

Volume XII, Number 2, Spring 1999

- [Cover Story](#)
- [In the News](#)
- [In the Societies](#)
- [Ethics, Law and Public Policy](#)
- [Resources](#)
- [Announcements](#)

Publication of the AAAS Scientific Freedom, Responsibility and Law Program, in collaboration with the Committee on Scientific Freedom and Responsibility Professional Society Ethics Group

Editor: Mark S. Frankel

Deputy/Managing Editor: Sanyin Siang

Contributing Editors: Michele Garfinkel, Rachel Gray, Bhavani Pathak, Matt Zimmerman

ISSN: 1045-8808

URL: <http://www.aaas.org/spp/sfrl/sfrl.htm>

Dealing with Academic Misconduct in Germany

By Bernhard M. Lippert

Bernhard Lippert oversees the research policy desk at the Hochschulrektoren Konferenz (HRK), the Association of Rectors and Presidents of Universities and other Higher Education Institutions in the Federal Republic of Germany. This essay reflects only his personal views and not those of the HRK.

Scientific standards, and the ethical values supporting them, such as honesty, integrity, openness, etc., are international standards and values. The way we conduct scientific progress and academic affairs in general certainly differs in some respects from discipline to discipline but not from nation to nation. Yet, historical and legal factors influence to some extent scientists' day to day routine, and national differences in the organization of science we find in the way with which academic misconduct is dealt in various countries. Let us have a look at the situation in Germany, starting with a few brief and only at first sight scattered remarks concerning the historical and legal background in order to understand an important legal problem.

A Wissenschaftler is someone who creates (schaffen) knowledge (Wissen). This etymology underlines the great ideals of science (Wissenschaft in German, comprising any scientific discipline from archaeology to zoology), which seems at first sight to be conducted only by really honest and hardworking people. In German society, the reputation of scientists has at most times and certainly for good reasons been very high, with the exception of the gruesome years of the Nazi regime, when quite a few scientists did not or could not, for whatever reason, live up to the moral standards of the international scientific community. After the second world war, Western Germany was reconstructed as a Federal Republic, consisting then of 11, now after reunification of 16 Länder (federal states), with the aim never again to allow a single person, movement or ideology to gain control over the system. In May 1949, the founding fathers and mothers of Western Germany stipulated in article 5(3) of the Grundgesetz ("basic law", i. e. the constitution): "Art and science, research and teaching shall be free. Freedom of teaching shall not release anybody from his allegiance to the constitution."

Apart from the purpose of promoting science, this constitutionally guaranteed freedom is seen as another barrier to anyone trying to suppress - and even more as a means to foster - individual rights and democratic principles. Constitutional rights, of course, rank highest and may be restricted only to save other constitutional rights. The state has the constitutional duty to provide education.

From kindergarten all the way to PhD-degrees, education is overseen - but not determined - by (one of) the Länder. School teachers and professors in higher education institutions are employed directly by their Land, the institution serving as the work place. This feature is of Prussian heritage: (tenured) professors are employed in the same fashion as civil servants (like policemen or tax inspectors) in public administration, i.e. as "Beamte," who enjoy a special status. A Beamter may be moved from one place to another, but the state guarantees him/her a place to work as well as a reasonable income and pension scheme. One is likely to lose tenure as a Beamter only if convicted of a serious crime.

Scientific misconduct of a German professor? For too long a time there seemed to be no need to prepare for such an event. But some severe cases of academic misconduct became public in recent years, and pressure has grown considerably to become organized to deal with such matters properly.

Compared to the situation in other countries, it seems that the legal scope available to German institutions of higher education and research institutions for taking action by themselves against academic misconduct is a bit more limited, and the role of the courts is correspondingly larger.

Legally essential in Germany is the borderline between a controversial scientific debate amongst individuals and any official action that may imply censorship of ideas. Of central importance in this context is the ruling by the Federal Administrative Court in Berlin from 11 December 1996. This ruling is related to the case of a professor who came up with irreproducible results and had unfortunately lost his primary data when questioned by a departmental ad-hoc committee. Concerning the possibility of an investigation committee set up by the university and regarding the particular rights of a professor - see above - the ruling generalizes:

- institutions of higher education may, provided that there is definite evidence to indicate that a scientist may be abusing his/her academic freedom, or jeopardizing or violating rights of others which enjoy constitutional protection, act upon this evidence and, should they deem it necessary, call upon the services of a committee, in which professors of higher education institutions must constitute the majority, to examine the circumstances of the case and draw the necessary consequences;
- such a committee may only act on the matters in question and only if and to the extent that serious charges are brought against a scientist; for example if he/she has irresponsibly acted in breach of the fundamental principles of scholarship or has abused the principles of academic freedom, or if there is reason to question the academic nature of his/her work, not only in special regards or according to the definition of a particular 'school', but on a systematic basis;
- the committee is authorized to make an appropriate statement and to criticize the work of the researcher in a suitable way, to the extent that the academic is found without any doubt to have overstepped the limits of academic freedom. Should, however, the committee come to the decision that the academic seriously endeavors, in his/her activities, to respect the principles of academic work and that he/she has likewise not violated the rights of others, it is not authorized to pass judgment on the work in question;
- the superior responsible for disciplinary action is to be informed of any disciplinary offense and he/she should then take further action; in the event of the rights of another having been violated, the committee is responsible for taking the necessary action to protect those concerned;
- confidentiality is to be respected; the standards upheld should be based on those of formal disciplinary proceedings.

