FROM MICROBE TO MAN

BY
U.S. SENATOR MARK O. HATFIELD*

This article discusses federal policy towards animal patenting, including the Senator's introduction of legislation to establish a National Ethics Advisory Board, and current issues in bioethics.

Society will reap great benefits from advances made by modern science. Cures for hereditary diseases, a revolution in agriculture, miracle drugs, and an end to human infertility are all being predicted for our future. History has taught us, however, that new technologies often bring with them costs as well as benefits. New capabilities often pose dilemmas for society because they exceed the ethical and legal parameters we have in place to deal with them.

As society scrambles to cope, genetic engineers are beginning to assume a new role in our evolutionary scheme. They are using their new-found abilities to alter the blueprint of life, to apply traditional engineering values such as efficiency, utility and predictability to the manipulation of life forms. Scientists are currently inserting human genes into animals, and beginning the process of altering the genes of humans. Many predict that within a few decades our biotechnologists could assume the roles of creator and designer of the biotic community—from microbe to man.

I have watched these advancements with great inspiration and continue to be one of the leading proponents of federal biomedical research funding in the Congress. At the same time, however, I have watched as the federal government has allowed many of the most difficult biomedical ethical questions of our time to linger with little guidance or dialogue. Public officials have too often preferred to allow such issues to be decided by default in a vacuum of leadership.

A few years ago, I had a chance to visit with a prominent scientist about the ethical issues raised by genetic engineering. He told me that science has only two options when dealing with this new technology: one is to stop research altogether and the other is to discover what science can achieve and then turn the results over to society to decide how it is to be used.

* Mark. O Hatfield is a Republican Senator from the state of Oregon. He is chairman of the Senate Appropriations Committee, and is a member of the Senate Energy and Natural Resources Committee and the Senate Rules Committee.

Congress—as the elected representatives of the people—must play a role in making these important decisions. I am troubled, however, that up to this point such monumental policy decisions have fallen squarely on the shoulders of the U.S. Patent Office. The underlying ethical decisions related to the developments in biomedicine transcend our present laws, particularly our patent laws. They transcend our national borders. They transcend the profit motives of the marketplace.

The decision to patent these developments is more than a technical or legal question of patentability. The direction and use of biotechnological research is a question of profound ramifications. Genetic advances have led to a rush on securing patent protection for the decoded human genes. On February 12, 1992, the National Institute of Health (NIH) filed patent applications on 2300 gene fragments. Many were astounded to learn that the Patent and Trademark Office (PTO), aided only by centuries old patent law, could offer such protection.

As more and more human genes and proteins are identified, the PTO has been inundated with patent claims on all manner of medical application. Even with the hiring of additional biotechnology examiners, the patent process remains confused, unpredictable, and governed by intramural rules that are not made public.[1]

Again, the PTO has no way of dealing with the various moral, international, economic and environmental questions which arise from the patenting of human genes, cells, and organs, or the patenting of genetically engineered animals. Careful consideration and examination has not taken place in the case of the genetic alteration and patenting of human genes and body parts, or in the case of the creation and patenting of transgenic animals.

In each session of Congress since 1987, I have introduced legislation to place a moratorium on allowing the Patent and Trademark Office to issue patents on living organisms. Until last year, Harvard University had received the only such patent for the so-called "Harvard Mouse." Since then, three other patents have been issued for transgenic mice. Nearly 200 applications for animal patents were pending as of June of 1995.

I did not introduce this legislative act to object to the research that is being conducted using these creatures. My record shows that I am committed to the advancement of scientific research. I believe, however, that the members of government have a solemn duty to ensure that serious social and ethical issues are addressed. For me, the idea of issuing patents on living creatures that have been somehow altered by humans raises many serious ethical questions related to human life and the natural order.

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[1] Eliot Marshall, *Biotech leaders give Patent Office litany of complaints,* SCIENCE, Oct. 28, 1994, at 537.

Those who have followed the rapidly advancing field of biotechnology know that ethical parameters are very difficult to formulate. However, I believe that we in Congress bear a large part of the responsibility for seeing that ethical issues such as these are raised, and where appropriate, lines are drawn.

In order to provoke greater discussion of the ethical implications of biomedical research, I joined my colleagues Senator Kennedy (D-Mass.), and Senator DeConcini (D-Arizona), in requesting two reports from the Office of Technology Assessment (OTA). In its first report, *Biomedical Ethics in U.S. Public Policy*, which was released in October 1993, the OTA reviewed the different governmental approaches to issues of bioethics, including the so-called President's Commission and the now defunct Biomedical Ethics Board. The OTA found that the United States is virtually alone in the industrialized world in not having a commission to examine bioethics issues. Early next year, the OTA plans to release a more detailed review of the ethical, privacy, environmental, and policy issues involved in different areas of biotechnology.

In addition, two Senate Committees have held hearings on this issue. The first hearing was held by Senator DeConcini in the Judiciary Committee's Subcommittee on Patents, Copyrights and Trademarks on September 22, 1992. The purpose of this hearing was to examine the ethical issues of gene patenting. A second hearing was held on October 12, 1993, by Senator Kennedy in the Labor and Human Resources Committee. This hearing focused on the findings of the aforementioned OTA report and the feasibility of creating a standing Ethics Advisory Board. Both of these hearings were constructive and helpful in raising the visibility of biomedical ethics issues.

It has been my goal to foster dialogue on the difficult bioethical issues faced by this country. My hope is that these efforts will result in the establishment of a broadly based body assembled to study biomedical policy issues and make recommendations to the Administration and Congress. I believe that it is important for the United States to have a commission which would deliberate about a broad range of bioethical issues (i.e., ethical, legal, social) and produce very useful advice to our executive and legislative branches, to the states, and to public and private institutions that carry out health policy and research.

