Scientists Confront Misconduct

Researchers and administrators have come up with a number of proposals for assuring integrity in biomedical studies; the government has come up with new proposals for regulations

This is the fourth in a series of occasional articles on conduct in science

"ETHICAL BEHAVIOR IN SCIENCE is not optional." With that brief and cogent declaration, Jules Hallum said what everyone was thinking at a recent Institute of Medicine conference on responsible conduct in research. Hallum, of the Oregon Health Science University, was one of more than 100 scholars and top chancellors and deans who came to Washington earlier this month for three full days of analysis of issues pertinent to integrity in research.

Just last week, another group met to tackle the same issues. Meeting under the joint sponsorship of the American Association for the Advancement of Science and the American Bar Association (AAAS/ABA), researchers, lawyers, and administrators participated in the second of three conferences focused on ethical behavior in science. One observation, framed by Stanford medical dean David Korn, was this: The most difficult challenge to science right now is not "rampant, black and white fraud." That, he speculated, is "very rare" and can be dealt with. The harder task is to get the research community at large to "pay closer attention to cultural norms" that seem to be eroding. Sloppiness. Minor forms of data manipulation. Honorary authorship. "We want to eliminate violations of the best standards of our profession," he said.

In May, the National Institutes of Health convened a conference on proper scientific behavior, this one focusing on publication practices. Next month, the National Academy of Sciences will host a meeting of the Council of Biology Editors on the same subject. Meanwhile, Representative Ron Wyden (D–OR) has plans to introduce legislation in the House that would make honorary authorship (a custom many scientists deplore) illegal.

Other organizations are also active players in what is loosely called the "fraud game." The Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), and the Federation of American Societies for Experimental Biology (FASEB) are among a band of ten that have just drafted a "framework for institutional policies and procedures to deal with fraud in research." It was unveiled last week at the AAAS/ABA conference, where there was vigorous discussion about the importance of distinguishing outright fraud from lesser breaches of conduct and from inevitable but innocent mistakes. "Institutions must take care that the process pursued to resolve allegations of fraud not damage science itself," the framework says, and states that "Research fraud is an act of deception; it is different from error."

It is clear that a large number of senior scientific leaders have come to recognize various gradations of fraud and misbehavior as a serious problem for the research community—serious in its own right and serious as a political problem because Congress and the general public think it is a problem.

Speaking at the AAAS/ABA conference, Washington attorney Barbara Mishkin summed it up. "The size of the problem—whether there are only a few cases or many more that have gone unreported—doesn't really matter," she said. "The fact is, there have been a handful of well-publicized cases that have led Congress and the public to perceive a larger problem."

While science is working diligently to get its house in order, the federal government is taking steps to move things along. Although a majority of researchers would just as soon see misconduct handled under voluntary guidelines, the government is on the verge of producing quite specific regulations.

The *Federal Register* of 19 September contains two documents of vital importance to biomedical research. First is a "notice of proposed rule-making" that is open to public comment for 60 days. The notice defines scientific misconduct as (i) fabrication, falsification, plagiarism, deception, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research; or (ii) material failure to comply with federal requirements that uniquely relate to the conduct of research. (The protection of research patients or proper care of animals would come under the latter provision.)

What the notice legalistically calls the "first element" of the definition is not intended to "stifle creativity," "institutionalize scientific conformity," or preclude "legitimate scientific disagreement."

The proposed rule also requires institutions to notify federal funding agencies about allegations of misconduct "prior to the institution's decision to initiate an investigation," in a broad number of circumstances: among them, an "immediate health hazard," and knowledge that the allegation is going to hit the press.

A third provision states that once regulations are in place, no institution will be eligible for any grant unless it has adopted policies for dealing with possible misconduct.

That, in sum, is the proposed rule.

The second *Federal Register* document, which is farther from implementation but no less important, is what is known administratively as an "advance notice of proposed rule-making." Here the government outlines in general terms what it is thinking about doing. Again, public comment is open for 60 days.

The advanced notice confirms what Mishkin and others have said about the motivation for writing down the rules of science. "The renewed concern has less to do with any documented increase in the frequency of misconduct than it does with a heightened awareness of the potential problem and its ramifications," it says forthrightly. Appearances count.

According to the advanced notice, the Secretary of Health and Human Services (HHS) is contemplating provisions that would:

- Formalize and centralize procedures for dealing with allegations, thereby requiring all institutions to follow the rules in precisely the same way.

This idea conflicts directly with the framework drafted by the AAU *et al.* who think variations among institutions must be accommodated. "The choice of the term 'framework' was deliberate," AAU says. "It is essential to provide for different institu-

tional (and inter-institutional) approaches to the resolution of allegations of fraud in research."

■ Adopt policies to deter and detect misconduct. For instance, HHS might conduct "routine or random on-site audits" of research data. It might require institutions or principal investigators to "archive raw data" and make them available to researchers who may want to see them.

HHS is considering a requirement that institutions repay the government grant money that has been spent by a researcher engaged in scientific misconduct. (There is no such rule now, although some repayment of NIH funds has been negotiated in past instances.) HHS might require institutions to educate their faculty and students on the ethics of science.