This ruling is now under final revision by the federal constitutional court, because the university involved is hoping for a (an even) better ruling for institutions. Until then, all public academic institutions in Germany - universities as well as other research institutions - follow the ruling's guidelines summarized above, with differences only in details in order to suit the organizational structure of the particular kind of institution.

The universities and the other higher education institutions in their capacity as institutional members of the Hochschulrektorenkonferenz—the Association of Universities and other Higher Education Institutions in Germany (<http://www.hrk.de>)—have adopted, on the occasion of a plenary session on 6th July 1998, the resolution “On Dealing with Academic Misconduct in Institutions of Higher Education,” which formulates suggestions as to how to proceed in cases of academic misconduct (for full details see HRK homepage). All HRK-member-institutions have established or are in the process of establishing their own regulations, which seem to follow closely the original though necessarily more general HRK-recommendations.

The Deutsche Forschungsgemeinschaft (DFG) - the major funding agency in Germany for research in universities, an autonomous institution funded by the Federal and Länder governments granting funds for projects strictly according to peer review - is insisting that such regulations be in place soon for continued funding. Since the universities constitute the majority of the DFG-members, the universities have bound themselves twice, to HRK and in DFG.

The HRK has defined scientific misconduct in agreement with the international scientific community to occur when “in a scientifically significant context false statements are made knowingly or as the result of gross negligence, the intellectual property of another is infringed or their research activities otherwise disadvantaged.” The corresponding catalogue of specific “serious examples of misconduct” includes in particular the category “joint accountability for academic misconduct,” including active participation in the misconduct of another, knowledge of falsification committed by another, co-authorship of publications affected by falsification, and gross neglect of supervisory duties.

The HRK emphasizes that each case be examined carefully and individually, and that final decisions must depend upon the circumstances of the specific case. Serious offenses against academic standards may finally deprive a researcher of his/her individual constitutional protection as researcher and/or teacher, because anyone working unscientifically should not be granted a scientist’s privilege. Whether someone has - in case of a severe accusation - worked according to the standards of the discipline, or not, must be determined by the scientific community, on pain of the community of scholars losing credibility, and irrespective of any legal action by anyone at any time. Special committees dealing with accusations of misconduct should conduct a preliminary inquiry before entering a formal investigation. If scientific misconduct has occurred, then the committee’s result is to be communicated to the governing body of the institution and might constitute an important factor in court.

But such an investigation committee is probably not a sufficient instrument by itself in the everyday life of a university. The HRK has, therefore, additionally suggested the appointment of one or more experienced members of the academic staff as ombudspersons who not only react to accusations, but on their own initiative follow any clue of possible academic misconduct. An ombudsperson should also advise in confidence anyone who notifies him/her of suspected misconduct, examining the charges in terms of their credibility in order to ascertain what concrete evidence there may be for them, their severity, possible motives, and any possible means of repudiating them.

At the end of official investigation proceedings, the ombudsperson should also identify all those persons who are or were involved in the particular case. The ombudsperson advises all those persons, in particular young academics and students, who, through no fault of their own, were mixed up in cases of misconduct, on how to safeguard their personal and academic integrity. The ombudsperson should store the files of the formal investigation for a period of 30 years (in analogy to related legal issues). During this period, any person mentioned in connection with a case of academic misconduct in that institution is entitled to request from the ombudsperson an official certificate as to his or her own exoneration.

In order to safeguard good scientific practice, post-hoc measures are indispensable but certainly not sufficient. The HRK has suggested to its member-institutions that they should reinforce existing or introduce new measures capable of preventing academic misconduct from arising in the first place. In their capacity as centers of research, teaching and the promotion of young academics, the institutions of higher education have an institutional responsibility in this regard. Each and every head or supervisor of a study unit has a duty to be an example to others in academic matters.

Students and young academics must, for the sake of safeguarding their own future plans, also be on their guard against the possibility of academic misconduct in their own environment. The faculties are called upon to cover the subject of “academic misconduct” in a suitable manner within the curriculum, hence raising the awareness of students and young academics towards such issues in an appropriate manner. Every young academic should be aware, for example, of how long different kinds of primary data must be retained, and he/she should, early on in his/her academic career, have enjoyed the experience of being personally treated in a just way. As to this permanent process, the “Proposals for Safeguarding Good Scientific Practice” - available in English under this title - by the DFG (<http://www.dfg.de>) are of great importance and assistance to German research institutions and scientific societies. I should be glad to report on successes in this process in due time.

