Balancing Science, Ethics and Politics: Stem Cell Research, a Paradigm Case

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INTRODUCTION

Every truly effective technological advance is a challenge to culture, politics and ethics. This is as true for the discoveries of fire, the wheel and gunpowder, as it is for the Atom Bomb, space travel and biotechnology. The more effective the technology, the more serious the challenges it poses.

Thomas Merton, with his acute sensitivity to the malaise of the soul of modern man, put it this way: "...the problem of getting technology back into the power of man so that it may be used for man’s own good is by all odds the great problem of the day."

At this writing, after the horrendous assault on human life in the terrorist attacks of September 11th, the "problem" of technology is easily displaced by the problem of injustice and violence of man against his fellow man. Yet on this same day, the National Academy of Sciences released its report and recommendation regarding Stem Cell research. We are just beginning to confront the challenge of biotechnology, a form of technology more personal, intimate and more challenging to our concept of what it is to be human than any past technological "advances," with the possible exception of the atom bomb. How do we use our technological prowess humanely, wisely and generously without being so overshadowed by its powers that we become its slaves?

How in essence do we place biotechnology within ethical constraints without losing its therapeutic potential? How do we do so in a democratic, morally and pluralistically divided society, driven equally by market forces and a yearning for immortality through technology?


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Stem Cell Research is a paradigm case illustrating the complex intersections of science, ethics and politics, which will characterize any powerful new technology. This essay seeks to outline the intersections of science, ethics and politics through which society shall navigate in the years ahead. The stem cell research issue will serve as an example for analyzing the questions the whole citizenry must confront with the introduction of biotechnological progress— not just scientists, bioethicists or legislators.

As a physician and a patient, the author sympathizes with the tremendous desire to make rapid progress in the therapeutic use of the fruits of our new knowledge. Persons of good will can differ on the nature, application and source of ethical constraints on research. The search for biological knowledge—within ethical constraints—should be praised and supported. However, the ethical, political, scientific and economic issues cannot totally be disentangled. If there is to be some moral order in the approach to policy formation and legislation, then there must be some moral compass points to guide both science and policy. No matter how much human good we envision, we cannot allow our zeal for knowledge, power, profit or even cure to displace our humanity.

There are three fundamental questions, and sets of relationships, which recur in any legislation or policy regarding the application of biological knowledge in the public arena. This paper will discuss three sets of questions, which anchor the debate and define the moral quality of policy and legislation.

First, what scientific facts support stem cell research and how secure are they? Second, what fundamental ethical issues are at stake? Third, what are the implications of questions one and two for politico-economic policy?

I. WHAT SCIENTIFIC FACTS SUPPORT STEM CELL RESEARCH AND HOW SECURE ARE THEY?

In any situation, good policy and good ethics depend on good facts. Even so, the individuals who gather and assess the facts are not the same ones who must make public policy or legislate. These latter must nevertheless base their decisions on the testimony of experts. They must probe expert testimony critically if they are to avoid automatic capitulation to the aura of authority that follows expertise. This can be extremely difficult to accomplish since scientists may honestly disagree about the same issue. The same data may be subject to different interpretations. This factor neither accuses scientists of insincerity nor deception, but emphasizes that legislators and the public must probe
scientific claims carefully if they wish to legislate and regulate wisely. This is especially true when prestige, power and profit are so evidently at stake as they are in stem cell research.

These concerns are not confined to legislators or policy makers. Ultimately they are matters of concern for every citizen. Bioethics is no longer the restricted terrain of physicians and health professionals, nor of bioethicists. The ethical issues are pertinent for the lives of all of us in the present and in future generations.

Let us look at a few examples of current stem cell research to illustrate this point more concretely. The discussion will focus on expectations of cure, terminology, the utility of existing stem cell lines and alternate sources.

