# 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.) 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

*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. ■ BARBARA J. CULLITON

grantees exclusive rights to the data they produce. "No one has an absolute ownership interest, as you have with a piece of land," he said. Federal data rights, according to Charrow, are like water rights: they may restrict access, but they require sharing and forbid pollution.

Several commissioned papers were presented, but neither these nor the exhortations of cochairman Friedman inspired a broad statement of consensus. It was clear from individual and small working group comments, however, that attendees held some views in common:

■ The raw materials produced by researchers vary so much from discipline to discipline, many speakers said, that it would be futile to try to write rules that apply across the board. It makes more sense to have problems—if any arise—handled by peer groups, professional societies, and journal editors. Most also said they were not aware of a crisis in data management, although they recognized that some people do not share their data. The broadly endorsed remedy: better education, not regulation.

■ There is a difference between sharing and archiving, many said, adding that the PHS is really interested in mandatory archiving. Some disputed the PHS's view that the law requires records to be kept for at least 3 years. Michael Jackson, dean of the George Washington University Medical School, said his policy is to keep records for 5 years, but that making the policy mandatory would add "two points" to the indirect cost rate charged to federal grants.

■ Most speakers felt that individual scientists should retain control of data, but that universities should share the maintenance duties. There was widespread concern that confidentiality might be lost if files were routinely opened to inspection by public officials.

As the meeting closed, Bivens said he was baffled by statements made during the session that there is no problem to discuss, because so many people seemed interested beforehand. But he felt that the meeting achieved its purpose, and the results will be written up and forwarded to assistant secretary Mason in a few months. Whether they will later appear as federal rules remains to be seen. ■ ELIOT MARSHALL

# NAS Elects New Members

The National Academy of Sciences has elected 60 new members and 15 foreign associates. They include President Bush's science adviser, D. Allan Bromley. Earlier this year, the National Academy of Engineering elected White House Chief of Staff John Sununu to its ranks. This brings the NAS membership total to 1601 and the foreign associates total to 272. The new members are:

**Sidney Altman,** Yale University; **Michael Aschbacher,** California Institute of Technology; **John E. Bercaw,** California Institute of Technology; **John S. Boyer,** University of Delaware, Newark; **D. Allan Bromley,** Assistant to the President for Science and Technology; **Lawrence D. Brown,** Cornell University; **Herbert B. Callen,** University of Pennsylvania, Philadelphia; **William K. Chandler,** Yale University School of Medicine; **Min Chueh Chang,** Worcester Foundation for Experimental Biology; **Ralph J. Cicerone,** University of California, Irvine; **Michael T. Clegg,** University of California, Riverside; **Esther M. Conwell,** Xerox Webster Research Center; **Bryce S. Dewitt,** University of Texas, Austin; **Floyd Dunn,** University of Illinois, Urbana; **Gertrude B. Elion,** Burroughs Wellcome Co., Research Triangle Park; **Nina V. Fedoroff,** Carnegie Institution of Washington, Baltimore; **M. Judah Folkman,** Harvard Medical School; **Alan B. Fowler,** IBM T. J. Watson Research Center, Yorktown Heights, NY; **Robert F. Furchgott,** State University of New York Health Center, Brooklyn; **John C. Gerhart,** University of California, Berkeley.

**John A. Glomset,** University of Washington, Seattle; **Patricia S. Goldman-Rakic,** Yale University School of Medicine; **Kenneth L. Hale,** Massachusetts Institute of Technology; **C. Vance Haynes, Jr.,** University of Arizona, Tucson; **Carl E. Heiles,** University of California, Berkeley; **Sarah B. Hrdy,** University of California, Davis; **John W. Hutchinson,** Harvard University; **J. David Jackson,** University of California, Berkeley; **W. Barclay Kamb,** California Institute of Technology; **David Kazhdan,** Harvard University; **Patrick V. Kirch,** University of California, Berkeley; **Edward D. Korn,** National Heart, Lung, and Blood Institute; **Louis M. Kunkel,** Harvard Medical School; **Syukuro Manabe,** Princeton University; **Louis H. Miller,** National Institute of Allergy and Infectious Diseases; **Peter Molnar,** Massachusetts Institute of Technology; **Cathleen S. Morawetz,** New York University; **Newton E. Morton,** University of Southampton, United Kingdom; **Howard A. Nash,** National Institute of Mental Health.

**Leslie E. Orgel,** Salk Institute for Biological Studies, **Lawrence R. Rabiner,** AT&T Bell Laboratories, Murray Hill, NJ; **Vernon W. Ruttan,** University of Minnesota, St. Paul; **Paul R. Schimmel,** Massachusetts Institute of Technology; **Andrew M. Sessler,** Lawrence Berkeley Laboratory; **Kenneth A. Shepsle,** Harvard University; **Richard E. Smalley,** Rice University, Houston, TX; **Hugh F. Sonnenschein,** University of Pennsylvania; **David B. Sprinson,** Columbia University; **Richard S. Stein,** University of Massachusetts, Amherst; **Thomas A. Steitz,** Yale University; **Norman Sutin,** Brookhaven National Laboratory; **John A. Swets,** Bolt Beranek and Newman Inc.; **Salih J. Wakil,** Baylor College of Medicine; **Duard L. Walker,** University of Wisconsin Medical School, Madison; **Frank A. Wilczek,** Institute for Advanced Study; **George M. Woodwell,** Woods Hole Research Center; **Keith R. Yamamoto,** University of California, San Francisco; **Shang F. Yang,** University of California, Davis; **Vernon R. Young,** Massachusetts Institute of Technology; **Jozef J. Zwislocki,** Syracuse University.

The new foreign associates are:

**Zhores I. Alferov,** A. F. Ioffe Institute, U.S.S.R. Academy of Sciences; **Maurice Allais,** Ecole Nationale Superieure des Mines de Paris, Paris X University, France; **Etienne-Emile Baulieu,** Unite de Recherches 33, University of Paris-Sud, France; **Vittorio Erspamer,** University of Rome, Italy; **Ludwig D. Faddeev,** Steklov Mathematical Institute, U.S.S.R. Academy of Sciences; **Marshall D. Hatch,** CSIRO, Canberra, Australia; **Warwick E. Kerr,** Universidade Federal de Uberlandia, Brazil; **Donald Lynden-Bell,** University of Cambridge, United Kingdom; **Nicholas A. Mitchison,** University College London, United Kingdom; **Christiane Nusslein-Volhard,** Max Planck Institute for Developmental Biology, Federal Republic of Germany; **H. Oeschger,** Physics Institute, University of Bern, Switzerland; **William J. Peacock,** CSIRO, Canberra, Australia; **C. N. R. Rao,** Indian Institute of Science, Bangalore, India; **Klaus von Klitzing,** University of Stuttgart, Federal Republic of Germany; **David Weatherall,** University of Oxford, United Kingdom.