IN THE NEWS

ORI GUIDELINES FOR EDITORS

The Office of Research Integrity (ORI) is developing a document, "ORI Guidelines for Editors: Managing Research Misconduct Allegations." Its purpose is to provide editors of scientific journals with guidance for dealing with manuscripts that contain information suspected of scientific misconduct.

The draft guidelines advise editors on: (1) reporting suspect manuscripts; (2) procedures for handling suspect manuscripts; (3) co-author signatures; (4) submission of data; (5) guidelines for reviewers; and (6) corrections and retractions. Additionally, the guidelines recommend ways that editors can avoid potential problems, including the adoption of editorial policies that may prevent misconduct.

The guidelines indicate several policies that editors could adopt to reduce the submission and publication of fraudulent manuscripts. ORI suggests that editors take the following steps in handling a suspect manuscript: (1) determine the funding source; (2) contact ORI; and (3) contact the responsible institutional official. According to ORI, the absence of such procedures reduces the likelihood that misconduct will be reported when detected. Instead, the suspect manuscript is more likely to be rejected and returned to its author, thereby creating the possibility that it will be published elsewhere.

Earlier reports by the International Committee of Medical Journal Editors, the Committee on Publication Ethics, and the Institute of Medicine of the National Academy of Sciences have recommended that editors take an affirmative responsibility to develop policies and pursue possible cases of scientific misconduct in submitted manuscripts. While ORI's proposed guidelines do not establish any legal rights or cause of action by or against an editor, individual whistleblowers, respondents or institutions, or the U.S. Department of Health and Human Services, they do promote a role for editors in fostering research integrity and responsible publications.

The ORI guidelines are posted on the WWW at http://ori.dhhs.gov/ori_guide-lines_for_editors.htm for comments until August 1, 1999.

COURT RULES IN ENCRYPTION CASE

In May 1999, the Ninth Circuit upheld the decision of the lower courts [[PER Vol. 10, Number 3, 1997](#)] by ruling in favor of the plaintiff in *Bernstein v. U.S. Department of Commerce, et al.* The case presented a challenge to the federal government's Export Administration Regulations (EAR), which require that a computer scientist (Daniel Bernstein) obtain a license from the government in order to publish the source code for a cryptographic system that he created. As a teacher and scientist, Bernstein claimed that this requirement was prior restraint on his right of free speech. He won at the U.S. District Court level and the government appealed.

The majority opinion basically dealt with two questions: (1) Does computer source code qualify for protection under the First Amendment? and, if it does, (2) Are the government's EAR an impermissible prior restraint? The Court answered the first question affirmatively, noting that source code, as those used for cryptography, is protectable under first amendment rights. As to the second question, the Court concluded that the regulations "allow the government to restrain speech indefinitely with no clear criteria for review" and thus, are "an unconstitutional prior restraint on speech." Moreover, this violation of the first amendment is supported by the application of the *Bernstein* case to scientific expression and the regulations' lack of procedural safeguards. However, the Court does "not hold that all software is expressive."

While the Court based its decision on narrow constitutional grounds, it nevertheless and most interestingly took the initiative to comment on three issues that are related to Bernstein's constitutional claims. First, the government's efforts to regulate and control the exchange of knowledge with regard to encryption stymies the flow of scientific ideas and thus, implicate the First Amendment right to freedom of speech. Second, these regulatory policies may also implicate privacy rights. Third, these export controls may limit the access to encryption technology by ordinary citizens.

The Ninth Circuit's ruling conflicts with a District Court ruling in another encryption case in the Midwest (now being appealed in the Sixth Circuit) and further heightens the prospect that this issue will go to the Supreme Court. The

concurring judge in the Appeals Court ruling observed that “The importance of this case suggests that it may be appropriate for review by the United States Supreme Court.” While the Court based its decision on narrow constitutional grounds, it nevertheless and most interestingly took the initiative to comment on three issues that are related to Bernstein’s constitutional claims. First, the government’s efforts to regulate and control the exchange of knowledge with regard to encryption stymies the flow of scientific ideas and thus, implicate the First Amendment right to freedom of speech. Second, these regulatory policies may also implicate privacy rights. Third, these export controls may limit the access to encryption technology by ordinary citizens. The Ninth Circuit’s ruling conflicts with a District Court ruling in another encryption case in the Midwest (now being appealed in the Sixth Circuit) and further heightens the prospect that this issue will go to the Supreme Court. The concurring judge in the Appeals Court ruling observed that “The importance of this case suggests that it may be appropriate for review by the United States Supreme Court.”

IBIA INTRODUCES BIOMETRICS GUIDELINES

In March 1999, the International Biometrics Industry Association (IBIA) an organization with 15 member companies, announced Privacy Principles to guard against the misuse of personal data.

