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**[Announcements](#)****FORMULATING INTERNATIONAL ETHICAL GUIDELINES FOR SCIENCE**

by Kathinka Evers

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In September 1996, the 25th General Assembly of the International Council for Science (1) (ICSU) established the Standing Committee on Responsibility and Ethics in Science (SCRES) in Washington DC. The suggested role of the Committee was to "prepare ICSU statements on responsibility and ethics in science to be widely disseminated." SCRES became primarily an analytic body that does conceptual, empirical or historical analyses to the extent that resources permit and issues demand. As a part of ICSU, it assists the Council in formulating statements in selected areas. It is not SCRES' task to formulate norms, but to present an informed background against which ICSU could decide whether or not a normative statement should be issued, and, if so, which. In the latter case, SCRES can assist in the formulation of any statement that concerns matters of ethics and responsibility, yet its primary task remains analytical.

SCRES focuses part of its present activities on *the possibility of formulating international ethical guidelines regulating scientific research*. Ethical guidelines have been formulated to regulate activities within various scientific disciplines and some of these go beyond the national perspective, e.g., the ban on human experimentation without informed

consent. Ethics in science has gained increasing relevance in the past decades when the development of science has been very rapid, and traditional values and familiar moral intuitions appear threatened by some discoveries, as illustrated by the heated debate around mammal cloning. Understanding of this development is limited to a select minority, which raises questions of how best to spread scientific education. The public perception of science has deteriorated dramatically in recent decades, and we need to develop an instrument to promote public trust in science.<sup>(2)</sup> Modern science and technology exert strong influence on the world's development, a power that can be dangerous unless restrained by principles or guidelines. Calls for international guidelines regulating scientific research on a global front have become more frequent, e.g., concerning socio-economic development, sustainability of natural resources, world peace, quality of life, equity between nations, the handling of scientific data, or problems in cyberspace.

Given the plurality that reigns within ethics as a result of different cultural backgrounds, political or financial systems, religious or other ideologies, levels of development, socio-economic systems, etc., is it possible to find international norms that combine broad acceptance with substance in their formulation? The institutions of science may provide a context for eliciting norms, this pluralism notwithstanding.

Three general problems (among many) challenge those who attempt to pursue global ethics in science: (1) *The trap of analyticity* poses the content of a guideline against its extension in terms of acceptance (the more content a principle has, the narrower is its extension, and vice versa; a principle's extension reduces its content); (2) *The norm trap* arises from the absence of a superior principle deciding between principles or values in conflict, or from a breach of the principle that 'ought' implies 'can'; and (3) *The executive trap* emerges when the proportions between the efforts required to follow a given rule and the expected results are unreasonable.<sup>(3)</sup>

Both within and beyond the scientific communities, there are evermore-frequent calls for a globalization of ethics in science. The main purpose of such ethics should presumably be to improve our chances to meet the great challenges that face human societies today, reduce the risk of abuse in methods or applications of scientific research, and, consequently, to increase public trust in science. There are those who envisage this ethical program as the formulation of an *ethos*, an *oath* or a *pledge* that scientists of all disciplines should respect. By a different approach, the goal would be the development of practical ethical guidelines, or codes of conduct regulating scientific research on a global front.

The word 'ethos' is Greek (*ethos*) and means custom, morals or mores. An ethos is something abstract that can be stated concretely in an oath, or a pledge. If an oath is sworn, or a pledge is made, this can be regarded as a concrete manifestation of an abstract ethos. The former notions ('oath' and 'pledge') are not identical, but can be treated as equivalent expressions. Both contain the important elements of testimony, word of honor and warrant. The word 'code' stems from the Latin word *codex*. Originally, a codex was a book made by wooden tables covered with wax. In its modern meaning, a code is a collection of laws, or a written text that offers *guidelines* – e.g., for moral conduct. In other words, the code is constituted by a collection of guidelines in some specific field.

Accordingly, the fundamental concept is the guideline, which can be rendered in a code and manifested in a pledge or an oath. An oath or a pledge makes appeal to a principle that must be universalizable, i.e., applicable to all individuals in relevantly similar circumstances. This principle (or a cluster of them) constitutes the code that can - but need not - be expressed in a ceremony where the individual swears to follow its dictate. It follows that oaths are conceptually secondary to codes.

There is some divergence concerning what the most important focus for science in this area should be. Some call for an oath for scientists to be developed,<sup>(4)</sup> because they feel that such a ceremony might serve to make individuals *more aware* of the ethical principles to which the oath would appeal. In contrast, others<sup>(5)</sup> are worried that this can make ethics seem optional, for an oath concerns only those who swear it. This particular problem might perhaps be partially avoided if all members of a given group are obliged to swear the oath in order to enter that 'society of honor'. The objection could then be raised that this image is antiquated, but that is a question of values. More seriously, the mere utterance of a pledge carries little guarantee of its subsequent application. Too many oaths have been mere veils or alibis for them to be quite convincing unless they are backed-up by sanctions.

