

PROFESSIONAL ETHICS REPORT

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COVER STORY: Research Integrity Commission Picks Up The Pace

By Mark S. Frankel

The Commission on Research Integrity, mandated by the NIH Revitalization Act of 1993, is quickly trying to make up for a slow start. Although its charter was formalized in November 1993 by the Secretary of the Department of Health and Human Services, the Commission did not convene its first meeting until June 1994. Since then, it has held just short of a dozen public meetings throughout the country in order to "interact extensively with all relevant constituencies of the scientific community ... to understand their particular experiences and perspectives ...," according to the Commission's chair, Harvard professor Dr. Kenneth J. Ryan. Earlier this year, the Commission issued its first formal report, in which it acknowledges that the "culture underlying research fraud and misconduct is a subject of widespread concern in the scientific community and in universities well beyond the details of a few highly publicized cases." While the report makes no pretense of forecasting the Commission's final recommendations, it identifies four main areas where it is focusing its attention.

The Commission is mandated by legislation to develop a *definition of research misconduct*. The current HHS definition includes "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." The latter part of the definition referring to "other practices that seriously deviate" has been embroiled in considerable controversy. Some scientists and regulators believe that it is too much of a moving target, subject to a wide range of conflicting interpretation, and that it might discourage creative approaches that challenge current scientific practices. Others,

however, embrace the clause as offering the necessary flexibility to police unethical conduct beyond specific acts of fabrication, falsification, and plagiarism. To address these concerns, the Commission reports that it has "been exploring a two-tiered approach that distinguishes between *research fraud* that must involve the oversight of governmental agencies, and other kinds of *scientific misconduct* that fall into the realm of institutional responsibility." In all cases, institutions would be responsible for implementing misconduct procedures, but only those falling under the first tier of government oversight would have to be reported to the government. At its May meeting, Commission members developed a preliminary definition that would fall within the responsibility of government: "Research misconduct consists of intentional or reckless forms of conduct by an individual or individuals that result in serious misrepresentation, interference with or misappropriation of biomedical, behavioral or social science research funded by the Department of Health and Human Services [some members believe that the definition should apply only to PHS funded research]. Research misconduct does not include honest error or honest differences in interpretations or judgments of data." The definition would be followed by a detailed explanation of the terms used.

A second issue on which the Commission is focusing is the feasibility of a *model assurance submitted by institutions receiving Federal funds that addresses the integrity of research*. Federal regulations now require that institutions submit an assurance to the Office of Research Integrity that they have established policies and procedures for reviewing, investigation and reporting allegations of scientific misconduct in connection with PHS funded research. The Commission is considering a companion assurance that would address the second tier of responsibility, the institutions. It would require that institutions certify that they have established good research practice standards and an educational program to foster a research environment that promotes the responsible conduct of science. Such efforts would, at a minimum, address issues related to data collection and management, publication and authorship practices, and supervisory responsibilities. Still under discussion is whether a commitment to protect witnesses and whistleblowers should be part of an institution's assurance. Discussion at the Commission's April meeting revealed some opposition to another assurance requirement. Concern was expressed in invited testimony that the assurance would add a new administrative and fiscal burden on institutions, and that it would undoubtedly lead to intrusive audits by the government. One critic claimed that an audit by the government distant from the culture of a particular research institution raises the specter of "ideological micromanagement." Commission members were sensitive to these concerns, and at their May meeting, members made it clear that they did not want to engage in the standardization of standards across institutions or increase the administrative burden for the institutions or the government.

Complementing the institution's role in articulating research standards are the professional associations, which the Commission's report declares have a "unique role in the preservation of scientific integrity...." The report is not clear about what that "unique role" is, but it notes favorably the adoption of *ethical standards by professional societies* and urges the societies to "reinforce and augment the influence of normative professional standards" by becoming "more active in defining, promulgating, and promoting compliance with these standards." The Commission devoted half of its January 5, 1995, meeting to exploring ways to foster research integrity, with special emphasis on the role of professional societies in promoting high standards of ethics and research practice. [A summary of some of this testimony appears on page ? of this issue.] Included among what the Commission heard from those invited to testify was that ethical standards can provide the public with a basis for assessing the propriety of scientific work, that such standards have the potential to empower scientists and students to resist pressure to cut ethical corners, and that professional societies should inform their members of how their standards apply to actual research practices. Commission members were also cautioned that many scientific and engineering societies have been reluctant to enforce their standards and discipline members because such efforts are expensive, subject the societies to the risk of litigation, and scientists generally find it distasteful to investigate and discipline one another. [For further examination of the enforcement of ethical standards, see this issue's *Ethics, Law and Public Policy* column.] At its May meeting, the Commission considered language recommending that "each professional association and institution in science adopt a code of ethics," and that professional societies "adopt society-specific definitions of misconduct and integrity as well as develop commentary and cases" to support those definitions.

