Business group presses for broader release of scientific data

The US Chamber of Commerce, a major business lobbying group, has begun mounting a challenge to new rules by the White House Office of Management and Budget (OMB), asserting that the OMB undermined a law designed to release research data to the public. The move is the latest volley in an ongoing controversy about the new law, which subjects raw data from many types of clinical and environmental studies to disclosure under the Freedom of Information Act (FOIA).

Industry groups like the chamber claim that the law will allow greater public scrutiny of data used to support new federal environmental regulations, but researchers fear that it will jeopardize the confidentiality of medical records and serve as a tool for industry harassment of scientists. The Shelby law, named after Senator Richard Shelby (R-Alabama), who slipped the measure into a budget bill last year, was implemented by the OMB in

October with a rule that specifically exempts medical and business-related data, answering some of the researchers' concerns (*Nature Med.* 6, 8; 2000).

The chamber, arguing that the OMB exemptions were not in the original legislation, filed a request on 14 December 1999 with the Environmental Protection Agency for raw data from an environmental health study done at Harvard University. If, as expected, the request is denied based on the OMB exemptions, the chamber may have grounds to file a lawsuit to test the OMB rules and try to overturn the exemptions.

William Kovacs, vice president for regulatory and environmental affairs for the chamber, claims that the OMB exemptions were unnecessary, as the FOIA already contains exemptions for confidential information, and that "three million other businesses figured out how to use [FOIA exemptions]."

Public health and environmental re-

searchers counter that the additional exemptions are necessary because the FOIA was not written with scientific studies in mind. Joel Schwartz, associate professor at the Harvard University School of Public Health, argues that the public perception of the Shelby law could be disastrous to research: "If people think their confidential medical records will be made freely available they will stop agreeing to participate in studies."

Schwartz and others also question the rhetorical invocation of the American public, arguing that only industry groups will be interested in obtaining raw data. Even before the Shelby law, Schwartz says he "had multiple teams of industry consultants attack my studies, and responding to those attacks had diverted me from doing research. The tobacco industry has harassed researchers ... and driven some from the field."

Alan Dove, New York

Insurers agree to cover cancer trial costs voluntarily

Leading health insurance companies in New Jersey are being hailed for agreeing to cover cancer patients' routine clinical trial costs. This is the first time insurers have voluntarily agreed to cover such costs, and the move is expected to boost trial participation. However, the state's top cancer institute says it won't see any immediate, or large, financial gain.

Ten insurers, including some of the largest US names such as Prudential, Cigna and Aetna/US Healthcare, covering 4.8 million New Jersey residents—60% of the state's residents—say that patients will be immediately reimbursed for physician fees and reasonable expenses for laboratory tests and routine care incurred in cancer therapy trials.

Under the agreement, patients will be reimbursed only for trials approved by the Food and Drug Administration, the National Cancer Institute (NCI), or the Department of Defense or Veterans Affairs. The plan includes investigational new drug, and phase I, II and III studies.

Mary Todd, deputy director of the Cancer Institute of New Jersey, which was involved in establishing the agreement, applauds the move: "We don't think it will actually increase the revenue stream to us," she says, and adds that financial gain was not the first concern. Knowing costs are covered will save both

the institute and insurers time and labor in fighting over claims denials, she explains. "Our goal in doing this is to decrease the barrier of cost as the reason for patients not enrolling," says Todd.

Todd believes that if care costs are routinely covered, the effect on cancer research could be tremendous. "If we are able to increase enrollment in trials, that will help us rapidly determine the clinical utility of the explosion coming out of research labs," she says.

The institute, which is affiliated with the Robert Wood Johnson School of Medicine, is the only NCI-designated

center in the state. In 1999, it enrolled 600 patients in 70 trials. Only 3% of adults participate in cancer trials in New Jersey, yet the state has one of the highest cancer morbidity and mortality rates in the US—ranked ninth, according to the Cancer Research Commission.

The American Cancer Society and the American Society of Clinical Oncology, who have been campaigning for trial insurance coverage (*Nature Med.* 4, 992; 1998), used the New Jersey deal to urge Congress to pay for Medicare patients' trial costs, and to push other insurers to follow suit.

Alicia Ault, Washington D.C.

From biotech to bank robbery

Pharmaceutical executive...college instructor...bank robber? That's how Michael Dickman's resume will read if he is convicted of the charges levied against him in a San Diego courtroom. Dickman, who in 1993 founded a successful biotechnology company called ChromaXome, was arrested after the holdup of a California bank. According to police, he is the "Gap-Toothed Bandit," the man in black with the distinctive smile who robbed about a dozen San Diego area banks by threatening to blow up buildings and harm tellers. Dickman, who is charged with six heists, has pleaded not guilty and is being held without bail pending an 18 February court date.

He had lived the life of a high-flying entrepreneur but had fallen on hard times, according to the *San Diego Union Tribune*. ChromaXome was sold in 1996 and a year later, a Dickman venture involving biomedical software developed at Stanford University also failed. He was teaching computer classes at a local university at the time of his arrest and had recently filed for bankruptcy.

Tinker Ready, Boston