By Margot Fenster

National Academy of Sciences Forum

Public Access to Research Data: A Right to Know or Off Limits?

The debate over how to balance the right of the public to access research data with the need to protect the privacy of individuals and the confidentiality of sensitive information has been ongoing for years. The National Academy of Sciences Forum on Public Access to Research Data: A Right to Know or Off Limits? aimed to address this issue.

So, which data should be protected, and which should be made public? The forum discussed the challenges of balancing privacy and public access.

Copyright and patent rights are important, but so are the rights of researchers. The forum highlighted the need to ensure that researchers are not precluded from accessing the data they need to do their work.

Dr. Kennedy explained that the regulations needed to be reviewed to determine which data could be made public and which should remain confidential. The forum emphasized the importance of finding a balance that respects both the public's right to access information and the rights of researchers and data owners.

The forum also addressed the issue of access to government-funded research data. The government has a responsibility to ensure that publicly funded research is made available to the public, but this must be done in a way that protects the privacy and confidentiality of individuals and organizations.

The forum concluded with a call for continued dialogue and collaboration among scientists, policymakers, and other stakeholders to develop a framework that balances the right to access research data with the need to protect privacy and confidentiality.
scientific papers; plans for future research, peer reviews; physical objects (literature samples and tape record-ings, for instance); trade secrets; com-mercial information; and information that could be used to identify a particu-lar person in a research study.

**Data: Definitions, Publication, Validation**

David Korn, MD, Senior Vice President for Biomedical and Health Sciences Research for the Association of Amer-i-can Medical Colleges (AAMC), moder-nated a panel at the forum on under-standing the scientific process. “The issue of individual privacy is red hot and highly contentious right now,” he said.

“AAMC is profoundly opposed to the proposed revisions to the Shelby amendment—known as the son/ daughter of Shelby—which would sig-nificantly widen the amendment’s applicability.” He has “envisioned the demise of new newspaper—and thousands of dollars in additional cost—that would be entailed in re-questing documentation, preparing it, prepa ring for transmission, and keeping records of the transmission.

But, said Dr. Korn, since the Shelby amendment and its proposed revisions are concerned with data and their pub-lication, one must first understand the universe of data and what it means to scientists and laypeople. For example, What is the nature of the scientific process? How are data collected and analyzed? What does peer review and publication mean? What are the strengths and limitations of meta-analy-sis?

Steve Goodman, MD, PhD, Asso-ciate Professor in Oncology at Johns Hopkins School of Medicine and a fac-ulty member in epidemiology and bio-statistics at Hopkins School of Public Health, discussed the scientific process to data reduction and said that all sci-entific claims contain some degree of uncertainty, although some, of course, are “more” certain.

There are many types of raw data, as well as many problems inherent in the collection, he said. All of it needs to be analyzed, and therein lies the rub—problems of accuracy and certainty. He described a number of ways to analyze data, including meta-analysis, and reviewed peer review, a concept, he said, that was much valued but greatly misunderstood.

“Peer review cannot detect fraud, and it does not validate data or their analysis,” Dr. Goodman said. “The major purpose is to advise journal edi-tors about the importance of a given research project and to provide some leverage to the claims that researchers make about the data they have collected and analyzed.”

He added that publication is a highly compressed summary of data and represents communication among scientists. It should not be construed as establishment of truth or fact. The issue is how sure one can be of the veracity of the claims and how much trust one can place in the researchers and their data analysis, which is particularly impor-tant for clinical trials, he noted. “Moreover, the much desired goal of replication may not be possible or even desirable.”

**Harvard Six Cities Study**

Another speaker, Douglas W. Dockery, ScD, Professor of Medicine in Epide-miology and Professor of Environmental Epidemiology at Harvard Medical School, was principal investi-gator for the Harvard Six Cities Study begun in 1973 to study the environmen-tal and health effects of air pollution at the behest of OMB and the National Institute of Environmental Health Sciences. Investigators measured air quality in six cities in the Midwest and East and analyzed the respiratory health of adults and children for more than 20 years.

To date, more than 100 papers have been published so far using those data, with more to come, he said. Most of the studies were reports of morbidity and mortality in relation to air pollution, and many concentrated on air pollution as one predictor of survival in the cities studied.

Dr. Dockery told the audience that the researchers knew from the outset that the data and their analysis would be used as a basis for public policy and legislation, yet they did not prepare the virulence and vari-ety of the criticism. “People questioned the validity of our data, the appropriateness of our statistical methods, and the biologic plausibility of the associa-tions between air pollution and mortalit-y,” he said.

Beset by an American Lung Association lawsuit against the Environ-mental Protection Agency (EPA), the Harvard scientists planned to use the data they had collected and ana-lyzed to force the agency to establish standards for particulate emissions, but they refused to make that data public. This was a major impetus for the Shelby amendment, Dr. Dockery noted.

He described the pains the researchers had taken to ensure the medical privacy of individuals partici-pating in the study and said that if this confidentiality can be breached or com-promised by access to data under FOIA, it would have a “chilling effect” on people’s willingness to participate in research.

