 heart attacks—thirty to forty percent of which were probably fatal—in the five years the drug was on the market.[101]

The raw data underlying study results are materials that should be considered in a Sarbanes-Oxley for Science initiative. Although raw data from government-funded studies are generally available to private parties for inspection and re-analysis (enabling product defense experts to conduct *post hoc* analyses that challenge troubling findings), industry actors are under no similar obligation to release comparable raw data from their own studies. When private sponsors conduct research to influence public regulatory

---

97. Claire Bombardier et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 343 N. ENG. J. MED. 1520, 1520 (2000).

98. *See, e.g.*, Marvin A. Konstam et al., *Cardiovascular Thrombotic Events in Controlled, Clinical Trials of Rofecoxib*, 104 CIRCULATION 2280, 2280–88 (2001); Marvin A. Konstam & Laura A. Demopoulos, Letter to the Editor, *Cardiovascular Events and COX-2 Inhibitors*, 286 JAMA 2809 (2001).

99. Merck conducted a trial to determine if Vioxx inhibited the development of colon polyps; since there are no other treatments that accomplish this, the study compared Vioxx with a placebo.

100. Press Release, Food and Drug Administration, FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product (Sept. 30, 2004) *available at* http://www.fda.gov/bbs/topics/news/2004/NEW01122.html; *see also* Robert S. Bresalier, Robert S. Sandler, Hui Quan, et. al., *Cardiovascular Events Associated with Rofecoxib in a Colorectal Adenoma Chemoprevention Trial*, 352 N. ENG. J. MED. 1092 (2005).

101. *FDA, Merk and Vioxx: Putting Patient Safety First?: Hearing before the S. Comm. on Finance*, 108th Cong. 1 (2004) (statement of David J. Graham, MD, MPH).

proceedings, these studies should be subject to the same access and reporting provisions as those applied to publicly funded science. Public health is not well served by the unequal treatment of public and private science.[102]

Independent processes and procedures—such as those that would be included in a Sarbanes-Oxley for Science—are needed to dictate the decisions to sequester or disclose scientific information, as well as to ensure accountability to the public of those who make such decisions. In the public sector, FOIA and FACA facilitate openness in decisionmaking, and these two valuable statutes need re-invigoration. For the private sector, additional accountability for those who make decisions around openness and sequestration would contribute to greater transparency and improved protection for the public health and environment.

## IV
## CONCLUSION

Data sequestration serves many functions, including protecting national security, investment value, and individual confidentiality. But it comes with societal costs, particularly around protecting the public health and environment, and excessive secrecy may damage the scientific enterprise itself.

The symposium papers in this issue tell us that, most basically, openness needs to be seen not as a simple characteristic of the scientific process, but as a dynamic process, in and of itself. Institutional structures and procedures must be built into a range of legal and regulatory activities so that all users of the results of scientific investigations—scientists and corporations, regulators and jurists, legislators and reporters—would be regularly required to ask and be asked if their actions sequestering data are truly necessary. Further, these users would have to consider whether the benefits that accrued from hiding the data outweighed those associated with openness—while also considering the fairness and impact of the ways in which those benefits are distributed.

The tension between openness and sequestration in science is not new, although we are at a point at which this conflict feels particularly acute, and the stakes seem particularly high. Secrecy is often the easier road, and transparency is not now, and perhaps never has been, the default position. We have learned from the debate reflected in these pages that it is exceedingly difficult to categorize in the abstract what types of data should be kept confidential and what should be released, and to whom. Sheila Jasanoff's words from this issue bear repeating: "[T]he degree of openness is context-specific and needs to be traded off against other important social values. The problem for contemporary law and policy is to develop principled approaches to

102. *See* Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research,* 30 AM. J.L. & MED. 119 (2004).

maintaining the desired balance."[103] The articles in this issue should contribute significantly to the continued pursuit of that balance.

103. Jasanoff, *supra* note 12, at 22.