Biometrics technology is a non-invasive, computer-based method of automatic identification or identity verification of an individual. It matches patterns of live individuals in real-time against enrolled records. Examples of biometrics include products that use face, iris, and hand patterns and applications include information security, physical access control, financial transactions, and law enforcement. The technology offers a major defense against identity theft.

The new Principles would call for regulation of government use of biometrics, but endorse a voluntary approach when it comes to private industry use. The Privacy Principles are as follows:

1. Biometric data is electronic code that is separate and distinct from personal information, and provides an effective, secure barrier against unauthorized access to personal information. Beyond this inherent protection, IBIA recommends safeguards to ensure that biometric data is not misused to compromise any information, or released without personal consent or the authority of law.
2. In the private sector, IBIA advocates the development of policies that clearly set forth how biometric data will be collected, stored, accessed, and used, and that preserve the rights of individuals to limit the distribution of the data beyond the stated purposes.
3. In the public sector, IBIA believes that clear legal standards should be developed to carefully define and limit the conditions under which agencies of national security and law enforcement may acquire, access, store, and use biometric data.
4. In both the public and private sectors, IBIA advocates the adoption of appropriate managerial and technical controls to protect the confidentiality and integrity of databases containing biometric data.

NIH DIRECTOR RECOMMENDS RELOCATING OPRR

In June 1999, Harold E. Varmus, the director of the National Institutes of Health (NIH), recommended that the Office for Protection from Research Risks (OPRR) be moved from NIH to the Department of Health and Human Services (DHHS). The recommendation is based on the advice of a special Panel appointed by Varmus to examine the organizational locus and authority of OPRR.

After a seven-month review, the Panel arrived at the following findings and recommendations: 1) OPRR should be administratively relocated from its present location within the NIH; 2) OPRR should be located in the Office of the Secretary of DHHS and report to either the Surgeon General or the Assistant Secretary for Health; 3) a relocated OPRR would best be able to reap the benefits of the move if the director of the office were to be a member of the Senior Executive Service; 4) as part of the move of OPRR to a new location, the Secretary should create an independent advisory committee to provide guidance, assist in setting standards, and review the operation of the office; and 5) current authority is adequate for addressing the tasks currently assigned to it, but the resources available to OPRR may be inadequate for fulfilling its mission.

The status of OPRR is important to university scientists and research officials because it ensures that campuses and the NIH follow government rules to protect human subjects in federally financed experiments. Some commentators have suggested that the location of OPRR in the governmental research structure - within the NIH, which is a component of DHHS - contributes to public distrust of the research enterprise with respect to the treatment of human subjects and animals. Some perceive that OPRR's location within NIH as compromising its ability to oversee research funded by other agencies and by NIH intramural programs.

The report and recommendations of the OPRR Location Review Panel can be found on the WWW at:
<http://www.nih.gov/welcome/director/060699b.htm>.

FDA POSTS INDUSTRY GUIDELINES FOR XENOTRANSPLANTATION

In April 1999, the Food and Drug Administration posted a notice of a new "Guideline to Industry" on the use of non-human primate cells, tissues, and organs for transplants to human beings (Federal Register 64:16743-16744). Comments will be accepted for 90 days. The document may be found at <http://www.fda.gov/cber/gdlns/xenoprim.txt>. This document describes known and predicted dangers associated with xenotransplantation (particularly concerning the cross-species transmission of infectious diseases) and underscores the need for more research and more policy discussion in this area. While the government is not placing a formal ban or moratorium on these protocols, the FDA's recommendations make clear that transplants from non-human primates are considered too dangerous to receive FDA approval, hence resulting effectively in a ban.

Except in a general way, the new guidelines do not address the dangers associated with xenotransplantation from non-primate species. But this is not meant to be understood as an endorsement of transplants from other species. At this time FDA is only making statements about non-human primates because the safety issues are now fairly well-documented. Transplants using pig cells are ongoing in the United States but are being very closely monitored by FDA. The general safety of transplants from distantly related species compared to closely related primate species has not yet been determined.

Despite the problem of raising enough animals for transplantation use even if all of the safety problems can be solved, the potential for using animal organs for transplants when no human tissue is available is still exciting. For this reason, several agencies, including non-governmental organizations, have taken an interest in exploring these issues. DHHS, for example, is assembling a xenotransplantation committee modeled on the National Institutes of Health's Recombinant DNA Advisory Committee. Further, a group of xenotransplantation experts is expected to initiate the formation of an international, independent broad-reaching think-tank to address issues of technologies that provide benefits that may be difficult to balance against risk, like xenotransplantation.

NIH RELEASES DRAFT MATERIALS TRANSFER GUIDELINES

As part of an attempt to clarify the basic principles that should govern the sharing of research resources, the National Institutes of Health released a draft set of guidelines to the public for comment. The guidelines aim to help NIH-funded researchers understand the acceptable restrictions on materials transfer and describe which conditions, if any, can be imposed by NIH-funded researchers as conditions for making their tools available.