The fundamental task from the ethical point of view is to analyze actual or possible codes and guidelines. A discussion whether to express these in an oath or a pledge may follow, but cannot precede that task, because the concepts of codes

and guidelines are primary to those of oaths and pledges. If you swear an oath, you do this by reference to a *previous acceptance* of some practical ethical principle, the endorsement of which entails regulated actions. Therefore, the initial task must be to develop codes regulating action, ethical guidelines for scientific research. Whether or not it is thereafter decided that these codes should be expressed in oaths is perhaps a cultural rather than a scientific/philosophical matter. It should be noted that any ethical oath for science must be a part of a larger social-political dialogue.

The subjects that these ethical guidelines concern are individual scientists, but also scientific institutions, academies, unions, associations, etc. When a code is binding for a given group it articulates a *cooperative practice* for all the members of that group. This practice may relate to individual moral qualities (such as honesty, conscientiousness, and integrity) or to the group's social relationship, e.g., to the state, or to bodies providing or offering financial support. (The group may assert social duties, political neutrality and incorruptible academic freedom, or its codes may require a different approach). Generally, it is important to distinguish between individual and communal perspectives. Clearly, the individual scientist cannot be held responsible for any and all applications of her or his research in a broader communal context. There is an equilibrium to be found between individual and communal responsibility. Furthermore, the individual scientist acts in a variety of roles that need to be distinguished, for each carries different (not necessarily compatible) responsibilities and the relevant codes of conduct will vary accordingly. In particular, we may note the difference between the scientist qua researcher, author of reports, social consultant, political tool or advisor, and advocate/witness.

Within a national perspective, the relationship between ethical codes for science and, for example, educational strategies and laws are relevant to establish. In international contexts this is equally important, but considerably more difficult. Already within Europe there are profound cultural disparities in the attitudes towards 'acceptable' behavior in science, and these differences appear to deepen when distinct continents are compared. Nevertheless, there seems to be a need for international agreements in many ethical issues, such as socio-economic development, sustainability of natural resources, world peace, quality of life, equity between nations, the handling of scientific data, or problems in cyberspace. It is therefore worthwhile to investigate if we can find a 'smallest common denominator' that might form a foundation for international agreement. In this context it will be of interest to draw comparisons to the declaratory tradition in international law and to the United Nations Charter.

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1 At the time of this meeting, 'ICSU' stood for The International Council for Scientific Unions. The name has since been changed, but the acronym remains unaltered.

2 Cf. ICSU's Standing Committee on Responsibility and Ethics in Science (SCRES): 1999, 'Ethics and the Responsibility of Science' Background Paper for the World Science Conference Budapest, Hungary June 26 - July 1, 1999 in *Science and Engineering Ethics* Volume 6 (2000): 131-142.

3 A more detailed analysis of these three traps can be found in Kathinka Evers: (1) 'International Guidelines for Ethics in Science' in UNESCO's forthcoming Encyclopaedia of Life Support Systems, and (2) 'The Possibility of Formulating International Ethical Guidelines for Science', in a forthcoming *Handbook on the Ethics of Science*, Kluwer Academic Publisher.

4 Cf. e.g., Joseph Rotblat (1999), address delivered at the World Science Conference organized by ICSU and UNESCO in Budapest, Hungary, 26 June – 1 July 1999. 5 E.g., Michael Davis, who makes a strong case for professional codes of ethics *Thinking Like an Engineer*, Oxford University Press 1998.

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## IN THE NEWS

### JOURNAL POLICY ADDRESSES RACE AND SCIENCE

In a February 2000 editorial, *Nature Genetics* announced that effective immediately authors submitting manuscripts will be required to "explain why they make use of particular ethnic groups or populations, and how classification was

achieved.” The journal will “ask reviewers to consider those parameters when judging the merits of a manuscript...” The journal hopes that this action “will raise awareness and inspire more rigorous design of genetic and epidemiological studies.”

The editorial observes that “scientists use racial terms when describing research results,...and frequently emphasize population-specific markers, alleles and disease susceptibility,” but “throughout history scientists have used social and politically determined racial categories to make scientific comparisons between races—with little or no discussion about the meaning or rationale.” It notes that while “race can be a valid variable in scientific studies. There is no justification, however, to use race as a substitute for other parameters that can be measured, such as genetic variation or differences in metabolism.” The “laudable objective to find means to improve health conditions for all or for specific populations must not,” the editorial stresses, “be compromised by the use of race or ethnicity as pseudo-biological variables.”