The NIH Revitalization Act of 1993 includes a provision for the protection of whistleblowers (Sec. 163), which requires the Secretary of HHS to promulgate regulations that will prevent or respond to any retaliation by officials at institutions funded by the Department against persons who, "in good faith," make an allegation of research misconduct or cooperate with an investigation into such allegations. [The Office of Research Integrity is preparing a Notice of Proposed Rule Making to implement this requirement.] For some Commission members, whistleblower reprisal is

viewed as an active interference with the scientific record because it represses the flow of information. Consequently, the fourth area of the Commission's attention is a possible *witness "bill of rights."* The report refers to "reprisals against witnesses [which] are not uncommon in the current culture, ..." and to witnesses' testimony describing "a broad range of techniques they perceived as being used to intimidate, punish, or discredit them." Witnesses at the Commission's December 1994 meeting testified that Federal rules that forbid retaliation against those bringing forth allegations of research misconduct are repeatedly ignored by universities. The chilling effect that such retaliation can have prompted the Commission to declare that "the choice between reprisal and silence is unacceptable,...." Witnesses also testified that the Federal government has not been able to "resolve expeditiously reprisal disputes between witnesses and their employers," leading the Commission to "consider recommendations that are consistent with existing whistleblower protection laws by assisting whistleblowers who are currently without redress to be made whole." Institutions found guilty of retaliation could be subjected to sanctions, including debarment from receiving federal funds.

In considering the disposition of its final report to the HHS Secretary and the implementation of its recommendations, the Commission discussed at both its April and May meetings the creation of a permanent committee that would advise the Secretary on research practices and research misconduct issues. Such a committee would, according to some Commission members, be a useful mechanism for research institutions and others to communicate their concerns about such matters to the government. That and all of the issues discussed in its interim report will be on the agenda for the Commission's next meeting on June 26-27.

SPECIAL CONTRIBUTION

Hearing, Commission on Research Integrity, January 5, 1995: Summary of Selected Testimony

The Commission on Research Integrity was created by Congress to advise the U.S. Department of Health and Human Services on how to improve the handling of cases of research misconduct. In the process of its deliberations and analyses, the Commission has held six prior hearings. By now, they have determined that there are multiple roles for different players, including the federal government and research institutions (universities, institutes, and foundations). Another role they consider to be very important is that of professional societies. This hearing focused on examining what professional societies could do to promote higher standards of ethics and research practice.

Among those testifying was Dr. Mark S. Frankel, Director of the Scientific Freedom, Responsibility and Law Program at the American Association for the Advancement of Science (AAAS). In that role, he also chairs the Professional Society Ethics Group (PSEG), which serves as a forum for the exchange of ideas and information relating to professional ethics among a diverse groups of scientific and engineering societies.

In his testimony, Frankel identified a clear need for normative standards of research practice against which allegations of misconduct could be judged. Such standards would give scientists fair warning of how they would be judged, clear lines of defense if accused of misconduct, and empower professionals and students to resist pressures to cut ethical corners. They would also provide the public with a basis for assessing the propriety of scientific work.

He noted that professional societies' ethical guidance fall into three basic categories:

- *Aspirational guidelines* encourage competent and moral practice in general, but do not provide specific rules of conduct.
- *Educational guidelines* articulate more clearly what constitutes ethical practice, often with interpretive commentary or case illustrations, but they do not imply or impose sanctions for deviations from the guidelines.
- *Regulatory guidelines* spell out adjudicable guidelines for practice and provide for sanctions, such as expulsion from the society, for failure to comply.

He stated that many scientific and engineering societies are reluctant to establish regulatory guidelines because they are expensive, subject the societies to litigation, and members find such regulation of their colleagues inherently

distasteful. Aspirational standards lack sufficient specificities to offer little guidance to graduate students or other new entrants into profession, or to empower individuals to resist improper pressures. As a result, Frankel stated that there is a trend away from the aspirational guidelines of the 1980's toward more specific educational standards in the 1990's. (Clearly, this is not universal. William Middleton of the Institute of Electrical and Electronics Engineers (IEEE) later testified that IEEE recently moved from regulatory to aspirational guidelines. IEEE also provides society support for individuals complaining of pressures toward unprofessional conduct.)

Joe Keyes, Esq., representing the Association of American Medical Colleges (AAMC), an umbrella organization for eighty-nine health science societies, also encouraged guidelines for teaching responsible research through case study methods. He reported that the AAMC had produced a casebook for that purpose. He also noted that some societies are reluctant to define standards, in part because of potential conflicts with other societies and institutions. He encouraged societies to provide communication about good research practice, strong publication standards for society journals, and "consciousness-raising" activities.

Dr. Martin Apple spoke for the Council of Scientific Society Presidents (CSSP), composed of past and present presidents of one hundred professional societies. He reviewed the Council's efforts regarding scientific misconduct. Dr. Stephanie Bird of MIT is conducting a survey of CSSP's member societies. Such issues as mentorship, intellectual property, authorship, peer review, whistleblower protection, harassment, and discrimination are of concern to CSSP member. Based on preliminary data, she estimated that 75% of CSSP societies have or are planning to have ethics codes or guidelines, but only 33% have regulatory codes [*A more complete report of the survey findings appears in PER, VIII(1), Winter 1995*]. Like Frankel, she advocated educational guidelines, including case examples. She singled out the 1993 code of the Association for Computing Machinery as an excellent example.