The system of Materials Transfer Agreements (MTAs) that has developed has become increasingly burdensome. NIH agrees that some conditions can be reasonable (e.g., nominal licensing fees or minimal delays in publication to apply for patents). It is specifically concerned that MTAs are being used by companies or by other universities to prevent publication, or worse, to prevent initial research by making the acquisition of research tools impossibly expensive or complicated. There is further concern about the construction MTAs to include "reach-through rights" (allowing claims by the original provider of the materials upon any resulting data).

The guidelines cover several interrelated principles that impact NIH-funded research scientists. These principles include the right to academic freedom and the responsibility to publish, the necessity for appropriate implementation of the Bayh-Dole Act (a 1980 provision that enabled universities and non-profit research institutions to own and patent inventions developed with federal funds), the need to minimize administrative obstacles to academic research, and the need to insure the dissemination of resources that are the products of research funded by the NIH. NIH says it will be diligent in enforcing the guidelines and may make grant awards conditional on agreeing to them.

The draft guidelines (entitled “Principles for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources”) were published in the Federal Register 64:28205, May, 1999 and are also available at <http://www.nih.gov/od/ott/RTguide.htm>. Comments may be submitted to NIH until August 23, 1999. A copy of the report of the Working Group on Research Tools presented to the Advisory Committee to the director is also available at http://www.nih.gov/news/research_tools/index.htm.

IN THE SOCIETIES

PROFESSIONAL SOCIETY ETHICS GROUP SPRING MEETING

On June 2, a panel of experts met at the American Association for the Advancement of Science (AAAS) for the spring meeting of the Professional Society Ethics Group to examine and discuss the threats and ethical issues posed by the use of computer and network technology to sabotage U.S. critical infrastructures. The meeting followed in the wake of a series of attacks by hackers on web sites operated by federal agencies, including the FBI.

Michael Vatis, Chief of the government’s National Infrastructure Protection Center, condemned the attacks and said that hacking is a crime and should be treated as such. “Messages that say, ‘If you continue to enforce the laws by conducting investigations against hackers, we are going to come after you,’ are an effort to intimidate government officials from enforcing the law,” he said. Vatis acknowledged though that it can be very difficult for law enforcement agencies to determine who actually perpetrated a computer crime.

Vatis also brought up some of the ethical issues raised by the prospect of infrastructure warfare fought with computers and information technology compared to more conventional kinds of force. For example, perpetrator identity is difficult to ascertain in cyberwarfare. Would it be ethical to respond or retaliate with this degree of uncertainty? Daniel Kuehl, professor of military strategy and national security policy at the National Defense University, urged a reconsideration of the notion of “force” since cyberwarfare is not explicitly recognized yet by the international codes of conduct that govern conventional war. “The technology is way ahead of the law and far ahead of the ethics,” he said.

Roger C. Molander, a senior research scientist for RAND, discussed the difficulties involved in anticipating and preparing for the possibility of attacks on national critical infrastructures. He warned that one of the chief problems is establishing a system of information exchange between the public and private sectors. This would involve not only determining what the government needs to know for purposes of national security, but also protecting the privacy of potentially sensitive industry-provided information about infrastructural weaknesses.

James Dempsey, senior staff counsel at the Center for Democracy and Technology, ended the meeting with a warning that efforts directed at safeguarding national infrastructures could serve as “a Trojan horse for infringement of civil liberties.” Dempsey expressed concern that the promotion of a public key management infrastructure had become linked to critical infrastructure protection. The government must get its own house in order, he said, before dictating policies that have more to do with surveillance than national security.

ACADEMIC FREEDOM IN MEDICAL SCHOOL

The following statement was originally adopted by the participants in the conference on academic values in the transformation of academic medicine, May 22, 1999, and subsequently endorsed by Committee A on Academic Freedom and Tenure of the American Association of University Professors on June 6, 1999.

The term “academic freedom” refers to the freedom of college and university faculty to teach, to conduct research and publish the results, and to fulfill responsibilities as officers of an educational institution. Academic freedom is a core value in the American community of higher learning. Its protection is a crucial responsibility of university faculties, administrations, and governing boards. While academic freedom clearly safeguards the work of professors and their institutions, its primary purpose is to advance the general welfare....

The modern medical school has many of the attribute of a complex, market-driven health care system with professors often acting as entrepreneurs in research and in patient care. It is marked by conflicting roles and responsibilities, both

academic and nonacademic, for faculty members and administrators alike. The intense competition for private or governmental funding can affect the choice of research subjects, and in some instances, scientists in academic medicine are finding it difficult to secure funding for unorthodox research or research on matters that are politically sensitive. The growing reliance on the clinical enterprise at many medical schools, and the resulting expansion of the number of professors who are engaged mainly in clinical work, may serve to divert the schools from their teaching mission, and may implicitly or explicitly dissuade professors from devoting their attention to such activities as a graduate teaching or university service that are not income-producing in nature. Further affecting the academic freedom of medical school faculty is the hospital pattern of hierarchical organization, with deans and department chairs – and often professional administrators who lack medical training or academic experience – making decisions that elsewhere in the university would be made collegially or left to individual professors.

