

A Clash Over Standards for Scientific Records

The Public Health Service invited scientists in to talk about rules for storing scientific data, but were told there's no problem

THE CIVIL SERVANTS who keep tabs on biomedical fraud held a meeting* in Washington last week to get advice on what national standards, if any, ought to be established for scientific record-keeping. But along with a bit of advice, they got a rebuke. Many of the academic leaders present said it was a waste of time even to hold a meeting like this (though they tarried long enough for lunch), and urged the government not to intervene in matters better handled by scientists themselves.

The main reason the Public Health Service (PHS) called the meeting is that it has encountered confusion more than a few times when it has asked researchers to produce backup material in defense of a published report, one PHS official said privately before the meeting. "If you publish, you should have some data" in the files to show how the work was done, he said. But often the material produced is not adequate. When queried, researchers may come up

with little data or data that can be interpreted only by the author. This experience "kind of blows away the image of the meticulous scientist" recording every observation in the lab notebook, said the official.

But David Korn, vice president and dean of Stanford University's School of Medicine, was not convinced. He rose several times during the 2-day event to ask what the purpose of the meeting was, asserting that "there is no problem" to be discussed. He said that universities and professional societies are well able to cope with these issues on their own, without external guidance, and have no need for a national policy.

If there is a problem, said Barbara Hansen, vice president of graduate studies and research at the University of Maryland in Baltimore, it has come about through the actions of the PHS itself. She was particularly concerned by the view, expressed by several PHS officials, that U.S. law already requires grant recipients to keep research data on hand for 3 years after submitting a final expense report. (In addition, PHS says it has the right to inspect such federally sponsored data at any time, if the files exist.)

*The Workshop on Data Management in Biomedical Research, 25 and 26 April, was sponsored by the Office of Scientific Integrity Review, U.S. Public Health Service.

Bromley Moves West

In Washington, where appearance often equals reality, where you sit says a lot about how much power you have. An office in the West Wing of the White House is the ultimate sign of having arrived and, by that criterion, D. Allan Bromley, science adviser to President George Bush, is in. Bromley recently acquired an office in the West Wing—a position most former science advisers only dreamed of.

Furthermore, he has managed to wangle space in the Old Executive Office Building for the entire staff of the Office of Science and Technology Policy, which in terms of status ranks a notch higher than the New Executive Office Building just across Pennsylvania Avenue.

Bromley announced these symbols of recognition last week at the first open meeting of the President's Council of Advisers on Science and Technology (PCAST). The council's first meetings took place at Camp David, the President's retreat outside Washington in the Maryland woods, a couple of months ago. The President was there, as he was last month at PCAST's second confab.

Bromley considers Bush's presence at the meetings as proof that he meant what he said when he told Bromley he expected science to play a real role in his Administration.

Two items dominated last week's PCAST meeting: maintaining America's lead in biotechnology and improving education in science and mathematics. No conclusions were reached.

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Hansen said this was "an extrapolation by the staff of PHS" of an accounting rule into the area of intellectual integrity, which she considered "a whole new ball game" and potentially a "major problem" for universities.

Drummond Rennie, medical professor at the University of California in San Francisco, agreed. "It is not at all clear there is a [record-keeping] problem severe enough to require action," he said, and the PHS's goal of preventing fraud is "an insufficient rationale for altering data retention practices." The PHS view that the 3-year rule applies to scientific as well as financial records, according to Rennie, is "inappropriate, unwarranted, and should be corrected."

The meeting was called by the PHS Office of Scientific Integrity Review, headed by Lyle Bivens, which is assigned to see that grantee institutions adhere to good research practices. Part of this office—based at the National Institutes of Health and headed by Jules Hallum—investigates cases in which a credible charge has been made that a grantee institution has not maintained standards in its realm.

Many researchers regard the concerns of the fraud squad as trivial. But Bivens and Hallum, like sheriffs in Dodge City, have a duty to perform and a good deal of unpopular work to do. Hallum reports, for example, that he now has 74 cases under active investigation and is monitoring 50 more for other agencies. Every time an old case is resolved, a new one seems to arrive, he says, although he looks forward to the day when universities will do their job so well that PHS will receive no new cases.

To hasten that day, PHS invited university administrators and data experts to become more involved in the quality control of research. The keynote speaker, Assistant Secretary for Health James Mason, said the aim was "not to arrive at a prescriptive statement," but to "invite a dialogue and identify areas of concern." He suggested that researchers should retain data "in a form that is interpretable by other scientists in the field," because this is a prerequisite for sharing.

Paul Friedman, cochairman of the workshop and dean of academic affairs at the University of California, San Diego, School of Medicine, conceded that the "prime cause" behind this workshop was PHS's investigative role. But he said it would be "incredibly wasteful" to make that the focus of academic concern. He added, "We must recognize what the ideals are and try to bring up the standards."

The other cochairman, Robert Charrow, a former PHS attorney now in private practice, noted that the law does not give federal