Regulatory Agencies Call on Scientific Institutions to Address Misconduct

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Publicity and heightened congressional and regulatory interest surrounding several cases of suspected scientific misbehavior have brought the issue of misconduct in science to the forefront over the past few years. Science hasn't experienced an obvious torrent of misbehavior, but since there's no hard data on the incidence of misconduct, no one knows for sure how prevalent it is. Regulations to date put the onus on institutions and scientists and have been aimed at individual cases rather than the underlying scientific research process. Both the regulators and the scientific community consider this the best approach at the present time.

The United States Public Health Service (PHS), an arm of the Department of Health and Human Services that funds close to $8 billion for research annually through the National Institutes of Health (NIH), the Food and Drug Administration, the Centers for Disease Control, the Alcohol, Drug Abuse and Mental Health Administration, and other offices has amended its regulations governing conduct under 10 CFR Part 50. A final rule, effective November 8 delineates the responsibilities of institutions for handling suspected or alleged misconduct in scientific research involving PHS funds (1).

According to Brian Kimes, PhD, acting director of the PHS's Office of Scientific Integrity, (OSI), which will co-administer the rule, the regulation was brought about by a combination of "increasing awareness" of the problem after the NIH started centrally receiving complaints and keeping records and "political pressures" being generated by congressional hearings on the subject (see *Newsline* September 1989, p.1469). "Now," he added, "everyone is just taking it seriously."

The PHS regulations, and the regulations that the National Science Foundation (NSF), established in July, 1987, constitute the Federal government's formal regulatory stance toward scientific misconduct. They cover funding for the gamut of scientific research endeavors from social sciences to physics to medicine.

John G. Weir, Jr., MD, staff nuclear medicine physician at the Marshfield Clinic in Marshfield, Wisconsin, expressed some concern about responding with regulations to an issue about which there is little incidence data. "I hope Congress and the public remember that the number of instances where there has been trouble has been small. I hope that as a society we don't overreact. While some of the cases have been extensive. . .compared to the amount of research that's going on, it's still small."

Even with the NSF regulations in place for over two years, Robert M. Andersen, deputy general counsel for the NSF, stressed that more attention should be paid to uncovering the true incidence of misconduct. "We don't know the precise nature of scientific misconduct and how prevalent it is. And we don't know how Draconian measures should be to eliminate it. . . . Evidence out there suggests that because of the disincentives to reporting, the number of cases reported is significantly below the number of cases not reported." Calling the issue "unresolved," he added, "There ought to be more research applied there."

In an attempt to quantify the prevalence of misconduct, said Dr. Kimes, HHS will "require institutions to report certain data. . . to show they're complying with the process. . . this will be the first time the scientific community will be able to have some data on what's happening. We all perceive this as a small problem, but we've never been able to give anybody any hard data."

Monitoring Needed

While these regulatory measures are not openly embraced by the scientific disciplines, many scientists ac-

knowledge that some form of government intervention was inevitable and necessary. Dr. Kimes told *Newsline*, "I don't think everyone is happy about having to do this. I'm not sure the PHS is happy to have to do it. The burden on the PHS to develop and implement this and the burden on institutions to do this is very real. But public perception of scientists has changed. We are no longer living in the ivory tower like we used to . We're going to have to become credible and monitor ourselves."

R. Edward Coleman, MD, professor of radiology, director of nuclear medicine, Duke University Medical Center, chairman of The Society of Nuclear Medicine's Scientific Affairs and Research Committee, agreed that "these steps have to be taken, and this is the right time — if measures are not taken appropriately locally [institutionally], then it would be done nationally."

Dr. Weir said, "It's unfortunate that the regulation is needed, but at this time, I don't think the scientific world has any choice but to accept the fact that the government was going to do this." Dr. Weir said, "institutions do need a policy and structure for evaluating complaints and monitoring research...in general [scientists] accept the need for some kind of surveillance kept as informal and unobtrusive as possible."

"There's nothing in the regulation that's particularly burdensome or a problem," said Dr. Weir. "The requirements are not terribly specific...but we won't know how they will impact until they're in place. Potentially, the demands of the Public Health Service could get excessive, but the regulations, as written, if applied reasonably, will not be a burden."

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The PHS Rule

The PHS rule defines misconduct in science as "...fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research." It excludes "honest error or honest differences in interpretations or judgements of data" (2).

The PHS will administer the regulations through two newly established offices, the Office of Scientific Integrity Review (OSIR), in the office of the Assistant Secretary for Health, and the OSI, in the office of the NIH director. OSIR sets PHS policies and procedures for dealing with misconduct, oversees PHS research agencies to ensure these policies are carried out, reviews reports of investigations, in some instances conducts its own investigations, and makes final recommendations to the Assistant Secretary. OSI oversees implementation of policies along with OSIR and monitors and conducts investigations.