Academic freedom, should be especially nurtured and supported because of the constraints surrounding medical research....

1. **Freedom to Inquire and to Publish.** The freedom to pursue research and the correlative right to transmit the fruits of inquiry to the wider community – without limitations from corporate or political interests and without prior restraint or fear of subsequent punishment – are essential to the advancement of knowledge. Accordingly, principles of academic freedom allow professors to publish or otherwise disseminate research findings that may offend the commercial sponsors of the research, potential donors, or political interests, or people with certain religious or social persuasions.... The pursuit of medical research should proceed with due regard for the rights of individuals as provided by National Institutes of Health and university protocols on the use of human and animal subjects. Any research plan involving such matters should be reviewed by a body of faculty peers or an institutional review board both before research is initiated and while it is being conducted. Any limitations on academic freedom because of the religious or other aims of an institution should be clearly stated in writing at the time of initial appointment.
2. **Freedom to Teach.** The freedom to teach includes the right of the faculty to select the materials, determine the approach to the subject, make the assignments, and assess student academic performance in teaching activities for which they are individually responsible, without having their decisions subject to the veto of a department chair, dean, or other administrative officer. Teaching duties in medical schools that are commonly shared among a number of faculty members require a significant amount of coordination and the imposition of a certain degree of structure, and often involve a need for agreement on such matters as general course content, syllabi, and examinations. Often, under these circumstances, the decisions of the group may prevail over the dissenting position of a particular individual.
3. **Freedom to Question and to Criticize....** In speaking critically, faculty members should strive for accuracy and should exercise appropriate restraint. Tolerance of criticism, however, is a crucial component of the academic environment and of an institution's ultimate vitality. No attribute of the modern medical school which may distinguish it from other units within a university should serve as a pretext for abridging the role of the medical faculty in institutional governance....

Despite the serious challenges currently facing them, our institutions of academic medicine should respect and foster conditions that are essential to freedom of learning, freedom of teaching, and freedom of expression.

ETHICS, LAW AND PUBLIC POLICY

FDA REGULATORY CONTROLS OVER HUMAN STEM CELLS

By Robert P. Brady, Molly S. Newberry and Vicki W. Gerard

This summary and the original paper on which this summary is based was written by Robert P. Brady, Molly S. Newberry and Vicki W. Gerard, members of the Food and Drug Practice Group at Hogan & Hartson, L.L.P. in Washington, D.C.

The National Bioethics Advisory Commission (NBAC) currently is considering the ethical issues surrounding the use of human stem cells in federally-funded research. Several statutes provide FDA with broad authority to regulate both the research into and the use of human stem cells (“stem cells”) intended to be used as biological products, drugs or medical devices to prevent, treat, cure or diagnose a disease or condition.¹ Scientific research not designed to develop any FDA-regulated product is not under the oversight and control of FDA. What follows is a brief summary of a paper prepared for the NBAC which describes FDA’s regulatory controls over stem cells intended to be used as therapeutic products regulated by FDA. The full paper, which does not take a position on whether the use of stem cells is acceptable public policy, was submitted to NBAC on May 12, 1999, and is available at <http://bioethics.gov/briefings/index.html#draft>.

FDA Has Jurisdiction to Regulate Stem Cells

Under section 351 of the PHS Act, FDA is authorized to regulate biological products introduced into interstate commerce.² The PHS Act defines a “biological product” to mean “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.”³ This definition includes stem cell products, which are considered by FDA to be analogous to blood, blood components or derivatives if they are used for the prevention, treatment, or cure of a disease or condition of human beings. All biological products must be approved prior to marketing.⁴ During their investigational stage, such products may be studied in humans pursuant to an Investigational New Drug (“IND”) Exemption.⁵

Cellular products currently regulated by FDA as biological products include (among other things): (1) activated and expanded lymphocytes; (2) encapsulated or cultured cell lines intended to secrete a bioactive factor or factors (e.g., insulin, growth hormone); and (3) somatic cells that have been genetically modified.⁶ In addition, peripheral and umbilical cord blood stem cells that (1) have been more than minimally processed; and (2) are intended to prevent, treat, or cure disease also are regulated as biological products.⁷

FDA also has authority to regulate stem cell products under another section of the PHS Act. Section 361 authorizes the Department of Health and Human Services (“HHS”) to “make and enforce such regulations as in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.”⁸ This provision provides FDA with broad discretion to enact regulations necessary to prevent the spread of communicable diseases.