A. Terminology

Stem cells are unspecialized cells found in the human embryo, fetus (germ cells) and adult. They are characterized by great plasticity, i.e., they can, spontaneously or by manipulation, are converted into the many types of specialized cells making up the human body. Those taken from very early embryos are “totipotent”, i.e., capable of developing into a complete new human being. Others taken at later stages of embryonic development are “pluripotent,” transformable into all other types of cells but not into a full and complete human being. Stem cells can also be found in adult human tissues, such as bone marrow, brain, muscle, umbilical cord blood, liver, and fetal tissue.

“Embryonic stem cells” are usually harvested for experimental or therapeutic purposes from embryos five days old. “Harvesting” these cells inevitably results in the death of the embryo. Thus, whether the embryonic stem cells are toti- or pluripotent, use of them poses two ethical challenges. First, they are obtained through deliberate killing of the embryo, and second, if they are gathered at an early stage, they are totipotent and can develop into complete human beings. Therefore, the source of embryonic stem cells and their age are ethically significant in an evaluation of the legitimacy of their use.

Another manner in which to obtain embryonic stem cells is somatic Cell Nuclear Transfer, or cloning. Through this method, a totipotential cell is produced which could, under the proper circumstances, become a complete human adult. This cell is grown in culture until it is five to seven days old, then its inner cell mass is harvested. This process, again, results in death of the embryo. This is an example of human cloning which is currently subject to a congressional ban. To circumvent this ban, it has been suggested that the term “nuclear transplantation” be used instead.
This semantic device does not alter the fact that a human embryo is destroyed for its stem cells.

A new method has recently been proposed for obtaining stem cells through a process called therapeutic cloning. The goal is to clone human embryos containing genes from a patient in hopes that the clone will produce normal cells that can then be implanted in the same patient without an adverse immune system response. The first attempts using nuclear transfer failed. Another attempt using unfertilized eggs artificially stimulated to undergo cleavage produced a blastocoele cavity but no stem cells.

This is the process of parthenogenesis and the cells thus produced are called "parthenotes." Parthenogenesis occurs naturally in simple species, but it has never been accomplished in mammals. Stem cells from parthenotes do not have the genetic make up to become a full term baby.³

Much depends upon whether the stem cells derived from so-called "excess" frozen embryos are totipotential or pluripotential. This is no mere semantic quibble. If they are totipotential and each can develop into a complete human being, then one is creating, experimenting with and killing a human embryo. If stem cells are not human embryos and not totipotential, then they can legitimately be used for experimentation and therapeutics. If there is a reasonable doubt, as any honest evaluation of the issue must conclude, the embryo deserves the benefit of that doubt and should not be used. After all, in most matters few of us would gamble what we cannot afford to lose.

Contemporary embryologists regard embryonic cells as totipotent from the zygote stage (the fertilized egg) through the blastula (four cell stage) and possibly up to the blastocyst (five to seven days). If these dividing cells are separated from each other in these early stages they are totipotent, meaning each one can develop into a complete human being. How far beyond the blastula the embryonic cells remain totipotent or can recover their totipotency is uncertain with the embryologic evidence now in hand. If at any point embryonic cells can become complete human beings, ethical objections arise not just with the source of such cells, but with their use, regardless of the source.

Much also depends upon whether or not the cells of the frozen embryos to be used to replenish existing cell lines are young enough to be totipotent. There is some evidence that some of these cells at least may be

³. "Cloning Announcement Sparks Debate and Scientific Skepticism," in SCIENCE. Nov. 30, 2001, at 1802. These scientists include O’Rahilly, Muller, Carlson, Sher, Davis and Stoess.
at the four to eight cell stage or somewhere between the blastula and the blastocyst stage when frozen. If this turns out to be the case, they could not be used under existing Congressional guidelines, which preclude experimentation with human embryos.