Dr. Bird suggested three criteria for societies to use in assessing their ethical guidelines: Do students and members know that they exist? Do they know how to get them? Do they know what is in them? Frankel agreed, and added that societies have to take steps to let students and members know both the contents of the guidelines *and how those guidelines apply to actual practice* (emphasis is Dr. Frankel's). This requires a continuing program of ethics-related activities.

Bird observed that societies tend to address matters related only to their own professions; she expressed the hope that the Commission would address interdisciplinary practices. Supporting that objective, I spoke as an individual, *ad hoc* commenter, saying it was not unusual for statisticians to be called in to analyze data only after the experimental or survey design and data collection had been completed by others. Often the data available were not suitable statistically to meet the research goal. Furthermore, it sometimes appeared that the real interest of the principal investigator was merely to get a statistician's name on the report or article, rather than honestly to employ the professional skills. This is just one of example of cross-disciplinary problems in research practice.

By John Gardenier, D.B.A. CDC/National Center for Health Statistics

IN THE NEWS

ORI Model Policy on Misconduct

The Office of Research Integrity has developed a Model Policy and Procedures for Responding to Allegations of Scientific Misconduct (April 1995) to assist research institutions in conducting inquiries and investigations in a manner that complies with requirements of the Public Health Service. The models are in response to "numerous requests for assistance" from institutions. In making the models widely available, ORI emphasizes that they are "intended for *guidance* only," and that institutions are under no obligation to adopt them, in part or in whole, to be in compliance with Federal regulations. They are "targeted primarily toward those institutions that recognize a need for detailed guidance on how to conduct inquiries and investigations in cases where ORI may review and follow-up on actions that the institution decides to take." Among other things, the models exceed the regulatory requirements of the PHS by including contracts in the definition of "PHS Support," and by recommending that institutions expand protection for good faith whistleblowers by providing "protection for those who cooperate with institutional investigations and those

who make allegations that the institution has inadequately responded to an allegation of misconduct." ORI observes that such protection "would be consistent with the new whistleblower protection statute" enacted as part of the 1993 NIH Revitalization Act. While regulations to implement the whistleblower protection provisions of the Act are not yet in place, the document "encourages institutions voluntarily to extend whistleblower protection to these additional individuals in the meantime."

Plagiarism Suit Results in Financial Windfall

A Federal judge has ordered the University of Alabama and four of its researchers to pay more than \$1.6 million to the Federal government and an epidemiologist for stealing her work and making false claims to the government in order to obtain Federal grants. The epidemiologist, Pamela Berge, ignored the Federal apparatus designed to investigate allegations of research misconduct and took her case directly to the courts under the False Claims Act. This was the first time that a case of alleged scientific misconduct went to trial under the Act and a jury found that the four Alabama scientists were guilty of claiming Berge's work as their own to obtain government grants and of publishing their findings without crediting her. The university was found to have aided the fraud. Under the provisions of the False Claims Act, Berge is entitled to \$498,000 in compensation. The four scientists also were ordered by the judge to pay Berge compensatory and punitive damages.

HHS Rules on Retention/Access Requirements

The Department of Health and Human Services has issued (*Federal Register*, Vol. 59, p. 43773, August 25, 1994) an interim final rule that took effect on August 25, 1994, regarding the retention and access requirements for records related to a Department award. Institutions receiving an award (grant, contract, etc.) from the Department are expected to retain all pertinent records for "a period of three years from the date of submission of the final expenditure report." One exception is if any litigation or audit is started before the expiration of the three-year period, the records must be retained until such matters are resolved and final action taken. The rule stipulates that the awarding agency, the Department's Inspector General, and the U.S. Comptroller General, or their designated representatives, have "the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the awards.... This right also includes timely and reasonable access to a recipient's personnel for the purpose of interview and discussion related to such documents."

Gallo Controversy Reopened

Controversy continues over the conduct of Dr. Robert Gallo of the National Cancer Institute in the dispute over his role in the discovery of AIDS virus and the conflict over patent rights for the HIV blood test that eventually led to an agreement between the governments of the United States and France. In 1992, the Office of Research Integrity issued its finding of scientific misconduct against Gallo -- that he falsely reported the status of his research in a 1984 paper published in *Science*. It dropped its case a year later, however, when Gallo appealed to the Department of Health and Human Services' (HHS) Appeals Board. But a new report has reopened the controversy. The report was prepared by congressional staff as part of a long-running investigation of scientific misconduct by the Oversight and Investigations Subcommittee of the Committee on Energy and Commerce in the House of Representatives, chaired until last November's election by John Dingell (D-MI). The report not only accuses Gallo of scientific misconduct in his appropriation of the HIV virus from the French, but offers a stinging criticism of HHS, accusing it of doing "its best to cover up the wrong-doing," which included "deliberately negligent 'fact-finding'" and the "deliberate suppression of incriminating evidence." The report is not an official congressional report, since it has not been approved by the House Energy and Commerce Committee, and Dingell has distanced himself somewhat from it in light of the controversy it has generated. The full length report and an executive summary can be found on the World Wide Web at: <http://nyx10.cs.du.edu:8001/~wstewart/>

NIH Simplifies Tech Transfers

In an effort to simplify the legal procedures required for exchanging reagents between biomedical laboratories, the National Institutes of Health has recently developed a protocol called the Uniform Biological Material Transfer Agreement (UBMTA). The protocol comes at a time when extensive legal documentation has impeded the transfer of biological materials between scientists despite their willingness to do so. The agreement details the rights of the

provider and recipient scientists which they themselves can sign to implement the transfer. Although the UBMTA might speed transfers of biological materials between academic laboratories, it might not suffice for similar exchanges in the biotechnology industry, where companies desire maximum protection for their products. Regardless of its application in the private sector, it is hoped that the UBMTA will reduce the legal quagmire that scientists and researchers have to confront before proceeding with the transfers of biological reagents.