FDA Has the Statutory Authority to Regulate Stem Cell Products as Drugs under the FD&C Act

In addition to having authority to regulate stem cell products as biological products under the PHS Act, FDA has concluded that it also has the authority under the Federal Food, Drug & Cosmetic Act (FD&C Act) to regulate any stem cell product that meets the statutory definition of a drug.⁹ The FD&C Act defines drugs as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”¹⁰ The vast majority of “new drugs” regulated under the FD&C Act are various dosage forms of synthetic chemicals or plant derivatives. In contrast, the majority of biological products licensed under the PHS Act are products derived from human cells or tissues. FDA exercises its discretion, based roughly on the product categories described above, in approving products either as new drugs or biological products. The PHS Act makes it clear that if a biological product is licensed under the PHS Act, it is not required to be approved also under the FD&C Act.¹¹

Comprehensive FDA Policy to Regulate Cellular or Tissue-Based Products, Including Stem Cells

In February 1997, consistent with the existing statutory framework set forth above, FDA proposed a new approach to the regulation of human cellular and tissue-based products. This framework is intended to “protect the public health without imposing unnecessary government oversight.”¹² The 1997 document establishes the further evolution of FDA’s application of the PHS Act and FD&C Act to cellular and tissue products. While still a proposal, it utilizes FDA’s existing statutory authority under both Acts to regulate a broad array of cellular and tissue materials.

The framework proposes a tiered approach to the regulation of cellular and tissue-based products.¹³ Products that pose increased risks to health or safety would be subject to increased levels of regulation (i.e., either licensure under

the PHS Act or premarket approval under the FD&C Act). For example, products that pose little risk of transmitting infectious disease would be subject to minimal regulation (i.e., facility registration and product listing). However, products that are: (1) highly processed (more-than-minimally manipulated), (2) used for other than their normal purpose, (3) combined with nontissue components (i.e., devices or other therapeutic products) or (4) used for metabolic purposes (i.e., systemic, therapeutic purposes) will be required to undergo clinical trials as investigational drugs, biologics, or devices, and obtain FDA approval before they may be marketed.

The Proposed Approach addresses FDA's regulation of stem cell products. In the case of a minimally manipulated product for autologous use, and allogeneic use of cord blood stem cells by a close blood relative, FDA has proposed requiring compliance with standards to prevent the spread of infectious diseases rather than premarketing approval. However, minimally manipulated products that will be used by an unrelated party will require premarketing approval by FDA. The FDA intends to develop standards for these products, including disease screening requirements, establishment controls, processing controls, and product standards. "If sufficient data are not available to develop processing and product standards after a specified period of time, the stem cell products would be subject to IND and marketing application requirements." 14 Stem cell products that are more than minimally manipulated will require clinical trials and premarketing approval by FDA. For example, based on FDA's "increased safety and effectiveness concerns for cellular and tissue-based products that are used for non-homologous function, because there is less basis on which to predict the product's behavior," stem cell products that will be used for a function different from the organ or tissue from which they were obtained or are more than minimally manipulated will be required to be licensed by FDA before they may be sold in interstate commerce. 15

Despite the patchwork quilt of regulations applied through the mid-1990's, FDA has now developed a comprehensive regulatory approach to the regulation of cellular and tissue-based therapeutic products, including stem cells. Nonclinical and clinical stem cell research undertaken to develop a therapeutic product intended to treat human disease will continue to be regulated by FDA while basic scientific research and other nonhuman research will remain outside the agency's purview.

References

- (1) See, the Public Health Service Act ("PHS Act"), the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), and the implementing regulations of the Food and Drug Administration.
- (2) 42 U.S.C. § 262(a).
- (3) *Id.* § 262(i) (emphasis added).
- (4) *Id.* § 262(a).
- (5) 21 C.F.R. § 312.1 et seq.
- (6) 58 Fed. Reg. 53248, 53250 (Oct. 14, 1993) ("Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products"; the "Somatic Cell Therapy Policy").
- (7) FDA, "A Proposed Approach to the Regulation of Cellular and Tissue-Based Products" (February 28, 1997).
- (8) 42 U.S.C. § 264.
- (9) 21 U.S.C. § 355.
- (10) 21 U.S.C. § 321(g).
- (11) 42 U.S.C. § 262(j). To the extent FDA concludes that stem cell products meet the definition of a device under section 201(h) of the FD&C Act and operate in a manner similar to human tissue products used for transplantation (e.g., heart valve allografts and human lenticules), they also may be subject to regulation as devices.

(12) "Reinventing the Regulation of Human Tissue," National Performance Review (February 1997) at 1.

(13) FDA, "A Proposed Approach to the Regulation of Cellular and Tissue-Based Products" (February 28, 1997) (the "Proposed Approach"). (14) Proposed Approach at 25. (15) Id. at 16.

ANNOUNCEMENTS

Conference on Teaching Ethics Across the Curriculum will convene on October 14-16, 1999 at the Rochester Institute of Technology. The Conference seeks to elicit the variety of issues raised by teaching ethics across the curriculum. Contact Wade Robison at Email: wlrghs@rit.edu; WWW <http://www.rit.edu/ethics>.