This raises the question of how we define an embryo. Authoritative Modern Biologists' regard the embryo to be present from the zygote stage or right after it begins to divide. Some embryologists and bioethicists speak of the "pre-embryo," postulating a stage from the zygote until the fourteenth day before which they do not consider the developing cells an "embryo." There is no biological warrant for such an arbitrary distinction. Rather, it has the earmarks of a convenient means for justifying treatment of the developing human with less respect than one would grant it after fourteen days. In much the same way, it has been recommended that the term "ES Cell" be used rather than Embryonic Stem cell to avoid the stigma of destroying human embryos, thus defining the embryo out of existence through a semantic ploy. The nature of the organism is not changed by changing its name.

Clearly, precision in scientific terminology is far more than an exercise in pedantry or taxonomy. Until the biological status of embryonic stem cells and their potentialities at each stage of development are clearly demonstrated, these cells should be given the benefit of the doubt and protected from destruction. Given the genuine probability that adult stem cells, in association with pharmacological and genetic manipulation, can be as useful therapeutically as embryonic cells, it is morally prudent and mandatory to concentrate on adult cells. This is a morally and scientifically sound position whether or not one favors, or objects to, the use of embryonic stem cells.

Similar controversy surrounds the debate of whether the embryo is classified as a human person. This is an even more complicated question than the question of totipotency or what is an embryo. One need only point out that the zygote is the result of two living cells, and both are human cells. There can be no question of the earliest stages of human life being both human and living. Whether or not the embryo is considered a person is a metaphysical question not susceptible to scientific proof or falsifiability. Any attempt to define "person" in terms of a set of arbitrary biological, physiological or sentient qualities is dangerous. Embryos, fetuses and even impaired members of the human species may lack one or another of the arbitrarily specified properties for personhood. Persons in

4. O'Rahilly, Muller, Carlson, Sher, Davis and Stoes are representative of these modern biologists.
coma, a permanent vegetative state, the retarded and the brain damaged human are all at risk of being deprived of "personhood" and of social moral right to protection against harm or destruction.

Alertness to terminology is essential in the stem cell controversy. Those who favor the destruction of embryos as a source want to avoid use of the term "embryo" because they think it is too inflammatory and generates resistance. They suggest a variety of euphemisms: "nuclear transplantation" or "therapeutic cellular transfer" for cloning humans. One ethicist, who heads the ethics panel of one of the involved companies – Advanced Cell – wants to substitute "activated egg" or "cleaving egg" for the term embryo. Another biologist offers "ovasome."

These euphemisms are intended to confuse the non-scientist public and decision-makers and divert their attention from the fundamental fact that human embryos are produced to be destroyed, – a practice currently at least subject to congressional ban. All terms used to support or denounce embryo sacrifice should be defined clearly. Non-scientists must not be reluctant to question a scientist who, like other humans, may have a vested interest in avoiding confronting some disturbing ethical challenges.

B. Therapeutic Claims

In the minds of many, including those who have reservations about the use of human embryos, the claims for therapeutic success seem overwhelming. Most of the public's information come from the popular media, which customarily celebrates whatever is new and sensational, or represents "progress." To be sure, responsible journalists and scientists have reported the scientific promise as well as the limitations of current research fairly and accurately. On the whole, however, the public has been exposed to a species of evangelical advertising, over promise and semantic prestidigitation overstatement that is morally and scientifically irresponsible.

The fact of the matter is that no one has yet been cured by the transplantation of embryonic stem cells. In fact, the one controlled trial of fetal tissue transfer in Parkinson's disease has resulted in failure and even worsening of the disease. One cannot deny the potentialities, the need and the understandable sense of urgency for new therapeutic hope among

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patients and families currently afflicted with an incurable disease. Attempts at moderation of expectations, critical analysis of data and the need for time to evaluate results are unfortunately regarded as insensitivity to human suffering, or an anti-science attitude. This attitude fails to take into account the even greater harm of raising expectations unrealistically and then failing to deliver on them. The fact of the matter is that miraculous cures are a long way off in the future.

What has not been sufficiently emphasized in the popular press and the media is the simple fact that clinical application of stem cells is in its infancy and the requisite scientific knowledge is still lacking. Very little is known about the intracellular signals that initiate and direct differentiation of cells. Equally little is known about what turns genes "on" and "off," about what controls expression and silencing of genes, or about the role of chromatin, the protein-DNA complex that helps DNA enter the nucleus or the enzymes that modify these proteins.

