

Scholars Promote “Sarbanes-Oxley for Science” and Other Solutions to Sequestered Science

October 10, 2006 - “Sequestered science” is scientific knowledge concealed from the public. Since science is built on the sharing of information, decisions to sequester data can hinder advancement in research and place public health in jeopardy. Legitimate claims to secrecy – to preserve national security, investment value, or individual confidentiality – must be weighed against their costs. *Sequestered Science: The Consequences of Undisclosed Knowledge*, the latest issue of the Duke University School of Law’s journal *Law and Contemporary Problems*, features several articles that discuss the tradeoffs involved in decisions to sequester science.

Most of the articles published in *Sequestered Science* were originally presented at the second Coronado Conference, which was organized by the Project on Scientific Knowledge and Public Policy (SKAPP) to explore the scientific and social consequences of failure to disclose scientific knowledge. Authors propose solutions to help balance the costs and benefits of such secrecy; these include altering courts’ settlement practices and treatment of confidentiality agreements, creating clinical trial registries, and adopting legislation modeled on the Sarbanes-Oxley Act to improve accountability in producing and submitting scientific data used in public health and environmental protection programs.

“The processes used to maintain secrecy are easily abused, and the institutional tools and imperatives that hide data are stronger than those that promote data sharing,” writes SKAPP Director David Michaels, PhD in the issue’s foreword.

Michaels cites tobacco and asbestos as “the best known and most tragic examples of data sequestration contributing to public health disasters” and adds Merck’s slanted interpretation of Vioxx clinical trial data to the list of cases in which a lack of transparency had widespread fatal consequences.

Michaels’s proposal, for a “Sarbanes-Oxley for Science,” involves mechanisms to ensure that scientific information provided to the public and regulatory agencies is accurate and complete, much as the Sarbanes-Oxley Act passed in the wake of the Enron and WorldCom accounting scandals attempts to ensure the accuracy of financial information. Scientists who reveal information improperly hidden from regulators would also receive whistleblower protections.

Other proposed solutions from this issue include the following:

- In “Transparency in Public Science: Purposes, Reasons, Limits,” Sheila Jasanoff, PhD, JD (Harvard University) describes some of the ways that court procedures often impede the free flow of knowledge. She recommends establishing a “register of studies, made suitably anonymous, conducted pursuant to products liability or environmental damage lawsuits.”

- In “Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at FDA,” Peter Lurie, MD and Allison Zieve, JD (both of Public Citizen’s Health Research Group) describe the difficulties confronting health advocates seeking data related to FDA’s drug approval process. They advocate that clinical trial registries (now a common policy proposal) include all efficacy trials for drugs and biologics; provide details on each study’s sample size, inclusion criteria, and planned endpoints; and have financial and other penalties for companies that fail to register their trials.
- In “Public Health Versus Court-sponsored Secrecy,” Daniel J. Givelber, LLM (Northeastern University School of Law) and Anthony Robbins, MD (Tufts University School of Medicine) suggest barring judges from enforcing confidentiality agreements between plaintiffs and defendants that suppress information relevant to public health. They also propose that juries be allowed to consider previously negotiated confidentiality agreements when deciding on liability for punitive damages.

These other articles explore additional cases of data sequestration, proposed solutions, and frameworks for considering the use of secrecy:

- “Scientific Secrecy and ‘Spin’: The Sad, Sleazy Saga of the Trials of Remune” by Susan Haack, PhD, University of Miami
- “Transparency and Innuendo: An Alternative to Reactive Over-Disclosure” by Scott M. Lassman, JD, Pharmaceutical Research and Manufacturers of America
- “The People’s Agent: Executive Branch Secrecy and Accountability in an Age of Terrorism” by Sidney A. Shapiro, JD, Wake Forest University, and Rena I. Steinzor, JD, University of Maryland Law School
- “Open Secrets: The Widespread Availability of Information about the Health and Environmental Effects of Chemicals” by James W. Conrad, JD, American Chemistry Council
- “Why We Need Global Standards for Corporate Disclosure” by Allen L. White, PhD, Tellus Institute

“The dialogue on secrecy and science, which these articles help to advance, is now more crucial than ever,” says Michaels. “The federal government is grappling with the balance between transparency and national security, while courts are hearing hundreds of cases about pharmaceuticals developed and approved in less-than-transparent processes. Judges, scientists, and lawmakers must have a clear picture of the tradeoffs involved when science is sequestered.”