EEOC Declares Genetic Discrimination Illegal

The Equal Employment Opportunity Commission (EEOC) released the first federal document that prohibits employers from discriminating against individuals based on their predisposition to genetic disease. It represents an interpretation of employment discrimination under the Americans with Disabilities Act (ADA). The EEOC anticipates that this legal protection will alleviate the fears of persons who have been unwilling to take advantage of the myriad of genetic tests which can reveal their risk of developing disease. These genetic tests can often prompt an individual to seek medical treatment and to make informed decisions that can prevent or delay the onset of disease. To qualify for protection under the ADA, people must demonstrate that they have a genetic defect and that their employer considered that defect a disability and discriminated against them on that basis.

Ontario Creates Environmental Bill of Rights

The Ontario Environmental Bill of Rights (EBR) provides people with the power to influence decisions concerning the environment made by the government. To encourage active public participation in shaping environmental laws and regulations, the EBR creates an electronic registry that will allow people to express their views on environmental proposals. The EBR also provides for greater whistle-blower protection for employees who expose environmentally threatening pollution caused by their employer and introduces provisions for requesting an investigation of wrongdoing concerning the environment. In addition, the EBR calls for the appointment of an environmental commissioner to ensure that the law is applied in a fair and consistent manner. The Bill of Rights became law in February 1994.

Religious Leaders Attack Patents on Life

At a May 18th press conference, a coalition of religious leaders representing 80 faiths and denominations led by the United Methodist Church (UMC) and Jeremy Rifkin, head of the Foundation on Economic Trends in Washington DC, and a perennial opponent of biotechnology, declared its vehement opposition to the patenting of genetically engineered organisms as well as genes, cells and organs. The statement by the coalition against human and animal patenting has added yet another dimension to the complex debate regarding patents in biotechnology. Religious leaders like Kenneth Carder, a UMC bishop and chairman of the task force studying the subject believe that, "humans and animals are creations of God, not humans, and as such should not be patented as human inventions" because "the patenting of life forms fails to recognize the sacredness of life." Although the religious leaders decry individual gene and animal patents as a "commodification of life," they do not oppose patents on the different DNA recombinant techniques called "process" patents developed for purposes of genetic engineering. Representatives of the biotechnology industry argue that the survival of the industry depends not only upon "process" patents but also on genetically altered genes, cells and animals. Precluding patents on genetic information in nature first identified by scientists would block an important financial incentive for investing in biotechnology. Although the US courts have ruled that genetically engineered life forms could be patented, whether basic genetic information can be patented still remains a question. The religious coalition intends to petition the Patent and Trademark Office to institute a moratorium on the patenting of life.

IN THE SOCIETIES

Ethics in American Archaeology

The Society for American Archaeology has published a special report on *Ethics in American Archaeology: Challenges for the 1990s*. The report includes several position papers and commentaries prepared for a public forum at the Society's 1994 annual meeting, which built on a 1993 workshop sponsored by the Society's Committee on Ethics in Archaeology. At the workshop, participants began a process of updating the Society's policy statement on

archaeological ethics. The report includes a set of six "Principles of Archaeological Ethics" drafted at the workshop and outlines some of the concerns and issues that arose in the process of drafting them. In a Preface to the report, the president of the SAA writes that "This volume, while representing the next step in a sequence of expanding consideration of the important and complex issue outlined herein, does not mark the end of a process. It is not a final product. To the contrary, this volume is an open invitation to the members of the Society for American Archaeology and other interested individuals to become active participants in what is an open and ongoing consideration of ethics in archaeology." For further information, contact the SAA at 202/789- 8200; fax 202/789-0284.

Scientific Integrity in Dental Research

The American Association of Dental Research (AADR) recently organized a symposium to explore its role in promoting scientific integrity. In addition to asking scholars from law, science and philosophy to reflect on the Association's role in monitoring research conduct, the AADR surveyed its leaders to determine their perceptions of the prevalence of questionable research and the possible roles AADR should play in promoting scientific integrity. The respondents rated practices ranging from those that might be considered as undermining the trustworthiness or reliability of science to actions that could be described as disrespectful of the work of other scientists. The AADR Ethics Committee will use the survey results, together with the symposium papers, to develop a consensus statement on the role of the AADR in promoting scientific integrity. For more information, contact Muriel BeBeau at the University of Minnesota; (612) 625-4633; Fax (612) 626-2654; E-mail bebea001@maroon.tc.umn.edu.

LETTER TO THE EDITOR

As an academic administrator who has just finished a doctoral dissertation on the development of scientific misconduct policies and procedures, I can say the results reported in Jorgensen's survey piece [*PER*, VIII(1), Winter 1995] on the lack of enforcement mechanisms comes as no surprise. Enforcement mechanisms may be ethically less important than developing a balance between accountability and research freedom.