### **DISTRICT COURT DECISION ON ENCRYPTION CASE REVERSED**

On April 4, 2000, the U.S. Court of Appeals for the 6th Circuit reversed and remanded for further consideration the U.S. district court’s opinion in *Junger v. Daley* [[PER Vol. 11, Number 3, 1998](#)]. In this case, Peter Junger, a law professor at Case Western Reserve University who teaches computer law, challenged the federal government’s export control regulations on source code for encryption programs.

Junger sought to post on his web site computer source code that illustrates how encryption programs operate. Doing so likely would require prior licensing by the Commerce Department. Junger argues that this scheme is a prior restraint that violates the First Amendment. The district court held that encryption source code is not protected by the First Amendment because it is predominantly functional, that the export regulations are content-neutral (an important test under First Amendment doctrine), and that the regulations therefore could not be challenged “on their face” as an illegal prior restraint.

The Court of Appeals, reversing the district court, held that computer source code is the optimum way for programmers to explain encryption programs to one another, and that this expressive aspect of source code undoubtedly makes it protectible under the First Amendment. Under Supreme Court precedent as explained by the Court of Appeals, the next analytical step is to inquire whether the government’s asserted interest in regulating speech is sufficiently important to justify the regulation under scrutiny. (The regulation must also meet certain other tests - it must be narrowly tailored and must substantially advance the government’s interest.)

The Court of Appeals noted that the Commerce Department recently changed the regulations on export of encryption source code. It said that the record was insufficient to allow it to analyze whether those new regulations were justified by national security interests. Therefore, it sent the case back to the district court to analyze the new regulations in the context of the Appeals Court’s ruling. As part of the district court’s review, it will examine the new regulations to see whether Junger is entitled to challenge them on their face, that is, to assert that there is no application of the regulations, to Junger or anyone else, that can be justified under the First Amendment. Likewise, for the Bernstein case [[PER Vol.12, Number 2, 1999](#)], the Ninth Circuit Court of Appeals has remanded the case to the district court to consider the impact of the new export regulations.

This decision is significant because it holds unambiguously that, in the territory of the Sixth Circuit, encryption source code is protected under the First Amendment, and that the code’s functional aspects do not take it out from under that protection. The decision also is significant because it instructs the district court about how to approach the next question, which is whether national security factors justify restricting the export of encryption source code, either in this case or for all cases.

The plaintiff, Junger, will now be allowed to try to prove at trial that the workings of encryption source code are so well-known, as a practical matter, that there no longer is any national security justification for restricting its export. Part of the government’s effort at trial will be to try to prove that there are some cases where national security considerations justify licensing, so that Junger should be allowed only to challenge the licensing scheme as applied to him, rather than as to every person who wants to export any kind (and strength) of encryption source code.

### **INTERNATIONAL CALL FOR GENOME ACCESS**

As scientists near the finish line in the race to sequence the human genome, international leaders have joined forces in support of free genome access. Ever since Celera Genomics announced in 1998 that it would decode the human genome well ahead of the deadline set by government researchers, concerns have been raised that the database of the human genome might be restricted from public access to protect industrial proprietary interests.

On March 14, President Bill Clinton and UK Prime Minister Tony Blair issued a joint statement calling for free access to human genome data. And on March 23, Bruce Alberts, president of the National Academy of Sciences, and Sir Aaron Klug, president of the Royal Society, put forth a joint statement pleading that “the human genome itself must be freely available to all mankind.” (Nature 404:325) The general assembly of the All European Academies, which includes 35 European academies of science, has endorsed the Alberts/Klug remarks, and has issued a statement that it is “critical” that the development of medical applications from the raw genome sequences is not impeded “by any restrictions on access to the raw material of the genome sequence.”

International pleas for access come largely as a result of the threat of monopoly by private companies. Celera and a group of not-for-profit research centers had discussed the possibility of collaboration in completing the human genome sequence, but talks broke down (Science 287:1723-25, 10 March 2000). In response to the joint statement by Clinton and Blair, Celera said that it welcomes the policy and that it is in line with the company’s mission and intended use of genome data.

**NEW GENETIC TESTING POLICY IN THE UK** In November 1998, the British government announced that people who have had genetic tests will get fair treatment from insurers and that genetic testing would be banned due to fears that it would create an underclass unable to obtain insurance [[PER Vol. 11, Number 4, 1998](#)]. Now, however, after consultation with the UK Department of Health’s Genetics and Insurance Committee (GAIC), the British government will sanction a series of genetic tests that insurance firms can use to assess a person’s risk of inheriting serious illnesses. By September, up to seven single gene tests will allow companies to determine whether a person with a family history of an illness is predisposed to develop that illness later in life.

According to the Department of Health, GAIC has been set up to receive applications from the insurance industry to demonstrate the validity of tests, monitor and regulate insurers’ use of genetic tests, and oversee laboratories that carry out genetic testing.