That is why I was pleased to take a step toward these objectives by introducing legislation during the 103rd Congress to establish a National Ethics Advisory Board to be located within the Department of Health and Human Services (HHS). The board established in this legislation would be composed of 15 members. While located under the umbrella of HHS, the board would report to the Administration and to Congress.

The board would be part of the federal research review process already in place at HHS. It would also take requests for review from Congress and would have the authority to choose issues to review on

its own motion, but would have no authority to veto research initiatives. The purpose of such a board would be to promote the dialogue that is lacking on so many ethical issues today. This is dialogue that must take place if we are to have any hope of rational and informed decision making in the field of bioethics.

The re-establishment of a permanent commission is not a universally supported idea. Students of this issue know that past attempts have taken place with mixed, and at times dismal results. I am not wedded to the idea of a permanent Ethics Advisory Board, although the information I have reviewed leads me to believe it is the best approach. One of my purposes in introducing this legislation is to provide a tangible proposal to be debated and considered as we continue the discussion of the ethics of biomedicine.

At this point, that debate is advancing. The Clinton Administration, led by Dr. Jack Gibbons, the President's advisor for Science and Technology, has recently set forth a proposal to establish a National Bioethics Advisory Commission within the executive office of the President. As proposed, the Commission would be charged to consider issues of bioethics arising from research on human biology and behavior, and the application of that research. The Commission would be asked to identify and develop broad overarching principles to guide the ethical conduct of biological and behavior research, and the application of that research.[2]

The proposed charter for the National Bioethic Advisory Commission specifies two prospective areas of inquiry: issues in the management and use of genetic information and protection of the rights and welfare of research subjects. Discrete issues that fall under these broad topics include: issues of genetic privacy, screening for genetic disorders, intellectual property rights, and access to research data or materials developed with public funding.[3]

While I welcome and am supportive of the attempt to create a national commission to examine issues related to biomedicine, I have several concerns about the draft proposal. First, I am concerned that the language of the Charter limits issues that the Commission can examine to issues arising from research relating to human biology and behavior and the applications of that research. In order to assure that the focus of the Commission would not be limited to research issues, I would prefer that the language in the Charter be expanded to include issues in medicine and research. This will make it clear that the Commission might examine clinical issues related to research.

Second, although intellectual property issues are mentioned in the Preamble as issues appropriate for consideration, I believe the reference to genetic information in the Charter should be clarified to include issues relating to patent rights and intellectual property. Finally, I am concerned about the role the Science and Technology

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[2] 59 Fed. Reg. 41,584-86 (August 12, 1994).

[3] *Id.*

Council will have in setting the agenda of the Commission. While I do not object to the Commission seeking suggestions from the Council and other appropriate agencies, I believe the Commission should be independent.

I look forward to working with the Administration and other members of Congress to refine the Charter and its mission. In the meantime, advances are continuing. Current issues which show the need for a bioethics review board are numerous:

Health Care Reform—The various health care reform proposals recently discussed in Congress raise a myriad of ethical issues. Choices in this area are not easily made, particularly in the face of scarce resources (i.e., medical decisions shaped by financial considerations, the realization that we simply cannot afford to provide every form of medical intervention available to everyone who wants it).

Genetic Privacy—The Human Genome may lead to cures for the approximately 4,000 known genetic diseases. Discovery of this information raises difficult questions of privacy, however. Should employers, insurance companies, government agencies, and educational institutions have access to genetic information? While the Genome Project did set up an Ethical, Legal and Social Issues division (ELSI), a House Government Operations Committee report indicates that the ELSI is not capable of performing an adequate ethical review of the Genome project. The report recommends setting up an independent board.

Human Growth Hormone—The NIH is currently conducting research using genetically engineered human growth hormone on dozens of healthy children of below average height to determine if it will increase their adult height. On June 29, 1993, this NIH research protocol was challenged in the U.S. District Court for the District of Columbia. Should NIH use genetically engineered drugs, and sponsor drug trials, to treat normal human traits?

Surrogate Motherhood—Early in 1994, the Supreme Court declined to hear the case of Anna Johnson, a surrogate mother seeking to maintain the custody of the child she carried for nine months. This allowed the ultimate resolution of this embryo implant/surrogate mother case to be decided on the basis of state contract law. Several states outlaw contracts for surrogate motherhood, while others allow it. Should pregnancy and birth-giving be services that can be paid for? Does state-level contract law allow for the proper ethical inquiry?

Exemptions to Gene Therapy Protocols—Recently, political pressure was put on the NIH to allow emergency exemptions so that certain patients could receive an unapproved gene therapy. Meanwhile, a controversial hepatitis trial took the lives of several patients. Do we need to reassess how patients are picked for trials of drugs and gene therapy? Do we need stricter regulations to ensure informed consent, and to safeguard patients from exploitation?

Patenting Life—Should transgenic animals or human genetic information be patentable subject matter?

In conclusion, let me reiterate that I am not arguing against advances in biotechnology or other advancing areas of science. I am simply saying that society must carefully evaluate new breakthroughs in science and technology and the implications of these new developments. While much of the scientific detail involved in these bioethical issues can be bewildering, my message is simple: we need more dialogue on the important bioethical issues of our time. The more complex the problem, the stronger the justification for a federal review board to address the problem.

Although it is difficult to legislate in these complex areas, Congress—as the elected representatives of the people—must play a role in seeing that a forum for discussion is provided and that these important problems are addressed openly.