It is a balance best described as that of responsible trust among the participants. That concept places the role of policies and procedures somewhere between the social mechanisms of science and the law. Jorgensen's comment that professional societies often limit their policies to very general statements would fit this function. The professional ideal is to be more collegial than legalistic, and the purpose of policy is not to maximize enforceable punishment for specific offenders, but rather to optimize good practice for the larger group.

It is interesting that the survey list does not include what has shaken down to be the essential elements in scientific misconduct policies - fabrication, falsification and plagiarism. What the list does represent is many of the issues that can influence the integrity of the research environment, and this may be the most effective approach in fostering ethical behavior. Some, like data management, may vary according to discipline. Some, like responsibility to expose misconduct, must be accompanied by institution-specific procedures to protect the whistleblower. A number of these issues require difficult definitions that have to balance freedom and innovation with practices that can directly harm science.

Sharing policies establishes a useful dialogue. This is important because it can positively affect the research environment where any meaningful change will occur and it mitigates outside political interference. Professional organizations can provide valuable leadership.

By Linda Malm, Ph.D.

ETHICS, LAW AND PUBLIC POLICY

Enforcing Codes of Conduct Through Professional Associations

The HHS Commission on Research Integrity has suggested that scientific societies establish and promote compliance

with research standards. Scientific societies independently have been considering their role in fostering ethical conduct among their members.^[1] The goal is to develop standards applicable to the different scientific disciplines and to enhance adherence to those standards, either by enforcement, education or some other approach. A secondary goal, perhaps, is to achieve this through the private sector, rather than through government action. It is generally accepted that voluntary regulation by scientific societies and professional associations, if effectively implemented, protects the public and maintains standards of practice more efficiently than government regulation.^[2] In addition, "privatization" is consistent with the current political focus on reducing the regulatory activities of the federal government. Before the Commission and scientific societies commit fully to this effort, however, they should consider the attendant financial costs and legal risks, as well as the time and effort likely to be required.

Establishing Standards Can Be Difficult

Scientific societies representing homogeneous subspecialty groups (*e.g.*, microbiologists, chemical engineers) will have less trouble agreeing on standards for the conduct of research than will associations that include multiple specialties. For example, the American Psychological Association has been successful in developing a detailed code of ethical conduct. But it has been a lengthy and resource-intensive process in part because the APA represents psychologists who practice and/or conduct research in a number of different fields, including: social psychology, educational psychology, industrial psychology, experimental animal psychology, school counseling, psychometric testing, developmental psychology, clinical psychology. In addition, psychologists use a variety of different experimental methods which, in turn, yield many kinds of primary data, including: responses to surveys and questionnaires; EEG tracings; serial sections of the brain; computer printouts; written, video, audio, and electronic records of animal or human behavior; and so on. Researchers working in specialized areas of science will have problems and needs relating to the creation, maintenance, and duplication of records and biological (or other) materials that may be unique to their specialty. They may also tend to collaborate with scientists in other specialties that have parallel scientific interests but different scientific traditions, primary data, and the like.

Establishing standards for the conduct of research that apply comfortably to so many different disciplines and subspecialties can be a formidable task. That is why Harvard Medical School, among others, established only very broad principles applicable to the entire School and requires each Department to establish its own, more specific guidelines.^[3]

In addition, the setting in which scientists conduct their research will affect the reasonableness of certain guidelines. Scientists working in commercial or industrial labs, for example, must comply with a provisions in employee contracts concerning, among other things, ownership of data, sharing of data, authorship and peer review. Scientists in academia work under a different set of conditions and traditions, and scientists working in government labs may have yet another set of standards and expectations to meet. The challenge of constructing a "one size fits all" code of conduct for such a disparate collection of scientists should not be underestimated.

Once a code of conduct has been prepared by a drafting committee, it typically must be reviewed and approved by the association's executive committee and then, by the general membership. At this stage, battles already fought and won, lost, or compromised in the drafting committee may be raised and fought again. The amount of time required to complete the process of drafting and adopting a set of standards often takes much longer than anticipated, with comparable wear and tear on the drafting committee.

Enforcing Standards Requires Fair Policies and Procedures

If the Association intends to enforce its standards by revoking the membership of individuals who fail to meet them, it will have to establish policies and procedures for reviewing complaints and determining what action to take based on its findings. These procedures must fulfill the basic elements of "fundamental fairness" in order to withstand legal challenge.^[4]

The "fairness" standard is similar to that of due process. While state and federal agencies are Constitutionally required to provide "due process," private organizations have been held to a standard of "fundamental fairness" in credentialing and expelling members.^[5] There is little practical difference between the two standards. In either case, the amount of procedural protection required by the courts depends on the extent to which the disciplinary action may affect the

individual's ability to practice his or her profession. Several models already exist.