The new policy reflects the British government’s position that unless genetic testing is permitted, insurers would carry out tests without appropriate regulation or oversight. Nevertheless, consumer and civil liberties groups worry that sections of society will face significantly higher premiums for medical, life and travel insurance. Or, in some cases, be left without insurance coverage. On the other hand, insurers believe that the use of genetic tests could help some people with a family history of a disease gain lower premiums, since they will be able to rule out the prospect of developing the disease.

Under the new policy, insurers will not have the power to administer genetic tests themselves, but will be able to ask people with a family history of a disease to take a test. Also, if a person has previously taken a genetic test, insurers have the right to demand to see the results.

More information on GAIC and how the new policy may affect insurance in the UK can be found on the WWW at <http://www.doh.gov.uk/genetics/gaic.htm>

### **NEW REPORT FINDS GOVERNMENT OVERSIGHT OF HUMAN SUBJECTS RESEARCH STILL INADEQUATE**

A report released in April 2000 by the U.S. Department of Health and Human Services concluded that current government protection of human research subjects is still inadequate, two years after a highly critical report urged large changes in government oversight. The new report, Protecting Human Subjects: Status of Recommendations, prepared by the Department’s Office of the Inspector General, praised improvements made in education and enforcement at the Office for Protection from Research Risks (OPRR) and at the FDA, but found that “minimal progress” had been made overall in instituting changes to improve human subjects safety.

Of greatest concern to the report’s authors was the lack of improvement in the efficiency and effectiveness of the

Institutional Review Boards (IRBs), the committees that oversee and approve research involving human subjects at federally funded institutions. The original 1998 report had cited problems at IRBs in many areas, among them education of committee members, conflicts of interest, workload, accountability, and federal oversight. The recent report found that few of the recommended changes had been made, and warned again that these changes were needed for IRBs to safeguard human subjects adequately. In addition, no progress had been made on recommendations to educate investigators about federal regulations and to better utilize the Data and Safety Monitoring Boards that oversee toxicity and safety monitoring for some clinical trials.

Current federal law makes changes to human subjects regulations very difficult, as the report acknowledged. The Common Rule, enacted in 1991 with the intent of creating a single standard for all federal research involving human subjects, requires that all 17 federal agencies conducting such research agree on any change, a requirement guaranteed to make any change almost impossible. Because of this impasse, the report noted that "legislative change may well be necessary to achieve a timely implementation of many of our recommendations." The report's authors urged greater haste in implementing the recommended reforms, observing that concerns about gene therapy oversight could act as a catalyst for improvements in human subjects safety in all areas of research. A hearing on human subjects research was held on May 3 by the House of Representative's Government Reform Subcommittee. At the hearing Rep. John L. Mica, chair of the Subcommittee, indicated that one possibility was to attach strings to next year's biomedical research appropriations if reform could not be brought about in any other way. The full text of the report Protecting Human Research Subjects: Status of Recommendations can be found on the WWW at <http://www.dhhs.gov/progorg/oei>

### **ONLINE HEALTH COMPANIES ANNOUNCE NEW SET OF ETHICS AND PRIVACY GUIDELINES**

On May 7, the Health Internet Ethics group (Hi-Ethics) issued a set of ethical standards and privacy guidelines aimed at protecting users of health-oriented Web sites in response to consumer concerns over inadequate safeguards for the privacy of personal health information exchanged over such sites. Endorsed by twenty major online health companies, the guidelines require all on-site advertisers and third parties to adhere to the companies' privacy policies, forbid the use of a customer's personal information without his or her consent, and require clear labeling to distinguish a site's advertisements from its editorial content.

Though the new guidelines are viewed by the Hi-Ethics group as a large step in the process of fostering consumer trust for online health sites, many feel that the absence of provisions for enforcing privacy safeguards indicate that the new standards do not go far enough in ensuring protection for consumers' privacy. Members of the Hi-Ethics group acknowledged the need for measures to enforce the guidelines, and plan to make such measures the group's next major initiative. The group plans to launch the new policies gradually over the next six months.

The new standards follow the results of a survey conducted by the California HealthCare Foundation and the Internet Healthcare Coalition. The survey data, released in January of 2000 [[PER Vol. 13, Number 1, 2000](#)], indicated that significant proportions of consumers avoid using the Internet to access certain health-related services or information due to privacy concerns. Survey results also indicated that 80% of consumers surveyed would become more willing to make use of online health resources if privacy policies were enacted to give them control over the sharing of their personal information.

In addition to industry-imposed guidelines, the Federal Trade Commission is involved in an ongoing deliberation of the issues involved in regulation of the privacy policies of health-related Web sites. President Clinton has also announced plans for the introduction of federal legislation to improve online privacy safeguards.

