

## National Academy of Sciences Forum

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

By Margot Fromer

Washington, DC—How much public access to scientific research data is appropriate? That question was debated

for a full day in March here at a National Academy of Sciences forum by a group of 200 scientists, attorneys, bureaucrats, and government regula-

Don Kennedy, PhD, President

Emeritus of Stanford University, Editor-in-Chief of *Science*, and Co-Chair of the Academy's Science, Technology, and Law Program, opened the forum by noting that two things have led to increased discussions of public access.

One is research fraud, and the other is the so-called Shelby amendment.

That amendment to the Freedom of Information Act (FOIA) was introduced by Senator Richard Shelby (R-AL) in 1997. Before its passage two years later, the Office of Management and Budget (OMB), which regulates FOIA, had not defined "data," but did permit the federal government to "obtain, reproduce, publish, or otherwise use the data first produced under an award."

Dr. Kennedy explained that the regulation applied (and still does) only to research conducted under federal auspices or with federal funds, but it was nevertheless confusing, because it also permitted agencies and other entities to limit public access to data if the scientists conducting the research could demonstrate reasons data should be kept confidential and exempted from disclosure by FOIA.

*"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 inchoate rights of researchers?"*

So, which federally supported data were subject to FOIA and which were not? It was extremely difficult to know, he noted, and the matter was further complicated by the fact that data that might be copyrighted also were excluded from work subject to public access.

In a letter to the Director of OMB, Senator Shelby and Senators Trent Lott (R-MS), Ben Nighthorse-Campbell (R-CO), and Phil Gramm (R-TX) said, "Such an exemption would eviscerate the proposal by allowing researchers and agency officials to deny any FOIA request for research data. The exclusion has no basis in FOIA and would significantly undermine the entire purpose of the law."

In one effort to clear up the confusion, the amendment defined research data as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. This does not mean that every conversation scientists have with one another will find its way into the public domain. There are exclusions: preliminary analyses; drafts of

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#### BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PROFESSIONAL INFORMATION BROCHURE)

#### INDICATIONS AND USAGE

ARIMDEX is indicated for the first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer.

ARIMDEX is indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following tamoxifen therapy.

Patients with CR-negative disease and patients who did not respond to previous tamoxifen therapy rarely responded to ARIMDEX.

#### CONTRAINDICATIONS

None known.

#### WARNINGS

ARIMDEX can cause fetal harm when administered to a pregnant woman. Anastrozole has been found to cross the placenta following oral administration at 0.1 mg/kg in rats and rabbits (about 3/4 and 1/5 times the recommended human dose, respectively, on a mg/m<sup>2</sup> basis). Studies in both rats and rabbits at doses equal to or greater than 0.1 and 0.02 mg/kg/day, respectively (about 3/4 and 1/5, respectively, the recommended human dose on a mg/m<sup>2</sup> basis), administered during the period of organogenesis showed that anastrozole increased pregnancy loss (increased pre- and/or post-implantation loss, increased resorption, and decreased numbers of live fetuses); effects were dose related in rats. Placental weights were significantly increased in rats at doses of 0.1 mg/kg/day or more.

Evidence of fetotoxicity, including delayed fetal development (i.e., incomplete ossification and depressed fetal body weight), was observed in rats administered doses of 1 mg/kg/day (which produced plasma anastrozole C<sub>max</sub> and AUC<sub>0-24</sub> that were 18 times and 9 times higher than the respective values found in healthy postmenopausal humans at the recommended dose). There was no evidence of fetotoxicity in rats administered doses up to 1.0 mg/kg/day. In rabbits, anastrozole caused pregnancy failure at doses equal to or greater than 1.0 mg/kg/day (about 16 times the recommended human dose on a mg/m<sup>2</sup> basis); there was no evidence of fetotoxicity in rabbits administered 0.2 mg/kg/day (about 3 times the recommended human dose on a mg/m<sup>2</sup> basis).

There are no adequate and well-controlled studies in pregnant women using ARIMDEX. If ARIMDEX is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus or potential risk for loss of the pregnancy.

#### PRECAUTIONS

**General:** Before starting treatment with ARIMDEX, pregnancy must be excluded (see WARNINGS).

ARIMDEX should be administered under the supervision of a qualified physician experienced in the use of anticancer agents.

**Laboratory Tests:** These-fold elevations of mean serum gamma-glutamyl transaminase (GGT) levels have been observed among patients with liver metastases receiving ARIMDEX or megestrol acetate. These changes were likely related to the progression of liver metastases in these patients, although other contributing factors could not be ruled out.