A whole new area of investigation called "epigenetics" has emerged to modify our conception of the gene as the unit of inheritance. No doubt as these new complex molecular and enzymatic entities are studied new complexities and new possibilities are certain to reveal themselves. The same can be said of the process of methylation of DNA in both healthy and cancer cells. Much remains to be learned about how the unspecialized stem cells can be made to become the specialized cells before therapy becomes a reality.

Another problem to be resolved is that of immune rejection of transplanted embryonic stem cells. This is the result of admixture with mouse cells now used as a means of accelerating growth. Obtaining stem cells by somatic cell nuclear transfer, or cloning, could prevent this, but it requires the production of a new embryo that would have to be destroyed to harvest its stem cells.

There is an enormous amount of research still to be accomplished in the fundamental cellular mechanisms if therapeutic applications are ever to become a reality. Like the Human Genome Project, the discoveries to date are only the end of the beginning. The public, policy makers and legislators must recognize the need for increased and superior research whenever they are subjected to public pressure to "do something." That research should focus on adult sources of stem cells – not on embryonic stem cells.

C. Limitations of Existing Cell Lines

In August 2001, President Bush ordered that federal funds be used to support stem cell research only under specified conditions. Specifically, embryonic stem cells had to have been derived prior to August 9th, the donors had to provide informed consent, the only approved source for embryonic stem cells had to be “excess” embryos created solely for reproductive purposes and no financial inducements for donors and funds would be provided for research on adult stem cells.

Since the President approved the use of federal funds for research in existing stem cell lines, new controversy has erupted about the number, viability, utility and sufficiency of the forty-to-sixty cell lines. The actual number is in dispute. Recent newspaper articles provide conflicting information. A survey of fertility clinics, for example, indicates that few “parents” of frozen embryos have come forward to offer them for research. Moreover, the number of cell lines actually in a viable or useful state is highly uncertain. One large source cited by the NIH is in Sweden; a spokesman from that laboratory has publicly stated that the number of available cell lines is far too high and that the number in a useful condition may be much smaller.

In addition, it is reported that perhaps a majority of the frozen embryos to be used to cultivate cell lines come from older patients and might not be of sufficient quality or viability to generate useful cell lines. Also, as cell lines age, harmful mutations occur. This is true of frozen embryos as well. Optimism about existing cell lines is also dampened by the fact that existing cell lines had to be “coaxed” to grow by incubating them with mouse cells. This raises the question of immuno-rejection problems and the possible introduction of some unknown virus into human recipients. All of these factors are coupled with a complicated and discouraging consent process. These factors have already raised a clamor for many more and newer cell lines, for fresh and better-prepared cell lines, and for relaxing the prohibition against creating new embryos as the source for those new cell lines. Progression down the slippery slope toward unrestrained research with embryonic stem cells is already underway.

Another limitation on the use of existing cell lines has evoked little discussion so far. Most of the existing lines have come from small segments of the human population. In the West, most of cells now

available come from the U.S., Sweden and Israel; in the East, they come from South and East Asia. This is a limited representation of the racial, genetic and ethnic diversity of today's world.

It is true that humans share most of their 30,000 or so genes. However, there are some subtle yet important differences in their expression to be understood in the face of the propensity of certain populations to exhibit high prevalencies of certain diseases, such as Diabetes, Hemoglobinopathios, Hypocholesteronemia and Hypertension. Similar differences exist in the response to a variety of medications or in the immune reaction to transplanted cells. A new field of pharmacogenetics has emerged to study some of these differences in drug reactions by individuals and ethnic groups.

The narrowness of the ethnic and genetic spectrum of existing cell lines means that research on fundamental mechanisms may not be readily transferable between and among ethnic groups. If there were therapeutic benefits forthcoming, they would be limited, at present, to those of European and some small number of Asian ancestries. This differentiation is also a matter of justice. For these reasons, the political pressure to expand and extend stem cell research beyond the lines approved by President Bush will increase. This in turn will generate demand for making and destroying more embryos as sources for the needed cells.

