VIEWPOINT

A Time for Restraint

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The debate on the use of human embryos for research will be one of the more important issues of the 21st century. Unlike recombinant DNA technology, embryonic stem cell research most probably will result in the destruction of living embryos. Many people consider this research immoral, illegal, and unnecessary. Therefore, it is imperative to proceed cautiously. Federal funding of research using human embryos or pluripotent cells derived from them would be inappropriate until further resolution of the ethical issues has been achieved.

The ability to grow human embryonic stem (ES) cells in vitro challenges governments, regulatory agencies, and scientific organizations to define the ethical boundaries of using these cells in research. In the United States, President Clinton charged the National Bioethics Advisory Commission (NBAC) to review the medical and ethical considerations of this technology. In September 1999, the NBAC released the Executive Summary of its report (*1*). While noting the existence of diverse views, it formulated a utilitarian approach, justifying public funding of research with human ES cells on the basis of the potential medical benefits. NBAC's primary concern was whether the "scientific merit and substantial clinical promise of this research justifies federal support, and if so with what restrictions and safeguards." Its ethical concern was focused on restricting the sources of embryos.

After National Institutes of Health Director Harold Varmus publicly supported the use of human ES cells for research, based on a decision of the General Counsel of the Department of Health and Human Services, 70 members of Congress signed a letter of objection. In a letter to *Science* in March 1999 (*2*), 73 scientists, including 67 Nobel laureates, endorsed Varmus' position, claiming that it protects "the of sanctity of life without impeding biomedical research." They noted many promising uses for ES cells, including therapeutic advances and reduction of animal studies and clinical trials needed for drug development. Again, the emphasis was on potential benefits, and the ethics of embryo destruction were not addressed.

The fact that experiments using ES cells, as currently performed, result in killing an embryo cannot be ignored so readily. In the United States, such action is in violation of many state laws that protect the embryo (*3*). The disintegration of human embryos or the extraction of cells from blastocysts of human embryos [as has been described in primates (*4*)] for the promised but as yet unrealized benefit of patients disregards concerns about the value of the individual that have already been raised by the prospect of human cloning (*5*). The devaluation of humans at the very commencement of life encourages a policy of sacrificing the vulnerable that could ultimately put other humans at risk, such as those with disabilities and the aged, through a new eugenics or euthanasia.

Although there is great scientific interest in ES cell research, other recent advances suggest that adult stem cells may be more widely distributed than heretofore recognized and may thus obviate the need for ES cells (*6*). Rather than risking public sanction and mistrust from those concerned with the ethical, legal, and moral status of the embryo, is it not wiser to give more than a passing mention to those concerns and in the meantime to do no harm to living embryos? It may be tempting to pursue a scientific imperative that impels us ever forward, but there are major costs. Regulatory policies and processes should take into account public confidence as well as the classical standards of safety and effectiveness. Our pluralistic society must consider the social, religious, medical, environmental, and scientific interests of its citizens. Once credibility is lost, acceptance is eroded.

Should scientific research be limited only by the value of its potential benefits? And who should make the decisions about the limits? To quote J. A. Robertson (*7*), "Society, as the provider of the resources, the bearer of the costs, and the reaper of the benefits, has an overriding interest in the consequences of science, hence an interest in the routes and direction that research takes." Scientists who proclaim First Amendment freedom of inquiry are countered by a public suspicion of an inherent conflict of interest when their research support depends on funding from federal and industrial sources. Therefore, any commission regulating research should be composed of individuals of many persuasions and should include people who have no direct or indirect dependence on public monies.

Observations from the recombinant DNA (rDNA) debate can be useful in considering policies regarding human embryo research. The process of policy development was public, and committees consisted of individuals with diverse expertise, opinions, and backgrounds, including those who opposed rDNA research. Although public debate was contentious, careful analysis of the issues prevailed. The results demonstrated that scientists and the public can successfully work together to decide the appropriate use of public funds and formulate regulatory guidelines (*8*).

The following recommendations are made to facilitate a consensus. Every nation conducting ES cell research should develop a national policy. In the United States, a representative commission should be appointed to review ES and adult stem cell research, develop an ethical framework for such research, and communicate with the public. It should also examine the adequacy of current guidelines and regulations for in vitro fertilization. A 3-year moratorium on human embryo research should be instituted while the commission completes its work. Sufficient funding for research on human adult stem cells and animal embryonic and germinal stem cells should be provided during the moratorium (*9*). International harmonization of guidelines could be accomplished through the Organization for Economic Cooperation and Development.

To rush to approve the destruction of embryos in order to harvest and experiment on ES cells is inadvisable and unnecessary. We should address the ethical concerns first.

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References and Notes

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7. J. A. Robertson, *South. Calif. Law Rev.* **51**, 1278 (1978).
8. Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment, *Fed. Regist.* **51**, 23302 (1986).
9. F. Young, testimony before Senate Appropriations Subcommittee on Labor, Health and Human Services, 4 November 1999.
10. F.E.Y. is a former commissioner of the U.S. Food and Drug Administration.