An online version of the new guidelines is currently available on the WWW at <http://www.hiethics.org>.

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## **ETHICS, LAW AND PUBLIC POLICY**

### **OF GENES AND MODIFIED FOODS: U.S. POLICY DEVELOPMENTS ON GMOS IN 2000**

by Sanyin Siang

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If the depiction of a scientific issue on the “X-Files” is a measure of the issue’s visibility in the national psyche, then the debate over transgenic or genetically modified organisms (GMOs) has been magnified in the American consciousness. This year’s April 16 episode featured a tobacco company that sought to create a safer cigarette containing less nicotine by genetically altering tobacco plants. Inadvertently, some of the new genes from the plants transferred to a few tobacco beetles, spawning a new species of super beetles. “Super tobacco plants producing super tobacco beetles,” Special Agent Dana Scully speculated warily, capturing a concern about the untoward effects of GMOS commonly expressed among its critics.

Perhaps the high profile of GMOs can be attributed, in part, to the revolutionary speed at which they have permeated our society. Since their introduction to store shelves in 1992, GM products have grown to account for a significant percentage of the world’s commercial food supply. From 1994 to 1998, the number of hectares of genetically modified crops cultivated in the US, Australia, Argentina, Canada, and Mexico sprouted from zero to 209 million.<sup>(1)</sup>

Genetic modification involves either deleting genes from an organism or borrowing specific genes from other plants or animals and implanting them into the organism, enabling the recipient to perform functions previously impossible with their standard genomes. Such a mix of genes may not occur in nature, or if it does, the mix results in closely related species through numerous generations of cross breeding. Hence, genetic modification is more efficient in creating a desired product and generates a greater range of possibilities than traditional animal or plant breeding practices. Furthermore, advocates of GMOs claim that no significant difference exists between products created using traditional methods and those using biotechnological means. They argue that the latter grants scientists greater control over the genetic recipe since it involves the transfer of one or a few genes as compared to traditional breeding methods which randomly draw from the genetic lottery.

Proponents also laud GM plants as “miracle crops” that can potentially solve world hunger, alleviate malnutrition and enhance health. Scientists can increase crop yield per acre by engineering more productive plants or decrease the cost of protecting crops by creating plants that are naturally resistant to pests and weeds. Moreover, researchers can combat malnutrition or enhance health by introducing genes for producing essential vitamins and vaccines for epidemics into food staples such as rice or bananas. The developments are not limited to plants, but extend to include a menagerie of animals such as pigs that can produce leaner pork chops through the deletion of a fat gene or salmon that can grow twice as fast as their natural counterparts with the addition of a growth hormone gene.<sup>(2)</sup>

However, some object to transgenic products on the grounds that potentially harmful consequences may result from tinkering with nature and proceed to label the products as “Frankenfood.” Furthermore, responding to the view that GMOs can potentially solve world hunger, critics contend that the majority of benefits cited about GMOs are reaped by industrialized nations and little is being done to ensure that third world nations can partake in the harvest.

The greatest concerns regarding GMOs focus on food safety and environmental issues. There is fear that in manipulating nature, new allergens could be unintentionally created and existing ones could be transferred from unaltered produce into genetically modified variants. For example, the growth hormone gene used in genetically modified salmon could unexpectedly trigger an increase in production of other compounds such as insulin.<sup>(2)</sup> Or the introduction of a nut gene into soybeans could induce allergic reactions in people allergic to nuts.

With respect to the environment, GMO critics fear a threat to biodiversity and the delicate ecological balance. Thus far, the fastest growing percentage of transgenic plants has been in crops containing either herbicide resistant genes, which allow farmers to kill weeds with herbicides without damage the crops, or crops inserted with the gene for Bt, an insecticide toxin, that helps the plant ward off common pests. By 1998, 71% of the world’s commercial genetically modified crops were herbicide-tolerant, 28% were Bt crops, and 1% were a combination of both.<sup>(1)</sup> While these crops can significantly decrease the cost for the agriculture sector as well as its reliance on chemical agents, they may pose unexpected problems for the environment. The Bt gene may harm other insects, such as the Monarch Butterfly, than those for which it was intended. Additionally, through natural exposure, the herbicide-resistant and pesticide genes could transfer to surrounding weeds, creating “superweeds” or “superbugs” as depicted by the “X-Files.”

In addition to points regarding the scientific merits and potential environmental consequences of GMO production,

scientific discussion of GMOs cannot be divorced from world trade and economic considerations. The U.S. is home to many of the major GMO biotechnology companies, such as Novartis and Monsanto. It is also the major producer of genetically altered foods and products with transgenic seeds, accounting for a significant percentage of American produce, such as 36% of the corn, 55% of soybeans, and 43% of the cotton.