Under the rule, each institution that applies for, or receives, funds from the PHS must provide an assurance to the HHS Secretary that they set up, no later than January 1, 1990, a pro-

(continued on page 1763)

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(continued from page 1762)

cess for reviewing and investigating allegations of misconduct and update that assurance each year. Dr. Kimes noted that institutions that do not assure the HHS that they have these policies and procedures in place could negatively "impact their ability to receive [PHS] funds."

The rule requires that the applicant's policies and procedures provide for an immediate inquiry into an allegation or other evidence of possible misconduct (to be completed within 60 days unless circumstances clearly prevent that); protect as much as possible the privacy of whistleblowers; provide those being investigated with a confidential, prompt, and thorough investigation as well as an opportunity to comment on allegations and findings; notify the OSI that an investigation is warranted before the investigation begins; notify OSI at once if there is an immediate health hazard, an immediate need to protect Federal funds, an immediate need to protect interests of whistleblowers or the subjects of allegations, if it is probable that the alleged incident will be reported publicly, or if there is a reasonable indication of criminal activity; maintain sufficient documentation of an inquiry for at least three years after its termination; start an investigation within 30 days of the close of the inquiry indicating the need for investigation; guard against conflicts of interest; prepare a report on each investigation describing the policies and procedures under which the investigation was conducted; take interim administrative actions to protect Federal funds if necessary; keep OSI informed of any developments that may affect current or potential HHS funding for the individual(s) under investigation; undertake efforts to restore reputations of those who engaged in alleged misconduct when allegations were not proved; impose appropriate sanctions when allegations have been substantiated (HHS also may impose its own sanctions); and notify OSI of the outcome.

Normally, the report on an investigation should be submitted within 120 days. An institution would need to request an extension to go beyond 120 days, explaining the reason for the delay, their progress to date, and an estimated date of completion. If an institution plans to conclude an inquiry or investigation without completing all the PHS requirements, the institution must submit a report to OSI, which shall decide whether the case should be further investigated.

Dr. Kimes summarized the main thrust of the rule: "You have to have policies and procedures in place and whatever those policies and procedures are, you have to follow them." In addition, he said, "the rule defines the time limits clearly" for the inquiry and investigative processes, "the process is blinded to the Federal government when the inquiry does not proceed to the investigative stage, giving the institution some degree of privacy," and the rule "clearly delineates what types of principles an institution should consider when conducting an inquiry or investigation."

Dr. Kimes further noted that the OSI can look retrospectively at inquiries to monitor the process and collect data. He said this oversight of the process is important because while "we're all interested in doing good science, institutions may make mistakes because of inexperience."

PHS and NSF Approaches

According to Mr. Andersen, the PHS and NSF regulations are "very similar. . . it's basically the same two

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tier process. . .their definition is a bit narrower, but substantively and in practice it will work out to be much the same. . . .Under both, the responsibility is on the institution and [the agency] steps in only when necessary . . . .They will end up sanctioning the same kinds of misconduct. . . fabrication, falsification, plagiarism, and unacceptable deviation from scientific practice."

Under the NSF rules, awardee institutions are responsible for conducting inquiries and investigations, if necessary, and must "take action necessary to ensure the integrity of research, the rights and interests of research subjects and the public, and the observance of legal requirements or responsibilities" (3). Like PHS awardees, NSF awardees must inform their staffs of the policies and procedures for dealing with misconduct; inform NSF if an investigation is indicated, before initiating it; inform NSF under any circumstances constituting immediate need; update the Foundation on the progress of each investigation; and give the Foundation a final report of the investigation. Under the time frame for NSF awardees, inquiries should be completed within 90 days and investigations within 180 days.

"The Federal government leaves much of the responsibility to individual scientists. This is a measured response — a good response. . . .NSF and NIH responses are calculated to deal with the level of misconduct that we are aware of now. We have to be watchful over the next few years."

One difference between the approaches, pointed out Dr. Kimes, is that the OSI "is managed by scientists" whereas the NSF's investigatory branch is in their Office of the Inspector General and is not run by scientists. "We feel very strongly that we can manage ourselves," said Dr. Kimes.

For the time being, both agencies have left the initial responsibilities up to the institutions. Mr. Andersen indicated this is a prudent direction for now. "The Federal government leaves much of the responsibility to individual scientists. This is a measured response — a good response. Some people say we haven't done enough, some people say we've done too much. NSF and NIH responses are calculated to deal with the level of misconduct that we are aware of now. We have to be watchful over the next few years." Dr. Kimes holds a similar view: "NIH's and PHS's philosophy has been that institutions should be managing their own affairs."

Dr. Weir partly blames the scientific world's inaction for the increasing government oversight. "If we had done our own policing, we wouldn't have gotten into this fix, and if we do our own policing from now on, we probably won't get into a worse fix."

HHS will "require institutions to report certain data. . .to show they're complying with the process. . .this will be the first time the scientific community will be able to have some data on what's happening. We all perceive this as a small problem, but we've never been able to give anybody any hard data."

Sarah M. Tilyou

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