Clearly, many scientific questions remain to be investigated before stem cells from any source can fulfill the enthusiastic promissory notes made for their curative posers. What are the best conditions for growing these cells and shaping the directions their development will take? What genes control the way the stem cells grow and differentiate? What are the immediate and remote steps in differentiation? What turns the genes “on” what turns them “off”? How can immune rejection of injected cells be prevented? Even more fundamental is the series of critical questions arising from the emerging field of epigenetics, the realm of research examining the place of Chromatin and Histones in influencing the DNA and its functioning. This is a relatively new sector of cellular biology that may reveal it has as much, or more, influence on how genes function than DNA itself.10

These are all complex questions, which should be answered before acceptable treatment protocols become practicable. Answering these questions will require many stem cells and many experimental observations in order to analyze them satisfactorily. As the overestimates

10. Pennisi, supra, note 7, at 1064-1070.
of the utility of existing cell lines suggest, many more new cell lines will be
demanded.\textsuperscript{11} Pressure to relax the President's conditions, particularly his
restrictions on the production of new embryos, will be extremely difficult
to resist. If promising therapeutic reports come from experimental animal
models of disease, then the "slippery slope" will be further greased.

These difficulties make it necessary to focus new attention on alternate
sources for stem cells, chiefly those not involving the death of human
embryos. It is providential that President Bush has set aside federal funds
to support research on alternate sources of stem cells derived from tissues
as varied as bone marrow, placental cord blood, muscle, bone and brain.
Animal studies indicate success in converting mouse bone marrow cells
into brain cells (glia), mouse skeletal muscle into all major blood cell types
even on second transplantation, adult marrow cells into brain, human
stromal cells into rat neurons, and neural cells into lymphoid and myeloid
cells. The scientific community should vigorously pursue all of these
possibilities.

The possibilities and limitations of adult stem cells must be appreciated
as well. Some of their advantages based on recent investigations include:
(1) stem cells of several types are already pre-disposed biologically to
generate a particular tissue and thus might be able to produce that tissue
or its components more readily than less specialized stem cells; (2) they
secrete growth factors, which might facilitate growth of other cells as well
in a transplanted tissue site; (3) some adult stem cells have been shown to
migrate to an injured tissue or other sites, for example, neutral stem cells
to brain tumor sites; and (4) they might be genetically engineered to
produce other compounds normally needed, but deficient, or even to
secrete a drug for therapeutic purposes.

Along with these advantages are certain current disadvantages when
using adult stem cells: (1) they are difficult to isolate; (2) their plasticity
might be minimal; (3) it is not known how to culture environment affects
their functions; and (4) they may not remain undifferentiated or even fail
to become differentiated into functional cells. These questions can be
resolved by intensive research on adult stem cells, which would be
ethically permissible since such research does not involve the death of
embryos.

There is also the possibility that embryonic stem cells are not
experimentally more beneficial than cells from these adult sources with
regard to their plasticity or the possibility of transformation into useful cell
types. The emphasis placed on the supposed superiority of embryonic

\textsuperscript{11} National Academy of Sciences Report, 2001, recommendations 1 & 2.
stem cells may even be misplaced on strictly scientific grounds. Attention must be turned to other sources that lack the moral objections that accompany the use of embryonic stem cells.

II. WHAT ETHICAL ISSUES ARE AT STAKE?

As difficult as the assessment of scientific facts may be, stem cell research is further complicated by the need to place those facts within an ethical framework. The mere fact that a therapeutic benefit may be scientifically demonstrable is insufficient to justify its adoption. The challenge in a technologically oriented society is to use capabilities wisely, humanely and within ethical constraints. In a morally pluralist society like ours, the identification, validation and application of moral norms is laborious and controversial. Often, no ethically satisfactory compromise is possible. Regardless, every effort must be made to confront the ethical questions first.