However, due to strong European consumer protest against GMO foods, the European Union's (EU) purchase of American corn decreased \$304 million from 1996 to 1998 and purchases of American soybeans have dropped drastically from an average \$2.6 billion per year to \$1 billion last year.<sup>(3)</sup> In response, Representative Bob Eithridge from North Carolina, a member of the House Committees on Science and Agriculture, has gone so far as to suggest that the barriers to widespread acceptance for biotechnology products is a "trap" by other nations to slow down the U.S. lead in developing the technology.<sup>(4)</sup>

To understand U.S. policy development in this arena, one can begin with the nature and historical context of the debate that originated in Europe. In 1996, as Europe was caught in a maelstrom of anxiety surrounding several food scandals such as "mad cow disease" and dioxin-tainted Coca-Cola, European consumer confidence in the safety of agricultural products dropped drastically.<sup>(5, 6)</sup> Additionally, the political atmosphere in European nations such as France, UK, and Germany was characterized by a left-wing ascension to power and a commitment to environmental concerns.<sup>(6)</sup> Within this context, the labeling and production of GMOs and their products grew to a heated debate and the presence of transgenic food products on store shelves elicited fierce opposition from consumer and environmental protection groups. Protesters stormed biotechnology conventions and destroyed fields of crops, transforming farmlands into political battlegrounds. In response to the furor and precipitous decline in consumer confidence, the EU legislated stricter laws requiring labels on food with 1% or more GM ingredients, and regulators have not approved any new seed strains for nearly two years.<sup>(3)</sup>

As the thorny debate began pollinating the American political landscape, American understanding of the issue evolved from ignorance to awareness, a sophistication brought about in part by aggressive campaigns from both fronts and extensive media coverage. Popular magazines ranging from *Newsweek* to *Marie Claire* devoted special sections to the topic and *New York Times* online added a GM forum and an archive of articles in its science and health section.<sup>(7)</sup> As the issue gained momentum, 1,500 protesters convened in Boston at a March 2000 biotechnology convention for an anti-GM foods rally and bills requiring labeling and special testing of GM products are pending in Congress. Furthermore, various American companies such as Frito Lay and Gerber have volunteered to ban genetically engineered food from their products, while Nestles has stopped buying any grain from genetically altered seeds for its European operations.<sup>(3)</sup>

The tension culminated in a recent wave of government activity. In early April, a panel of 12 scientists from the National Academies of Science's National Research Council (NRC) issued a report titled, *Genetically Modified Pest-Protected Plants: Science and Regulation*. Although the report pronounced the pest-protected GM plants safe based on the absence of adverse data, it acknowledged that potential environmental risks may occur and recommended more rigorous regulation. For example, it urged the Environmental Protection Agency (EPA) to reconsider current plans to grant regulatory exemptions to certain transgenic pest-protected plants.

The NRC report also called for better coordination among the three agencies, the EPA, Department of Agriculture (USDA), and Food and Drug Administration (FDA), charged with oversight of GMOs. It recommended a more open and accessible regulatory process for fostering public understanding of the issues. It addressed environmental concerns by encouraging further research to assess the likelihood and the rate at which genes might spread, as well as techniques to decrease the probability of such change. It also emphasized that regulation and public scrutiny should be based on the product and not the creation process.<sup>(8)</sup>

A week following the release of the NRC report, the House Science Committee released the first extensive study on GMOs by Congress. Similar to the NRC Report, the House Report recommended that the focus be on the characteristics of the plants, their intended use, and the environment into which they will be introduced, rather than on the breeding process. However, the tone of the House Report differed substantially from the that of the NRC. While the NRC Report exhibited a cautious endorsement of GMOs, the House Report, *Seeds of Opportunity*, brimmed with unbridled optimism. Based on a series of 1999 hearings by the Committee's Subcommittee on Basic Science Research,

*Seeds of Opportunity* recommended a revision of existing and proposed regulations at USDA and EPA that target genetically engineered products. It opposed product labeling, deemed special testing unnecessary, and encouraged government funding of basic research in plant biotechnology. Furthermore, it recommended that the U.S. refuse any international agreements that “violate the scientific principles and limit trade in, or mandate labeling of, a plant or food product based on the method used to develop it.” Contrary to the environmental concerns of the NRC Report, *Seeds of Opportunity* exhibited skepticism of research that suggested that Monarch butterflies may be harmed by toxins in genetically engineered crops.<sup>(9)</sup>

In early May, prompted by a request from food companies to help quell consumer fears regarding GMOs, the Clinton administration announced a plan to begin a six-month review of current regulations.<sup>(10)</sup> The plan also encouraged greater funding for research on the potential risks of transgenic plants and a review of environmental regulations. As a part of the plan, the FDA would tighten its review of the products, develop guidelines for labeling, and require biotechnology companies to discuss product safety issues with regulators at least 120 days before the products are sold.<sup>(10)</sup> Under the plan, the USDA would cooperate with farmers and industry to create a system in which GM crops are separated from unaltered ones.<sup>(11)</sup>

As the debate over GMOs rages on, the need for critical thought and informed policy will become greater. Scholars have suggested increasing public accessibility to knowledge about GMOs, establishing an independent scientific research organization that can raise and field key regulatory questions and sponsor research into them, and the creation of a national advisory committee to review all elements of the process for approving genetically modified products.<sup>(12)</sup> Whatever the approach, it is clear that much remains to be done to close the chasm between GMO proponents and critics before we reach a consensus or compromise on the regulation of genetically modified organisms.