The Six Cities Study went to great lengths to have the data validated by scientists and auditors at the Health Effects Institute, a nonprofit organiza-tion jointly supported by EPA and industry to provide independent research on the health effects of air pol-lution. The data and analysis were eventually validated, but it took more than a year and cost over a million dol-lars.

**Data Used in Role Making**

Another panel focused on the problems inherent in public accessibility to research data used in rule making—who should have access, the process used to provide that access, and protec-tions designed to protect trade secrets and individual privacy.

The panel moderator, Alan B. Morrison, LLB, Acting Director of Public Citizen, Inc. in Washington, DC, and Director of its Litigation Group, said that Public Citizen encourages OMB to improve public access to feder-ally funded research records and urges the agency not to impose limitations on that access.

Bruce Alberts, PhD, President of the National Academy of Sciences and Chair of the National Research Council, said there is a “fatal flaw” in using FOIA as a basis for the Shelby amend-ment.

“It is vague, unclear, and compli-cated, and places unnecessary burdens on scientists,” he said. “Furthermore, anybody can request any information for any reason because there is no need-to-know provision. The whole thing increases the amount of bureaucracy associated with doing science and makes the field less appealing as a career choice for young people.”

Wendy Baldwin, PhD, Deputy Director for Extramural Research at NIH, said that data sharing is much more public now than it was a decade ago and will probably be even more so in the future. “Research subjects need to be protected, and for this reason, FOIA, which is designed for public access, is not the proper vehicle. Science is not a public activity,” she added.

William H. Farland, PhD, Acting Deputy Assistant Administrator for Science in the EPA’s Office of Research and Development, described how data are treated in his agency. The flow is from data collection and analysis through risk assessment to risk man-agement to decision-making: “This is a legal deliberative process, and we believe that data in the hands of agency personnel represent confidential business information.”

Also on the panel, David G. Hawkins, JD, Director of the National Research Defense Fund Air and Energy Program, said that the Shelby amendment is “bad public policy.” It escates the bureaucracy of regulatory agencies and imposes costs on scien-tists and researchers. Moreover, the amendment applies only to federally funded research, so it is very one-sided,” he said.

William Kovacs, Vice President for Environment and Regulatory Affairs at the US Chamber of Commerce, said that data relevant to and part of public policy need to be shared. “The Shelby amendment is a way for FOIA to allow the public to hold federal agencies’ feet to the fire when they are reluctant to share research claimed to provide justi-fications for policy,” he remarked.

Jim J. Tozzi, co-founder of the Center for Regulatory Effectiveness in Washington, DC, and former Deputy Administrator of the OMB Office of Information and Regulatory Affairs, said that he opposes OMB’s proposal to exempt FOIA access to information that may be copyrighted, because “that includes practically everything.” The work of what can be covered under copyright is infinitely vast and includes all documents that researchers consider data, he said.

**Secrecy in Law and Science**

In a keynote speech, Jack Weinstein, LLB, Senior Judge for the US District Court for the Eastern District of New York, said, “Our society’s democratic ideology is based on the assumption that nothing should be hidden. However, it is also based on privacy—that every-thing should be hidden.”

He noted that each year he tells his new law clerks that everything they hear in chambers is sacrosanct. But he also tells them to keep their ears open to what’s going on elsewhere in the courthouse—and to tell him about it.

**Scientists, lawyers, and bureaucrats hold widely differing views on the issue of public access to research data.**

This drew a laugh, but Judge Weinstein was serious when he commented on the inconsistency of federal policies. On one hand there is FOIA and all that it requires, and on the other, the Fourth and Fifth Amend-ments of the Constitution, which pro-tect privacy.

“While the policies are inconsis-tent, we manage to apply both in a dynamic balance of shifting details,” he said. “I strongly support aspects of both, even though openness leads to more accurate fact-finding in court.”

The enormous scope and depth of the privacy-right-to-know dichotomy, he noted, permeates society, particularly the overlapping work of the judiciary, is largely irreducible except in prag-matic terms on a case-by-case basis, he (continued on page 34)
Advocate Program
continued from page 1

Mentors present their assessments of the day’s research highlights and then open the floor to advocate questions, either on the overview information just presented or relating to an assigned hot topic.

Peter M. Ravdin, MD, PhD, Associate Professor of Medicine and Oncology at the University of Texas Health Science Center at San Antonio, served as a mentor at the most recent San Antonio Breast Cancer Symposium: “I don’t know of a similar kind of program anywhere else,” he said in an interview in March.

Now beginning its fourth year, the Alamo Breast Cancer Foundation Patient Advocate Program brings together a select group of breast cancer advocates from across the country and around the world.

“And it certainly has been a big success. Many of the advocates are extremely knowledgeable about breast cancer. But the mentoring sessions are pitched so that anyone can understand the information. The questions range from actually quite sophisticated to more broad and general. Although the sessions are scheduled to last about an hour and a half, they often continue for two hours or more.”

Each advocate is required to write a two- to five-page summary of the information they have gathered on their specific topic. The summaries are discussed among the group and later published in a booklet that can be shared with other advocates. The up-to-the-minute information acquired on the various research topics—which number more than 40 at the most recent meeting—spreads quickly to breast cancer patients through local advocacy group newsletters, support groups, and word-of-mouth.