**Drug Interactions:** (See CLINICAL PHARMACOLOGY) Anastrozole inhibited in vitro metabolic reactions catalyzed by cytochromes P450 1A2, 2C8, 2C9, and 2A4 but only at relatively high concentrations. Anastrozole did not inhibit P450 2A6 or the polymorphic P450 2D6 in human liver microsomes. Anastrozole did not alter the pharmacokinetics of arifloprone. Although there have been no formal interaction studies other than with arifloprone, based on these *in vitro* studies, it is unlikely that co-administration of a 1 mg dose of ARIMDEX with other drugs will result in clinically significant drug inhibition of cytochrome P450-mediated metabolites of the other drugs.

An interaction study with warfarin showed no clinically significant effect of anastrozole on warfarin pharmacokinetics or anticoagulant activity.

**Drug/Laboratory Test Interactions:** No clinically significant changes in the results of clinical laboratory tests have been observed.

**Carcinogenesis:** A conventional carcinogenesis study in rats at doses of 1.0 to 25 mg/kg/day (about 8 to 200 times the daily maximum recommended human dose on a mg/m<sup>2</sup> basis) administered by oral gavage for up to 2 years resulted in an increase in the incidence of hepatocellular adenomas and carcinomas and uterine cervical polyps in females and thyroid adenomas in males at the high dose. A dose-related increase was observed in the incidence of ovarian and uterine hyperplasia in females. At 25 mg/kg/day, plasma AUC<sub>0-24</sub> levels in rats were 119 to 125 times higher than the level indicated in postmenopausal women at the recommended dose. A separate carcinogenicity study in mice at oral doses of 5 to 50 mg/kg/day (about 20 to 200 times the daily maximum recommended human dose on a mg/m<sup>2</sup> basis) for up to 2 years produced an increase in the incidence of benign ovarian stromal, epithelial and granulosa cell tumors at all dose levels. A dose-related increase in the incidence of ovarian hyperplasia was also observed in female mice. These ovarian changes are considered to be solvent-specific effects of anastrozole inhibition and are of questionable significance to humans. The incidence of lymphocytosis was increased in males and females at the high dose. At 50 mg/kg/day, plasma AUC levels in mice were 35 to 48 times higher than the level exhibited in postmenopausal women at the recommended dose.

**Mutagenesis:** ARIMDEX has not been shown to be mutagenic in *in vitro* tests (Ames and *in vivo* bacterial tests, CHO-K1 gene mutation assay) or clastogenic either *in vitro* (chromosome observations in human lymphocytes) or *in vivo* (interactions test in rats).

**Impairment of Fertility:** Studies to investigate the effect of ARIMDEX on fertility have not been conducted; however, chronic studies indicated hyperplasia of the testes and the presence of follicular cysts in rats administered doses equal to or greater than 1 mg/kg/day (which produced plasma anastrozole C<sub>max</sub> and AUC<sub>0-24</sub> that were 18 and 9 times higher than the respective values found in healthy postmenopausal humans at the recommended dose). In addition, hyperplastic uteri were observed in chronic studies of female dogs administered doses equal to or greater than 1 mg/kg/day (which produced plasma anastrozole C<sub>max</sub> and AUC<sub>0-24</sub> that were 22 times and 19 times higher than the respective values found in

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postmenopausal humans at the recommended dose). It is not known whether these effects on the reproductive organs of animals are associated with impaired fertility in humans.

#### Pregnancy/Pregnancy Category B: (See WARNINGS).

**Nursing Mothers:** It is not known if anastrozole is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ARIMDEX is administered to a nursing woman. (See WARNINGS and PRECAUTIONS.)

**Pediatric Use:** The safety and efficacy of ARIMDEX in pediatric patients have not been established.

**Geriatric Use:** In studies 0027 and 0028 about 50% of patients were 65 or older. Patients ≥ 65 years of age had moderately better tumor response and time to tumor progression than patients < 65 years of age regardless of randomized treatment. In studies 0024 and 0025 60% percent of patients were 65 or older. Response rates and time to progression were similar for the over 65 and younger patients.

#### ADVERSE REACTIONS

**First-Line Therapy:** ARIMDEX was generally well tolerated in two well-controlled clinical trials (i.e., Trials 0026 and 0027). Adverse events occurring with an incidence of at least 5% in either treatment group of trials 0026 and 0027 during or within 2 weeks of the end of treatment are shown in Table 5.