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- 9 “Seeds of Opportunity: An Assessment of the Benefits, Safety, and Oversight of Plant Genomics and Agricultural Biotechnology,” Report Prepared by Chairman Nick Smith of the House Subcommittee on Basic Research April 2000
- 10 “FDA Announces New Steps for Regulation of Biotech Food,” *New York Times*, May 3, 2000  
<http://www.nytimes.com/yr/mo/day/news/national/science/03gm-foods.html>

11 “US to Keep a Closer Watch on Genetically Altered Crops,” *New York Times*, May 4, 2000  
<http://www.nytimes.com/library/national/science/health/050400hth-gm-foods.html>

12 Carole Tucker Foreman, “Genetic Modification of Foods: the Public’s Mistrust of Science and Science’s Misunderstanding of the Public,” AAAS Science & Technology Policy Colloquium, April 13, 2000 Washington, DC

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## IN THE SOCIETIES

### SUPPORT FOR VICTIMIZED EPIDEMIOLOGISTS

For epidemiologists who encounter on-the-job health hazards and political or economic resistance, the International Society for Environmental Epidemiologists (ISEE) has proposed a procedure to offer them support. The procedure deals with support for any “environmental epidemiologist who claims to be made to feel threatened for having identified a hazard and/or for proposing to study a suspected hazard.”

Members of the ISEE Ethics Committee worked with a writing group to produce the report. One of the authors told the *Epidemiology Monitor* (20:1, May 1999) that the procedure will be especially helpful for epidemiologists working in poorer countries. These countries frequently have the greatest environmental problems and the fewest safeguards to protect free speech and other liberties.

The ISEE procedure consists of the following eight steps:

1. Complaints must be filed in writing with the President or the Chairperson of the Standing Committee on Ethics and Philosophy (SCEP) of the ISEE.
2. If the case is deemed worthy of investigation, the Chairperson will form an ad hoc committee to review the case and make recommendations to the President.
3. The committee will contact the membership by e-mail (unless there is a reason for confidentiality) for information regarding the case. Members will be invited to take action on their own.
4. If the case requires confidential treatment, information will be sought only from directly implicated parties. If a decision is made by the complainant and the President and Chairperson to bring the case into the public sphere, ISEE members will be informed of the investigation and invited to contribute additional information.
5. The investigation will be confidential and will respect the rights of all parties and the rights for due process. After investigation, the facts will be summarized by the committee and a recommendation will be made to the President.
6. The President will decide on a course of action in conjunction with elected Counselors. The decision will be shared with the membership by e-mail, posting on the ISEE home page or in the ISEE newsletter. If the SCEP disagrees with the course of action, its views will be added as a “minority report.”
7. Summaries will be compiled into case studies by the SCEP to serve as an educational resource and as a surveillance tool for the attempted intimidation of environmental epidemiologists. To obtain the full proposal, contact Carol Rougvie, ISEE, c/o JSI Research and Training Institute, 44 Fansworth St., Boston, MA 02210; (617) 482-9485; Fax (617) 482-0617; Email [carol\\_rougvie@jsi.com](mailto:carol_rougvie@jsi.com).

### TWO SOCIETIES ADDRESS FINANCIAL CONFLICTS OF INTEREST IN GENE THERAPY TRIALS

Questions about the safety and oversight of gene therapy trials have been numerous since the death of a research subject, Jesse Gelsinger, in September 1999. That some scientists conducting trials have financial investments in the pharmaceutical companies funding their studies has only exacerbated worries that the best interests of patients/subjects may not be adequately protected. Two genetics societies recently released statements opposing this practice in response to these concerns.

In April 2000 the Board of Directors of the American Society of Human Genetics (ASHG) released a position

statement on the safety of gene therapy trials. As part of the statement, the society acknowledges that many question whether scientists should be allowed to participate in trials funded by companies in which they have investments. Institutional Review Boards (IRBs) are urged to be more careful in monitoring these conflicts in order to "ensure that decisions regarding clinical trials are...unclouded by motivations related to personal gain or publicity." The responsibility of the trial investigator and the IRB for protecting the well-being of the trial's human subjects is emphasized, but other researchers in the genetic sciences community are also reminded that they have a responsibility to protect study subjects. "All scientists and clinicians with the relevant expertise, whether or not they are involved in clinical trials, have a responsibility to speak up if a gene therapy protocol seems inadequate or dangerous."