The scientific misconduct regulations of the Public Health Service^[6] form a basis for institutional policies that could be used as models. The Model Policies and Procedures, recently distributed by the HHS Office of Research Integrity (ORI), provide a template that can be adjusted to meet the needs of individual institutions or associations.^[7] A Briefing Paper recently published by Federal Publications summarizes federal requirements and provides general guidelines for implementing the PHS regulations.^[8] The AAAS has published two binders of "how-to" materials that provide practical advice, model documents of all kinds, and helpful "nuts-and-bolts" suggestions.^[9]

Another model is the federal Health Care Quality Improvement Act, which protects medical "professional review groups" from legal liability so long as they provide minimal due process to practitioners whose performance they are evaluating.^[10] A "professional review action" is defined in the Act as "one which is based on the competence or professional conduct of an individual physician [or other health care practitioner] (which conduct affects or could affect adversely the health or welfare of a patient or patients), and which affects (or may affect) adversely the clinical privileges, or *membership in a professional society*, of the physician."^[11] Because the Act applies only to entities that provide health care, it would not apply to a peer review group of a scientific society. The procedural requirements set forth in the Act, however, reflect the views of Congress as to what constitutes minimal due process in proceedings to evaluate the competence and integrity of a professional individual, the results of which may affect that person's ability to practice his or her profession.

In 1988, I suggested that the due process procedures described in the Health Care Quality Improvement Act should be applied by academic institutions in responding to allegations of scientific misconduct.^[12] That was because the result of a university finding of scientific misconduct can end a scientist's career.^[13] Minimal procedures would include:

- Reasonable notice of the charges
- Prior notice of a hearing
- An opportunity to refute all charges
- A hearing before an unbiased tribunal.^[14]

Fairness also would require: the right to counsel, the right to review and copy relevant documents, the right to a list of witnesses to be called at the hearing, the right to introduce evidence and to suggest witnesses, the right to respond in writing to the charges, to appear in person or by counsel at the hearing, to receive a copy of the proposed findings, to submit comments on the draft or final report, and to appeal.^[15]

The hearing should be conducted by individuals who have no personal or professional conflict of interest, and at least some of them should have expertise in the particular scientific matters at issue. At some point in the proceedings, the accused should have an opportunity to call, examine, and cross-examine witnesses. (In an academic institution, this may occur either during the scientific misconduct investigation/hearing, or during subsequent disciplinary proceedings.) Unless the scientific society plans to offer another proceeding prior to expulsion of a member, all of these procedural protections should be afforded during the misconduct proceeding. The costs can exceed \$100,000 in relatively modest cases, and multiples of that amount in complex situations.

The Effect of Expulsion Dictates the Amount of Due Process Required

If membership in a particular scientific society has little or no bearing on a scientist's ability to obtain employment and practice the profession, then expulsion from the society may be a trivial matter. For example, if membership requires only that one pay nominal dues, and the benefits include only receipt of a monthly journal and reduced registration fees at an annual meeting, the loss of membership will have little impact on a scientist's career. In that case, the requirements of procedural fairness may be minimal. On the other hand, if membership in the society is a prerequisite for practicing the profession (for example, if it is a necessary condition for academic employment or for state licensure), then the full panoply of procedural protections would be required.

Membership in most scientific societies today has minimal impact on professional employment and related opportunities. This could change, of course, if the societies become involved in enforcing standards of conduct. Then, academic and research institutions might require membership in order to assure that their faculty or employees

maintain high standards of conduct. This would serve the purpose for which the Commission on Research Integrity is considering such a recommendation, but it would impose significant burdens on the scientific societies. It would require not only that they provide due process before expelling a member, it also might require ultimately that the society review applicants' credentials before accepting them as members, and perhaps even conduct performance reviews at regular intervals. In the process, scientific societies would become licensing boards.

Licensing boards must be careful to treat all applicants fairly, to evaluate them according to standards that are rationally related to ensuring professional competence and ethical conduct, and to avoid activities that might constitute a restraint of trade in violation of anti-trust laws.^[16] In order to accomplish those goals, licensing boards typically develop academic and practicum requirements for membership, examinations of competency, and often, periodic recertification. They then become targets of lawsuits filed by disgruntled, unsuccessful applicants and individuals who have been expelled from the organization.

Conclusion

The task is first to be clear about what would be gained by assigning an enforcement role to scientific societies, and then to consider whether it is worth the cost in terms of the resources that would be required and the liabilities that would be assumed. If the consensus is that the goal is worth the cost, the mandate to the societies should be limited, and the description of it carefully crafted, to avoid forcing them to assume licensing responsibilities.

By Barbara Mishkin

Endnotes:

1. See A. Jorgensen, "Survey Shows Policies on Ethical Issues Still Lacking Enforcement Mechanisms," *Professional Ethics Report*, Vol. VIII, No. 1 (Winter 1995), p. 1.
2. See, e.g., Jerald A. Jacobs, *Certification and Accreditation Law Handbook*, Amer. Soc. of Assoc. Executives (1992) at 1-4.
3. Harvard Medical School, "Faculty Policies on Integrity in Science" (1994) at 6-7. The policy has been in existence since 1988.
4. See, e.g., Jacobs, *supra* n. 2, at 21-25.
5. *Id.*
6. Public Health Service, Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science, 42 C.F.R. Part 50.
7. DHHS, Office of Research Integrity, "Model Policies and Procedures for Responding to Allegations of Scientific Misconduct," (April 1995).
8. B. Mishkin and W. Bradford, "Scientific Misconduct by Contractors & Grantees," Briefing paper No. 95-3, Federal Publications (March 1995).
9. One binder concentrates on conducting an inquiry, the other focuses on conducting a formal investigation. Both were prepared primarily by C.K. Gunsalus, a member of the HHS Commission on Research Integrity, and are available from the AAAS Scientific Freedom, Responsibility and Law Program.
10. Health Care Quality Improvement Act of 1986, P.L. 99-660, Title IV, § 401, 100 Stat. 3784, 42 U.S.C. § 11101 et seq.
11. *Id.*, § 11151(9).
12. B. Mishkin, "Responding to Scientific Misconduct: Due Process and Prevention," *Journal of the American Medical Association*, vol. 260, No. 13, (October 7, 1988), pp. 1932-1936.
13. *Id.* at 1935.
14. George B. Webster, *The Law of Associations* (Bender 1993) § 9.05.
15. *Id.*
16. See, generally, C. Stromberg and J. Schneider, "Designing a Fair and Legally Defensible Process for Board Certification," *Journal of the American Veterinary Association*, Vol. 205, No. 12 (December 15, 1994), pp. 1664-1667.

RESOURCES

In Print

Professional Values and Ethical Issues in the Graduate Education of Scientists and Engineers: Project Bibliography, March 1995 (The Acadia Institute, 118 West Street, Bar Harbor, ME 04609; \$11.25 per copy, prepaid to The Acadia Institute).

This 71-page bibliography covers literature published through January 1995 and is organized into eight major subject categories: (1) Education and Socialization of Graduate Students; (2) University Faculty: Roles, Rights, and Responsibilities; (3) The Research University; (4) Professional Ethics; (5) Scientists and Research: Sociological Perspectives; (6) Issues in Proposing, Performing, and Reporting Research; (7) Integrity and Misconduct in Research and Scholarship; and (8) Teaching and Learning Scientific Research Ethics. The authors intend for the bibliography to be useful to persons interested "with the nature and transmission of the professional values and ethical standards that graduate students are acquiring, the types of ethical problems that they and their faculty are encountering, how such problems are being handled, and how they might be dealt with more effectively."

Applying Professional Standards and Ethics in the Nineties: A Workbook and Study Guide with Cases for Public Administrators. Contact the American Society for Public Administration, 1120 G Street, NW, Suite 700, Washington, DC 20005.

The workbook is intended for use in small group settings and serves "as a diagnostic guide rather than prescriptive approach to professional standards and ethics...." It is directed "primarily toward individual situations with which... [an] administrator may cope, not to theoretical 'there and then' problems that one addresses in a detached way." The workbook includes brief, general essays on a range of issues faced by public administrators -- conflict of interest, whistleblowing, public disclosure and confidentiality, to cite a few -- and then follows with a series of case vignettes intended to flesh out ethical considerations for discussion. [A call for vignettes for the next edition of the workbook appears in **Announcements**.] The ASPA Code of Ethics is also included.

On-Line

There are several new ethics resources on the World Wide Web that are under development. The **Centre for Applied Ethics**, The University of British Columbia, has developed a homepage featuring a useful collection of links to other WWW resources. Point your Web browser to <http://www.ethics.ubc.ca/> The **Massachusetts Institute of Technology** has created an ethics homepage including sections on research ethics, 7 codes of ethics, and 13 National Society of Professional Engineers cases. Point your web browser to <http://web.mit.edu/ethics/www/> The **DePaul University Institute for Business and Professional Ethics** homepage is still under development, but will include a calendar of events, summaries of ethics-related articles and books, as well as numerous other professional and ethics resources. Point you web browser to <http://falcon.depaul.edu:80/ethics/>

There are two new electronic discussion lists dealing with environmental bioethics and the public communication of science and technology. As part of the International Bioethics Institute and the *Cambridge Quarterly of Healthcare Ethics*, the listserv "Environmental Bioethics" has been founded. To subscribe, send your name and e-mail address to Andrew Jameton, ajameton@unmcvm.unmc.edu. The Public Communication of Science and Technology Network, Poitiers, France, is sponsoring the new discussion list, PCST-L to provide an opportunity for discussion among practitioners, researchers, and scientists interested in science popularization. To subscribe, send e-mail that reads "subscribe PCST-L firstname lastname" to listproc@cornell.edu.

Multimedia

The Office of Government Ethics is making available its first CD-ROM titled, **The Ethics CD**. The CD contains a collection of Federal executive branch ethics laws, executive orders, regulations, opinions, and selected OGE policy letters. It also includes ethics program administration aids, such as ethics reporting forms and several OGE publications. At present, the Superintendent of Documents stocks the CD (GPO stock number 052-003-01337-1) at a

cost of \$28.00. For more information, contact Jim Parle at (202) 523-5757, ext. 1113.