Table 5  
Number (%) of Subjects

Adverse event	ARIMDEX (n=500)	megestrol Acetate (n=511)
<b>Whole body</b>		
Arthralgia	83 (16.4)	81 (15.9)
Pain	70 (13.8)	73 (14.3)
Back pain	60 (11.9)	60 (11.7)
Headache	47 (9.3)	40 (7.8)
Abdominal pain	40 (7.9)	35 (6.8)
Chest pain	37 (7.3)	37 (7.2)
Flu syndrome	35 (6.9)	30 (5.8)
Pelvic pain	23 (4.5)	30 (5.8)
<b>Cardiovascular</b>		
Vasodilation	128 (25.3)	186 (36.2)
Hypertension	25 (4.9)	36 (7.0)
<b>Objective</b>		
Nausea	94 (18.6)	186 (36.2)
Constipation	47 (9.3)	86 (16.6)
Dizziness	43 (8.5)	33 (6.4)
Vomiting	38 (7.5)	36 (7.0)
Anorexia	26 (5.1)	46 (8.9)
<b>Metabolic and nutritional</b>		
Peripheral edema	51 (10.1)	41 (7.9)
<b>Musculoskeletal</b>		
Bone pain	54 (10.7)	52 (10.2)
<b>Nervous</b>		
Dizziness	33 (6.5)	22 (4.3)
Insomnia	30 (5.9)	30 (5.8)
Depression	23 (4.5)	27 (5.2)
Headache	19 (3.7)	26 (5.0)
<b>Respiratory</b>		
Cough increased	55 (10.9)	52 (10.2)
Dyspnea	51 (10.1)	47 (9.2)
Pharyngitis	49 (9.7)	88 (17.2)
<b>Skin and appendages</b>		
Rash	38 (7.5)	34 (6.6)
<b>Unspecified</b>		
Leukopenia	9 (1.8)	31 (6.1)

\*A patient may have had more than 1 adverse event.

Less frequent adverse experiences reported in patients receiving ARIMDEX 1 mg in either Trial 0026 or Trial 0027 were similar to those reported for second-line therapy.

Based on results from second-line therapy and the established safety profile of anastrozole, the incidences of 9 pre-specified adverse event categories potentially causally related to one or both of the therapies because of their pharmacology were statistically analyzed. No significant differences were seen between treatment groups.

Table 6  
Number (%) and Percentage of Patients

Adverse Event Group <sup>1</sup>	ARIMDEX 1 mg (n=500)	megestrol Acetate (n=511)
Depression	20 (4.0)	37 (7.2)
Tumor Pain	16 (3.2)	18 (3.5)
Thrombotic Disease <sup>2</sup>	10 (2.0)	23 (4.5)
Vascular <sup>3</sup>	5 (1.0)	15 (2.9)
Cardiomy and Coronary	15 (3.0)	19 (3.7)
Gastrointestinal Disturbance	170 (33.8)	196 (38.4)
Hot Flashes	134 (26.8)	115 (22.5)
Vaginal Dryness	9 (1.7)	2 (0.4)
Leukopenia	6 (1.2)	15 (2.9)
Vaginal Bleeding	5 (1.0)	11 (2.2)
Weight Gain	11 (2.2)	8 (1.5)

\*A patient may have had more than 1 adverse event.

<sup>1</sup> Includes pulmonary embolism, thrombotic thrombocytopenic, retinal vein thrombosis.

<sup>2</sup> Includes myocardial infarction, myocardial ischemia, angina pectoris, cerebrovascular accident, cerebral ischemia and cerebral infarct.

Despite the lack of estrogenic activity for ARIMDEX, there was no increase in myocardial infarction or fracture when compared with tamoxifen.

**Second-Line Therapy:** ARIMDEX was generally well tolerated in two well-controlled clinical trials (i.e., Trials 0024 and 0025), with less than 3.3% of the ARIMDEX-treated patients and 4.3% of the megestrol acetate-treated patients withdrawing due to an adverse event.

The principal adverse event more common with ARIMDEX than megestrol acetate was diarrhea. Adverse events reported in greater than 5% of the

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patients in any of the treatment groups in these two well-controlled clinical trials, regardless of causality, are presented below.