“Advocates take the knowledge they’ve acquired and go back to their groups and work with them,” explained Eileen Mueller, Coordinator of the Patient Advocate Program. “The information empowers advocates to do more. We see participants writing articles and taking more of a leadership role. I see their names everywhere, and we see them in Washington when we lobby. The whole premise of the program is that participants go back to their groups and teach others what they have learned—that they take this new knowledge and let it multiply.”

A Seat at the Table
Ms. Mueller credits symposium directors C. Kent Osborne, MD, and Charles A. Colman, Jr., MD, for originally suggesting the idea of a patient advocate program at the San Antonio meeting.

“We had been badgering symposium organizers for more involvement,” she said. “When we first started out, we practically had to beg to have a table at the meeting. But I think they watched us as we established a 24-hour help line and lobbied in Washington, and over time they came to realize that advocates can play an important role.

“When the symposium organizers came to us with the idea of forming an advocate program in conjunction with the symposium, we had no idea what we would be doing, but we jumped at the chance. The symposium funded us that first year, and we brought 13 advocates to the meeting. The next year we funded 36 advocates, and last year we funded 46 participants, including advocates from Canada, Israel, Germany, and the African nation of Cameroon.”

The Alamo group offers partial scholarships to advocates selected to attend the meeting. The scholarships, which are advertised through breast cancer advocacy groups and are now funded through pharmaceutical company support, are based on estimated travel costs and hotel accommodations.

Last year’s participants represented a diverse array of breast cancer advocacy groups, such as Y-ME, the Susan G. Komen Breast Cancer Foundation, the YWCA, the Women of Color Breast Cancer Support Group, Companeras en Accion, the Canadian Breast Cancer Network, and Patient’s Friends Society—Jerusalem.

Participant Selection
Participant selection criteria are strict and now require graduation from Project LEAD, a four-day science course conducted by the National Breast Cancer Coalition. Project LEAD (for Leadership, Education and Advocacy Development) brings in faculty from institutions such as Harvard, UCLA, and NIH to give advocates an intensive short-course in the basic science and epidemiology of breast cancer.

The topics include the biology of cancer; basic genetics, DNA, RNA, and proteins; statistics; descriptive and analytical studies; clinical trials; causality; meta-analysis; and screening. Participants also learn leadership and advocacy skills and are coached in how to participate in the scientific community.

More Involvement
The Alamo advocate-mentor program reflects the growing involvement and acceptance of breast cancer advocates in general throughout the scientific community.

Long-time advocate Barbara Parker, who participated in the most recent Alamo program, recalls how dramatically things have changed in the last decade, particularly in the last five years. She describes attending medical meetings on her own in the early ’90s and not feeling comfortable enough to step up to the microphone to ask questions. Within a few years, however, she was being invited to participate in research groups.

“At that time, the idea of having an advocate presence in the research community was quite a new concept,” said Ms. Parker, who in recent years has served on the breast committee of Cancer and Leukemia Group B, the steering committee of the Cancer Genetics Network, and the core committee of NCI’s Central Institutional Review Board.

“My reception at the time was polite, but skeletal. I sensed unspoken questions: What are you doing here? How could you possibly understand what we are doing? Are you going to interfere with our real work? What value could you possibly add?”

“Now, however, most researchers have been associated with advocates in one way or another, and I don’t have any feeling of ‘You don’t belong’ or ‘What could you possibly add?’” she continued. “Researchers’ fears have proved unwarranted, and there actually are occasions when we can add value to the discussion. Not all the time, but certainly some of the time.”

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Access
continued from page 53

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Judge Weinstein discussed privacy issues in a few highly publicized cases such as smoking bans, tobacco industry penalties, and breast implants, and he enumerated the following key questions that underlie the issues under consideration:

■ Are scientists entitled to the privacy of their files before they publish research findings?
■ What about the privacy rights of the subjects of scientific research, as well as their right to know that they are being experimented on in the first place, or even to profit from it?
■ If scientists do not publish their findings, should they be able to conceal wrong paths they have taken when they testify as experts?
■ Should attorneys be able to keep hiring successive experts, covering up failures to support their litigation until they find one who is compatible?
■ What is the judge’s role in deciding how and when to seal information from the public and from scientists that was obtained in the discovery and settlement phases of litigation?

Although Judge Weinstein did not answer these questions, he did say, “Scientific research would be enhanced by a limited scholar-researcher privilege that would increase confidence that government will not unnecessarily interfere with it. Such a privilege also would protect researcher-participant relationships and increase accuracy, thoroughness, and reliability of research data.

“Since, therefore, a strong argument in favor of a national researcher’s privilege. Copyright and patent rights are protected, so why not go one step beyond the patent and into the data that often lead to intellectual property and thus protect the inhoothe rights of researchers?”

What do breast cancer advocates bring to the table? Ms. Mueller points to a number of successes, including a role in increasing government funding for breast cancer research—from just under $900 million when the National Breast Cancer Coalition first began lobbying in Washington to $700 million in 2001.

John Mendelsohn, MD, President of the University of Texas MD Anderson Cancer Center in Houston,