ANNOUNCEMENTS

The Professional Ethics Committee of the American Society for Public Administration is seeking ethics vignettes for possible use in the next edition of its workbook, *Applying Professional Standards and Ethics in the Nineties*. The vignettes should be brief (one page is preferred), real-life ethical concerns confronting professionals in public administration that will provoke discussion. The Committee is especially interested in receiving vignettes that focus on international ethics issues, cyberspace, and legislative activities. The workbook is used extensively in public administration classes and practitioner training workshops. [See *In Print* for a description of the workbook.] Send vignettes to: Professor Frances Burke, School of Management, Suffolk University, Boston, MA 02108; e-mail: F.Burke@Suffolk.edu. All contributors will be acknowledged.

On June 25-29, 1995, the second annual **Midwest Intensive Bioethics Course** is being held at the University of Wisconsin-Madison. For registration information, contact Sandy Arneson, Program in Medical Ethics, University of Wisconsin, Room 1420, MSC, 1300 University Avenue, Madison, WI, 53706; (608) 263-3414; Fax (608) 262-2327; E-mail mdethics@macc.wisc.edu.

The **Third International Jerusalem Conference on Ethics in the Public Service**, titled "Politics, Ethics, and the Professions," is being held on June 25-30, 1995, in Jerusalem, Israel. For more information, contact the Conference Secretariat/Correspondence, Politics, Ethics and the Professions '95, c/o International Travel and Congresses Ltd., 10 Rothschild Blvd., P.O. Box 29313, Tel Aviv, 61292, Israel; 972-3-510-2538; Fax 972-3-660-604.

The Association for Practical and Professional Ethics is sponsoring its second government ethics workshop, **Ethics Education for Federal, State, and Municipal Government Employees: A Training Session**, to be held on July 13-15, 1995, at Indiana University, Bloomington, Indiana. Contact APPE, 410 North Park Avenue, Bloomington, IN, 47405; (812) 855-6450; Fax (812) 855-3315; E-mail appe@indiana.edu.

On July 16-20, 1995, the American Society of Law, Medicine & Ethics, the University of Amsterdam and the Dutch Society of Health Law are sponsoring **The Fourth International Conference Amsterdam '95: Health Law and Ethics in a Global Community**. The conference is being held at the University of Amsterdam, The Netherlands. For more information, contact the American Society of Law, Medicine & Ethics, 765 Commonwealth Ave., Suite 1634, Boston, MA, 02215; (617) 262-4990; Fax (617) 437-7596.

The Third International Conference on Social Values is being sponsored by the Department of Educational Studies, University of Oxford, and the Oxford Center for the Study of Social Values in Education and Business Partnerships, at St. Catherine's College, Oxford University, July 19-23, 1995. Contact Dr. Samuel Natale, Hagan School of Business, Iona College, 715 North Avenue, New Rochelle, NY, 10801.

The Society for Business Ethics is holding its **Annual Meeting** on August 4-6, 1995, at the Hotel Georgia in Vancouver, British Columbia. Contact Ronald Duska, Executive Director, Society for Business Ethics, Rosemont College, Rosemont, PA, 19010; (610) 527-0200, ext. 2346; Fax (610) 527-0341; E-mail duska@ucis.vill.edu.

On August 7-11, 1995, the International Program in Bioethics Education and Research is sponsoring **European Bioethics Seminar: Health Care Issues in Pluralistic Societies**, Nijmegen, The Netherlands. For more information, contact J.C.M. Felet-de Haard, Catholic University of Nijmegen, 232 Dept. of Ethics, Philosophy & History of Medicine, P.O. Box 9101, 6500 HB, Nijmegen, The Netherlands; [31] (0) 80-615320; Fax [31] (0) 80-540254.

"(How) Can we Handle Information Technology?" is the title of the Second IFIP Summer school being held in Nijmegen, The Netherlands on August 13-18, 1995. Applications are due by August 1, 1995. Contact Marc van Lieshout, University of Nijmegen, Congress Organisation, P.O. Box 9111, 6500 HN Nijmegen, The Netherlands; [31] (0) 80-652368; Fax [31] (0) 80-652084; E-mail marc.v11@cs.kun.nl.

The Victoria Free-Net Association and the Department of Writing, University of Victoria, are sponsoring **Telecommunities '95 Conference: Equity on the Internet** on August 19-23, 1995, at the University of Victoria, British Columbia, Canada. Contact Pat McGuire, Program Coordinator, Division of Continuing Studies, University of Victoria, P.O. Box 3030, MS 8451, Victoria, British Columbia, Canada, V8W 3N6; (604) 721-8746; Fax (604) 721-8774; E-mail pmcguire@postoffice.uvic.ca.

On September 8-10, the **American Association of Bioethics** is holding its **Annual Meeting** at the University Sheraton in Philadelphia. For more information, contact the Center for Bioethics, University of Pennsylvania; Fax (215) 573-3035; E-mail clinkscales@mail.med.upenn.edu.

The Australian Bioethics Association is sponsoring its **Fourth National Conference on Autonomy, Community & Justice in Bioethics**, September 25-28, 1995, at St. Johns College, The University of Queensland, Australia. Following this conference, on September 28-30, 1995, the Australia Association for Professional and Applied Ethics is convening its Second National Conference, **Ethics in Practice: Applying Ethics in Workplace and Society**. For information on both conferences, contact the Conference Secretary, St. John College, College Road, St. Lucia, Queensland, 4067, Australia; (07) 871 831; Fax (07) 870 51; E-mail jordan@qut.edu.au.

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