Table 7  
Number (%) and Percentage of Patients with Adverse Event

Adverse Event	ARIMDEX 1 mg (n=282)	ARIMDEX 10 mg (n=248)	megestrol Acetate 160 mg (n=253)
Arthralgia	40 (14.0)	32 (12.9)	47 (18.6)
Nausea	45 (15.9)	48 (19.5)	38 (15.1)
Headache	34 (12.0)	44 (17.8)	34 (13.5)
Hot Flashes	32 (11.2)	29 (11.8)	21 (8.3)
Pain	28 (10.1)	38 (15.4)	29 (11.5)
Back Pain	28 (10.1)	26 (10.6)	19 (7.5)
Dyspnea	24 (8.2)	27 (11.0)	33 (12.9)
Vomiting	24 (8.2)	28 (11.4)	16 (6.3)
Cough increased	22 (7.8)	18 (7.3)	19 (7.5)
Diarrhea	22 (7.8)	18 (7.3)	7 (2.8)
Constipation	18 (6.4)	18 (7.3)	21 (8.3)
Abdominal Pain	18 (6.4)	14 (5.7)	15 (5.9)
Anorexia	18 (6.4)	18 (7.3)	11 (4.3)
Bone Pain	17 (6.0)	26 (10.6)	19 (7.5)
Pharyngitis	16 (5.7)	23 (9.3)	15 (5.9)
Insomnia	16 (5.7)	12 (4.8)	13 (5.1)
Rash	15 (5.3)	15 (6.1)	19 (7.5)
Dry Mouth	15 (5.3)	15 (6.1)	13 (5.1)
Peripheral Edema	14 (5.0)	21 (8.5)	28 (11.1)
Pelvic Pain	14 (5.0)	17 (6.9)	13 (5.1)
Depression	14 (5.0)	6 (2.4)	5 (2.0)
Diarrhea	13 (4.6)	12 (4.8)	13 (5.1)
Flu Syndrome	12 (4.3)	15 (6.1)	9 (3.6)
Vaginal Hemorrhage	8 (2.8)	4 (1.6)	13 (5.1)
Weight Gain	4 (1.4)	3 (1.2)	10 (3.9)
Swelling	4 (1.4)	3 (1.2)	16 (6.3)
Increased Appetite	3 (1.1)	1 (0.4)	13 (5.1)

†A patient may have more than one adverse event.

Other less frequent (2% to 5%) adverse experiences reported in patients receiving ARIMDEX 1 mg in either Trial 0024 or Trial 0025 are listed below. These adverse experiences are listed by body system and are in order of decreasing frequency within each body system regardless of assessed causality.

**Body as a Whole:** Flu syndrome; fever; neck pain; malaise; accidental injury; infection.

**Cardiovascular:** Hypertension; thrombotic thrombocytopenic.

**Respiratory:** Cough increased; SOB; increased; SGGT increased.

**Metabolic and Nutritional:** Anorexia; hypotension; weight loss.

**Musculoskeletal:** Myalgia; arthralgia; pathological fracture.

**Nervous:** Somnolence; confusion; insomnia; anxiety; nervousness.

**Respiratory:** Sinusitis; bronchitis; rhinitis.

**Skin and Appendages:** Hair thinning; pruritus.

**Genitourinary:** Urinary tract infection; breast pain.

Vaginal bleeding has been reported infrequently, mainly in patients during the first few weeks after changing from existing hormonal therapy to treatment with ARIMDEX. If bleeding persists, further evaluation should be considered.

During clinical trials and postmarketing experience joint pain/syndrome has been reported in association with the use of ARIMDEX.

The incidences of the following adverse events groups potentially causally related to one or both of the therapies because of their pharmacology were statistically analyzed: weight gain, edema, thrombotic disease, gastrointestinal disturbance, hot flashes, and vaginal dryness. These six groups, and the adverse events shown in the groups, were prospectively defined. The results are shown in the table below.

Table 8  
Number (%) and Percentage of Patients

Adverse Event Group	ARIMDEX 1 mg (n=282)	ARIMDEX 10 mg (n=248)	megestrol Acetate 160 mg (n=253)
Gastrointestinal Disturbance	27 (9.6)	81 (32.8)	54 (21.3)
Hot Flashes	38 (13.5)	29 (11.8)	36 (14.2)
Edema	18 (6.4)	26 (10.6)	36 (14.2)
Thrombotic Disease	9 (3.2)	4 (1.6)	12 (4.7)
Vaginal Dryness	3 (1.1)	3 (1.2)	2 (0.8)
Weight Gain	4 (1.4)	10 (4.1)	36 (14.2)

More patients treated with megestrol acetate reported weight gain as an adverse event compared to patients treated with ARIMDEX 1 mg (p<0.001). Other differences were not statistically significant.

An examination of the magnitude of change in weight in all patients was also conducted. Thirty-four percent (37/103) of the patients treated with megestrol acetate experienced weight gain of 5% or more and 17% (17/103) of the patients treated with megestrol acetate experienced weight gain of 10% or more. Among patients treated with ARIMDEX 1 mg, 13% (33/253) experienced weight gain of 5% or more and 5% (13/253) experienced weight gain of 10% or more. On average, this 5 to 10% weight gain represented between 6 and 12 pounds.