The American Society of Gene Therapy (ASGT) has taken an even stronger stand on the issue of conflicts of interest in trials, issuing a policy on financial conflicts of interest that forbids such arrangements in some circumstances. ASGT members who are "directly responsible for patient selection, the informed consent process, and/or clinical management of a trial must not have equity, stock options or comparable arrangements in companies sponsoring the trial." The society will not enforce its new policy, but hopes that members will voluntarily comply. The new policy was developed by the ASGT Ethics Committee and approved by the Board of Directors in April 2000.

The full text of the ASGT Policy on Financial Conflict of Interest is available on the WWW at <http://www.asgt.org/policy>. The full text of the ASHG Statement on Gene Therapy can be found at <http://www.faseb.org/genetics/policy>

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## ANNOUNCEMENTS

The Advanced European Bioethics course **Ethics and Genetics** will be held November 16-18, 2000, in Nijmegen, The Netherlands. The course is organized by the Department of Ethics, Philosophy, and History of Medicine at the University of Nijmegen. Contact Norbert Steinkamp, 232 Department of Ethics, Philosophy, and History of Medicine, Catholic University of Nijmegen, PO Box 9101, 6500 HB Nijmegen, the Netherlands; [31](0)24-361 53 20; Fax [31](0)24-354 02 54; Email [n.steinkamp@efg.kun.nl](mailto:n.steinkamp@efg.kun.nl); WWW [http://www.azn.nl/scientist/Departments/Ethics\\_Philosophy\\_and\\_History\\_of\\_Medicine/frames-Ethics\\_Philosophy\\_and\\_History\\_of\\_Medicine.html](http://www.azn.nl/scientist/Departments/Ethics_Philosophy_and_History_of_Medicine/frames-Ethics_Philosophy_and_History_of_Medicine.html)

**Wisdom in Healthcare**, the 15th annual European Conference on Philosophy of Medicine and Health Care is soliciting abstracts. The deadline for submission is January 1, 2001. Conference topics include health care ethics, evidence based medicine, and philosophy and clinical epidemiology. The conference to be held on August 16-18, 2001, in Lisbon, Portugal, is sponsored by the European Society for Philosophy of Medicine and Healthcare (ESPMH) in cooperation with the Centro de Estudos de Filosofia de Medicina in Lisbon. Contact Henk ten Have, ESPMH Secretariat, Dept. of Ethics, Philosophy, and History of Medicine, Faculty of Medical Sciences, University of Nijmegen, PO Box 9101, 6500 HB Nijmegen, The Netherlands; Email [h.tenhave@efg.kun.nl](mailto:h.tenhave@efg.kun.nl)

The Markkula Center for Applied Ethics at Santa Clara University is sponsoring the conference **At Our Best: Moral Lives in a Moral Community**. It will be held on February 22-23, 2001, at the university. Submissions of papers are invited in all areas of business ethics, including moral imagination, virtue and character in business ethics, stakeholder theory, international business ethics, ethics and finance, ethical issues in high technology business, moral development, and ethics and leadership. The deadline for papers is August 15, 2000. Contact Dennis J. Moberg, Markkula Center for Applied Ethics, Santa Clara University, 500 El Camino Real, Santa Clara, CA 95053; (408) 554-4713; Email [Ethics@scu.edu](mailto:Ethics@scu.edu) t Challenges of the New Millennium, the fifth annual Ethics & Technology conference at Loyola University Chicago, will be held July 21-22, 2000. The conference will focus on issues of ethics and technology (computers and other electronic related forms). Contact Ronald J. Kizior, ISOM Department, Loyola University Chicago, 820 N. Michigan Avenue, Chicago, IL 60611-2103; Email [rkizior@luc.edu](mailto:rkizior@luc.edu); WWW <http://www.ethicstech.org>

The Center for Bioethics at the University of Minnesota will be hosting the Midwest Intensive Bioethics course 2000 entitled "Ethics of Sexuality and Reproduction in Health Care." This two-and-a-half-day course will focus on ethical issues that arise at the intersection of health care and human sexuality and reproduction. It will examine the ways in

which these issues differ for adolescents, the elderly, and those in the middle of their lives. It will also emphasize the ways in which different sociopolitical, ethnic, and economic factors, as well as technological innovations, influence our views on issues of sexuality and reproduction. The course will be held in Minneapolis, MN on July 20-22, 2000.

Contact Center for Bioethics at (612) 624-9440; WWW

<http://www.med.umn.edu/bioethics/announcements/MIBC2000.html>