The **Institute for Ethics at the American Medical Association** seeks candidates for its Fellowship Program for the 2000-2001 academic year. Two to four qualified individuals will be given an opportunity to start or advance their scholarly pursuits in bioethics through independent research and writings. The Institute for Ethics was established to address the dynamic ethical issues facing today's medical community. Functioning as an independent academic organization, the Institute strives to enhance the caliber of medical ethics by conducting research studies and developing outreach programs specializing in managed care, end-of-life care, professionalism, and genetic medicine. The Fellowship Program invites applications from both younger scholars who plan to continue their studies in professional or graduate school, as well as more advanced scholars. Doctoral students at the dissertation writing stage and individuals at the post-doctoral level are also welcome to apply. Designed as a one-year fellowship program, the Institute will consider applicants for a shorter period of time. Contact Carol E. Sprague at Division of Placement, American Medical Association, 515 North State Street, Chicago, Illinois 60610. (For more information regarding the Institute for Ethics academic programs, contact Kayhan Parsi at kayhan_parsi@ama-assn.org)

A special issue of **Science and Engineering Ethics**, Volume 5, No. 2, 1999 draws together a major collection of papers and commentaries on the subject of scientific misconduct in the United States. Contributions document differing practical approaches to dealing with misconduct issues, examine the complexity of developing a government-wide definition, and predict concerns that will affect the scientific community in the future. Authors include scientists, ethics scholars, lawyers and policy specialists from the U.S. Office of Science and Technology Policy, the Office of Research Integrity, National Science Foundation, Institute of Medicine and leading academic institutions. Contact Opragen Publications, PO Box 54, Guildford, Surrey GU1 2YF, UK; WWW <http://www.cableol.co.uk/opragen/>

The **Division of Medical Ethics at Harvard Medical School** encourages research and teaching on ethical issues in medicine. The Fellowship in Medical Ethics is open to physicians, nurses, lawyers, and others in academic fields related to medicine who have a serious academic interest in medical ethics and wish to further their knowledge of the philosophical, social, historical, and political aspects of contemporary medical ethics. Fellows are expected to conduct original research in medical ethics as well as to develop their teaching and clinical skills in ethics and related disciplines. Fellows must have external salary support from a training program grant or a sponsoring institution; the Division will provide support for other academic and research needs. Applicants should submit a curriculum vitae, including email address and a brief statement (not more than 1,000 words) describing their interest in ethics and research plans for the fellowship. Applicants should also indicate the nature of their salary support and provide two letters of reference. Contact Walter Robinson at (617) 432-3041; Email Walter_Robinson@hms.harvard.edu.

Ethics & Behavior is planning a special issue on the topic of Academic Dishonesty. Data-based and theoretical papers on causes, incidents, contexts, types, and characteristic of academic dishonesty are welcome. Data-based papers (including well-designed case studies) on the resistance to student faculty/administrative involvement in promoting academic integrity and dealing with academic dishonesty and reports of effective deterrants and prevention programs are also of interest. Deadline for manuscript submission is December 15, 1999. Contact P. Keith-Spiegel at Department of Psychological Science, Ball State University, Muncie, Indiana 47106; (765) 285-1620; fax (765) 285-8980; 00pcspiegel@bsuvc.bsu.edu

Education and Technology II: Exploring Ethical Issues and Interactions will convene on September 16-18, 1999 at the Penn State Conference Center Hotel at State College, Pennsylvania. The conference will explore issues related to

the high-tech transformations in the natural environment of the campus, the new computer-mediated means of teaching and communication, and the medical services provided both students and faculty. It will add to contemporary discussions of applied ethics issues with two unique approaches: promote the dialogue between three otherwise distinctly pursued subfields of applied ethics; that is, environmental ethics, computer ethics, and biomedical ethics; and bring to bear on educational institutions and practices themselves critical analyses that these institutions otherwise direct primarily toward the world beyond the schools, college, and universities. Contact Richard Deitrich, STS Bulletin, 106 Materials Research Lab, Pennsylvania State University, University Park, PA 16802; Ph. (814) 865-1643; Fax (814) 863-7039; Email rad119@psu.edu; WWW <http://www.outreach.psu.edu/C&I/Education&Technology>

The **Societal Dimensions of Engineering, Science, and Technology (SDEST)** program at the National Science Foundation is soliciting proposals. The program includes Ethics and Values Studies (EVS) and Research on Science and Technology (RST). It focuses on improving knowledge of ethical and value dimensions in science, engineering, and technology, and on improving approaches and information for decision making about investment in science, engineering, and technology. SDEST considers proposals that examine the full range of questions that arise in the interactions of science, technology and society. The program is particularly interested in encouraging analysis of ethical questions surrounding new developments in biotechnology and information technology. It is also interested in proposals that identify and evaluate the implications of different strategies for support of scientific and engineering research and innovation on quality of life. Contact Rachelle D. Hollander at SDEST Program, NSF, Room 995, 4201 Wilson Blvd., Arlington VA 22230; Ph. (703) 306-1743; Fax. (703) 306-0485; Email rholland@nsf.gov