No patients receiving ARIMDEX or megestrol acetate discontinued treatment due to drug-related weight gain.

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scientific papers; plans for future research; peer reviews; physical objects (laboratory samples and tape recordings, for instance); trade secrets; commercial information; and information that could be used to identify a particular 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 American Medical Colleges (AAMC), moderated a panel at the forum on understanding 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 significantly widen the amendment's applicability." He said he envisioned the mountains of new paperwork—and thousands of dollars in additional cost—that would be entailed in requests for data: documenting it, preparing it 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 publication, 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-analysis?

Steve Goodman, MD, PhD, Associate Professor in Oncology at Johns Hopkins School of Medicine and a faculty member in epidemiology and biostatistics at Hopkins School of Public Health, compared the scientific process to data reduction and said that all scientific claims contain some degree of uncertainty, although some, of course, are "iffier" than others.

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 editors 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

*"Data sharing is 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."*

analysis, which is particularly important 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 Epidemiology and Professor of Environmental Epidemiology at Harvard Medical School, was principal investigator for the Harvard Six Cities Study begun in 1973 to study the environmental and health effects of sulfur oxide. 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 air-pollution regulations, but they were not prepared for the virulence and variety of the criticism. "People questioned the validity of our data, the appropriateness of our statistical methods, and the biologic plausibility of the associations between air pollution and mortality," he said.

Bolstered by an American Lung Association lawsuit against the Environmental Protection Agency (EPA), the Harvard scientists planned to use the data they had collected and analyzed 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 participating in the study and said that if this confidentiality can be breached or compromised 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 organization jointly supported by EPA and

industry to provide independent research on the health effects of air pollution. The data and analysis were eventually validated, but it took more than a year and cost over a million dollars.

### **Data Used in Rule 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 protections 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 federally 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 amendment.

"It is vague, unclear, and complicated, 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 management 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 Council Air and Energy Program, said that the Shelby

amendment is "bad public policy." It escalates the bureaucracy of regulatory agencies and impedes the work of scientists 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 justification 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 universe 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 openness—that nothing should be hidden. However, it is also based on privacy—that everything 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 Amendments of the Constitution, which protect privacy.

"While the policies are inconsistent, 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 that permeates society, particularly the overlapping worlds of science and law, is largely irresolvable except in pragmatic terms on a case-by-case basis, he

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## Advocate Program

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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

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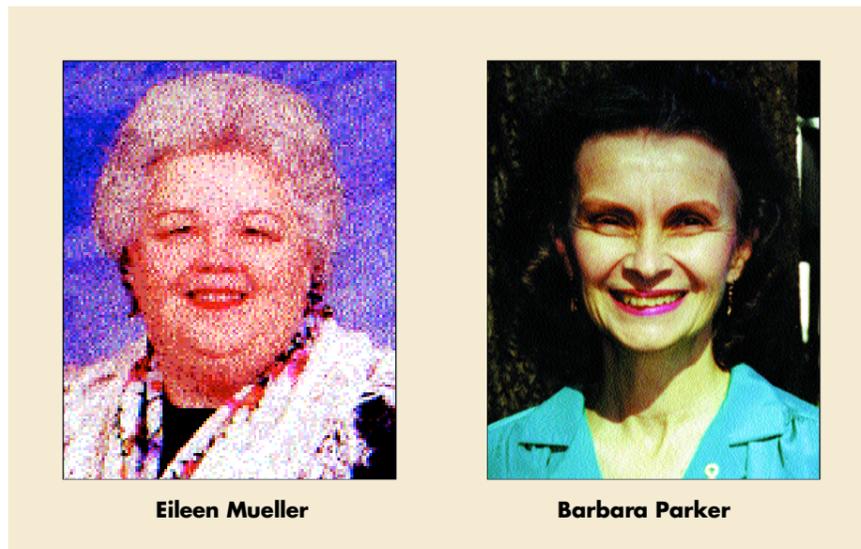
Judge Weinstein discussed privacy issues in a few highly publicized cases such as smoking bans, tobacco industry penalties, and breast implants, and he enumerated the following key questions that underlie the issues under consideration:

- 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



Eileen Mueller

Barbara Parker

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 numbered 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. Coltman, Jr., MD, for originally sug-

gesting 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.

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### 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. Partici-

pants 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 skeptical. 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."

*"The premise of the program is that participants go back to their groups and teach others what they have learned—that they take the new knowledge and let it multiply."*

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 \$90 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, (continued on page 56)