Certain foundational ethical norms and principles must be examined to make this analysis. Admittedly, they may be defined, interpreted or applied in different ways. Nevertheless, a few moral principles will make their appearance recurrently in the debates. These principles have been prominent in the paradigm case of stem cell research. The ordering of science in relation to politics must be done in an ethical framework, or its decisions will simply be reduced to expediency or exigency.

A. The Ethics of Science

The first ethical norm is the norm of good science, or science that fulfills the obligations of the scientist as scientist. Much of what has been discussed thus far in this essay relates to the ethics of good science, establishing certainty with the factual foundations of the information supplied by one's colleagues, the public and the policy makers. This means accuracy and honesty in both reporting and sharing those results so that they can be falsified or validated by other investigators. It also means providing negative as well as positive evidence for one's hypothesis or experimental results.

In the case of therapeutic research, special attention must be placed on these requirements for several reasons. First, the anxiety and eagerness for a cure for those afflicted with any illness for which a new treatment is described must be considered. Second, the implication for public policy if a new technique or treatment will be made widely available is another factor. Third, the whole realm of ethical implications to society when the data focuses on control of some aspect of the beginning and ending of
human life is also significant. Economy of pretension is a particular virtue for the responsible scientist.

**B. Respect for the Dignity of the Human Being**

The moral use of biotechnology must recognize the inherent worth of the human being as a human, and as a being capable of a rational self-determining existence. Most of the rights in the United Nations Declaration are expressions of this principle, such as the right to life, liberty, freedom from oppression, equality of opportunity and access to health care.\(^\text{12}\)

In the stem cell controversy, the focal issue is the moral status of the embryo. At what stage of human development do we impute respect for the dignity of that embryo? It does not help to evade the issue by the invention of euphemisms like the "pre-embryo" or the "ES Cell" for embryonic stem cells. Nor does it help to reduce a metaphysical concept like personhood to a biological construction. Personhood is not definable in terms of length of gestation, development of certain anatomical structures or the capacity for sentiency or social relationships.

Such definitions are far too often semantic contrivances designed to escape the stigma of destroying a human life in its earliest and most vulnerable stages. Moreover, these definitions would also exclude from personhood those persons afflicted by mental retardation, senility, or lack some modicum prescribed of physiological or other sociological characteristics arbitrarily defined.

From the philosophical point of view, the embryo is a human being in the state of active potency. That is to say that from its inception, the embryo is set on a course of development, which will actualize its potentialities. Unless interrupted by man or nature, the embryo possesses the characteristics essential to a human being at the earliest stages of its development. It is actually, not just potentially, a human being. Consequently, destruction of an embryo is the destruction of a human being. Stem cell research, any method of which relies on the death of the embryo as a step in stem cell retrieval, is morally wrong. This contravenes use of fertilized zygotes, embryos or clones human ova. Use of adult stem cells would be licit unless they were made first to made embryos.

**C. Avoiding Evil Even if Good Comes of It**

In a highly pragmatic society like ours, the probability of a good result for many, or for a noble cause, may well override the respect owed

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harm to some humans is thus justifiable if it will help others or benefit the common good. Human decisions are made with some good in mind, therefore what is evil is always done under the appearance of good. This is the argument of those who justify destruction of human embryos on utilitarian grounds to obtain cells for experimental or therapeutic purposes. The "special" nature of the embryo will be "recognized," but it will be set aside if its death can bring life to others. This is the argument now being used to justify relaxation of the congressional and presidential ban on producing new embryos or establishing new cell lines. It is also essentially the argument used by the President's National Bioethics Commission to justify embryonic stem cell research.

What is at issue here is a choice between two theories of ethics - consequentialism and deontology. The former argues that the morality of an act depends upon whether its consequences are so good that they outweigh the wrong necessary to bring those consequences about. The deontological view holds to the contrary, that certain acts are so wrong in themselves that they may never be done even if good may come of it. Of course, if one holds that there is no wrong done in destroying very young embryos in the first place, then the debate becomes moot. In any case, the question must be faced that some choice must be made between truly respecting the human embryo and overriding that respect when the embryo's death provides significant benefits for others.