■ Place control of misconduct investigations in federal hands. For instance, HHS might take responsibility for investigating allegations away from institutions and turn it over to a new "office of scientific integrity" that would have power not only to investigate but also to adjudicate. The adjudicating panel, in one scheme, would include scientists. A variation on the theme of a new integrity office is a proposition to turn the whole business over to the existing Office of the Inspector General.

Although researchers and regulators can agree on any number of points about ethical conduct in science, the research community bridles at government intervention, arguing that science can police itself with voluntary guidelines.

At the recent Institute of Medicine conference, there was consensus that researchers should be expected to share raw data with colleagues who want to reproduce work once it has been published. A show of hands came out in favor of courses or seminars on ethical behavior in the laboratory. And there were repeated statements to the effect that accepted practices in scientific publication warrant stringent reassessment. But no one suggested these goals be legislated. Quite the contrary.

Not surprisingly, the AAAS/ABA conference participants reached a similar stance. "The notion that ethical behavior needs to be legislated by Congress is just plain dangerous for science," one opponent said.

But all present indications are that both Congress and the Administration will press on regardless, unless they are somehow persuaded that the research community can, in fact, resolve these matters through guidelines now being developed.

■ **BARBARA J. CULLITON**

Preceding articles in this series ran in Science, *24 June, 1 July, and 29 July.*

Army Shifts on Dugway Lab

Faced with mounting public opposition, the Army has scaled down its plan to build a new laboratory in the Utah desert to test defenses against biological warfare agents. The Army had been planning to construct a maximum-containment facility capable of handling the most dangerous pathogens known, including genetically engineered organisms. Last week, however, Utah governor Norman Bangerter announced that the Army now intends to build a less sophisticated laboratory that would be restricted to studies involving less hazardous disease agents.

The change of plan, which has been confirmed by the Army, has been welcomed by some critics of the facility. It will, however, not preclude any of the tests the Army currently has in mind because none of them requires a maximum-containment lab.

The original proposal, put forward 4 years ago, was to build a sophisticated testing lab at the Army's Dugway Proving Ground, 70 miles southwest of Salt Lake City. One of only about half a dozen facilities in the country with the highest level of biosafety, known as BL4, it would be used to generate aerosols of infectious agents that could potentially be used as biological weapons. The chief purpose of the facility would be to test whether the agents penetrate protective clothing and filters. It would also be used to develop sensitive monitors capable of detecting minute amounts of specific agents to provide warning that an attack is under way.

According to Army documents, the tests will involve a variety of pathogens, including the organisms that cause tularemia, anthrax, Q fever, and encephalitis. All these organisms could be handled in a less secure laboratory, with a biosafety rating of BL3, however. In a draft environmental assessment produced earlier this year, the Army said it wanted to build a BL4 facility to have the option of working with more hazardous pathogens if the need arises. For now, "BL4 organisms or techniques, including areas of research involving genetic engineering, will not be used in the new facility," the Army said.

Army spokesman Lieutenant Colonel John Chapla said last week that the Army has since "reviewed whether we really need a BL4 facility at Dugway, and the answer came back 'no'." (The Army already has a BL4 laboratory at Fort Detrick, Maryland, that can be used for some types of research, though it cannot be used for creating aerosols.) Consequently, the Army now plans to build a BL3 lab at Dugway. Chapla acknowledged that local opposition was "a factor" in reaching that conclusion.

Although the Army's environmental assessment indicated that the proposed facility would pose virtually no hazard to the surrounding community, much of the local opposition has revolved around safety concerns. The decision to build a BL3 instead of a BL4 lab will, ironically, result in a somewhat less secure facility but it may nevertheless help soothe local fears. It "is a step in the right direction," says Steven Erickson of the Downwinders, one of the groups opposing the facility. "We are pleased the Army has heard the public outcry and has backed off from plans for a facility that could be used for testing genetically engineered pathogens," he says.

The decision may also help alleviate some concerns about the arms control implications of the proposed facility. The United States renounced biological weapons in 1969 and is prohibited by the 1972 Biological Weapons Convention from stockpiling or developing new agents. Some critics have argued, however, that building a facility to test the ability of aerosolized pathogens—especially genetically engineered organisms—to penetrate defenses would blur the line between defensive and offensive research.

Barbara Rosenberg of the Memorial Sloan-Kettering Cancer Center says "the potential escalation to BL4 was the most provocative aspect" of the Army's original proposal because it would have permitted the testing of novel organisms.

Critics of the facility are not entirely satisfied by the change in plan, however. Cedric Davern, a biologist at the University of Utah, argues, for example, that the Army does not need even a BL3 lab, because "they can do entirely what they want with simulants." This point is echoed by other critics, including Rosenberg.

Governor Bangerter, a Republican who is in a tough election race, is expected soon to announce the formation of a citizens' committee, including several scientists, to monitor operations at the Dugway lab. Erickson of the Downwinders warns, however, that his group " will continue to oppose efforts to aerosolize any pathogens, whether in BL3 or BL4."

■ **COLIN NORMAN**