D. Avoiding Complicity

Even if one does not do harm oneself, one may share in the guilt of an ethically improper act or decision. The degree of moral complicity in a morally wrong act will depend upon whether or not the wrong intent is shared and how closely one facilitates the wrong act. The resulting "moral distance" is crucial in separating morally licit from illicit cooperation. This is not the place to review the well-established distinctions between different degrees of moral complicity.13 Better familiarity with the ethics of cooperation is requisite if moral judgment is to be made about the use of embryonic stem cells obtained by the destruction of embryos, even if one does not do the actual destroying oneself.

This is necessary because some investigators have tried to escape association with the killing of embryos to obtain their stem cells or avoid the congressional sanction against such use with federal funds. They do so by using cells obtained in this manner under private auspices.

Nevertheless, using cells obtained from the death of human embryos is an instance of moral complicity. An individual shares the intent for which these cells were harvested when one uses them for experimental or therapeutic purposes. One also encourages further harvesting by providing an outlet for the cells thus obtained.

**E. The Reality of the Slippery Slope**

Once a major moral principle is compromised it becomes incrementally easy to extend that compromise to analogous or similar cases. Logically, one finds it difficult not to assent to extension of the compromise to similar related cases. With each incremental compromise the principle becomes progressively diluted until it becomes all but non-existent. Little is left that can be defended.

Once a principle is relaxed, it becomes easier psychologically to accept compromises even of morally robust norms. It is always the first infraction that is most difficult. Moral revulsion, once some individuals are able to overcome it, loses its power to restrain others. Moral revulsion is easier to overcome with each subsequent compromise. Although many ethicists revile the slippery slope and label it a myth, they fly in the face of logic, psychology, history and fact when they do so.

One needs only recall here the history of *Roe v. Wade* to see this principle in action. First, abortion was limited to the first trimester, then allowed in the second and third, and then to late term pregnancy. Going from the evacuation of a week old fetus to the evacuation of the living brain of an easily identified human baby in late term abortion is the inevitable result. Similarly, assisted suicide and euthanasia in the Netherlands began with certain restrictions for physical illness and "unbearable" suffering. Today it has been extended to children, infants and psychological suffering as well. All this has occurred despite regulations and laws designed to control abuse.\(^\text{14}\)

Already, the National Academy of Sciences has stated that research will be impeded if it is confined to currently available cell lines, as the President's decision requires. The National Academy emphasizes that mutations occur as cell lines age and become less useful as a result. In addition, current cell lines have been admixed with animal cells, raising the probability of immunogenetic responses if they are transplanted into humans. Furthermore, the Academy Report asserts that private

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entrepreneurs are unlikely to develop new lines of cells until the profit potential is more apparent.\textsuperscript{15}

In the stem cell controversy, there is already mounting pressure to use federal funds to support to use of cells obtained from killing of embryos under private auspices not supported by private funds. Already the quality, quantity, and variety of existing stem cell lines is insufficient, and more embryos must be created to make needed research possible. In the same way the actual totipotentiality of embryonic stem cells is being re-interpreted as pluripotentiality — ostensibly to avoid the stigma of destroying cells from early embryos each of which is capable of, on its own, becoming a complete new human being. The slippery slope is as applicable to compromise in the meaning and use of words as it is with respect to principles and actions.

This is not, nor is it intended to be, the sum total of relevant ethical principles requisite to an analysis of policy formation and legislation regarding biotechnology. The goal has been to illustrate some of the ethical issues in assessing the ethical aspects of legislation and regulation.

III. WHAT ARE POLITICAL AND ECONOMIC ISSUES?

Any effective technological innovation applied over a wide range of population must, in a democratic society, be subjected to some societal regulatory mechanism. In the ordinary course of events, this will mean legislation and regulation. In the end this will involve some limitation on the use of the technology in order to protect the common good of all society. Deciding what should be legislated, and how, will mean that public policy must be derived from a careful balancing of scientific knowledge, ethical principle and constitutional rights.

In this respect, stem cell research is a paradigm case. The difficulties of striking a reasonable balance were illustrated on August 6, 2001 when President George W. Bush announced his decision on the use of federal funds for stem cell research. The President attempted, with great sensitivity, to balance the putative therapeutic benefits of stem cell research with the respect owed the life of the human embryo. He also tried to consider the divided opinions of Americans on these issues. As a result, he struck a politically attractive compromise of the ethical and scientific issues.

On the one hand, the President affirmed the sanctity of the life of the embryo by forbidding further destruction of frozen embryos. On the

other, he permitted use of existing cell lines, which had been harvested after the destruction of human embryos. He established a Commission to examine ethical issues as they arise, authorized funding for research in adult stem cells not involving embryo destruction and forbade human cloning for any reason. The President's rulings applied only to the use of federal and not private funding.

As the debate resumes, the focus will be on the ethical principles mentioned earlier in this essay and, in the public arena. It will also involve the principles of freedom of choice and social justice. State and federal legislators must confront the practical problem of protecting the rights of freedom, personal choice, privacy and conscience. They must also consider the life of the embryo, while avoiding exploitation in the use of the knowledge and power of this new technology.

There is no way such power can be left entirely to the individual choice of investigators, entrepreneurs or private persons. To argue that the pursuit of knowledge, even if ostensibly for human good, should be unrestricted is to submit the public good to the fortuitous will of a small group of experts and entrepreneurs. Some undoubtedly will be ethically responsive, while others will not. History and the frequency curve of the distribution of the moral sense among people do not justify such naïve confidence.

In any case, personal freedom and autonomy are neither ethical nor legal absolutes. To live in society peaceably and safely, certain restrictions on both have always been necessary in civilized societies. However, once public policy has been decided, the choice between using a new technology or not using the results of stem cell research will reside with the individual. Those who find a policy morally reprehensible should be free, within the methods available in a democratic society, to object and to work for changes in the policy.

A clear distinction must be preserved between what is legislated and legal and what is moral. Legality does not confer moral status upon stem cell research anymore than it confers moral status upon abortion or euthanasia. Given the moral and religious diversity of present day America and the greater diversity of its future, we must expect to live with such differences peaceably. We must depend on persuasion, debate and clarification of differences when public policy violates our sense of what is morally permissible.

This surely seems to be the future for such technological innovations as stem cell research, genetic engineering and therapy and perhaps even cloning. On the other hand, if a particular technology is deemed ethically wrong, then it should be forbidden in the private as well as the publicly
supported sector. Surely, the morality of stem cell research cannot depend on the source of its funding. In any case, each of us will be challenged to determine whether we can in good conscience make use of knowledge and techniques obtained from morally improper sources of stem cells.

Whatever decision is taken as public policy, it must be arrived at and administered justly. This means conforming to the requirements of both commutative and distributive justice. Even when the decision regarding what to legislate is taken, the decision must also be made to legislate justly. This means conforming to the principle of justice - rendering to each his due, equally to equals and unequally to unequals. This principle operates at the level of individual relationships where it is called commutative justice and at the societal level as distributive justice. Only a few examples of each will be mentioned.

In the realm of commutative justice lie the moral obligations of individual investigators to individual patients and experimental subjects and of physicians to individual patients. Investigators are, in justice, obliged to obtain properly informed consent; to be objective in reporting their results; to share results that are crucial to the health of the population with the public and other investigations. Premature and inflated reports of success in order to gain a competitive advantage are not morally admissible. These obligations are derived from the trust society and persons must place in the expertise of physicians and scientific investigators. Ensuring these and other aspects of commutative justice is a fit subject for regulatory consideration in stem cell research legislation and policy.

In the realm of distributive justice lie the broader political and economic questions of availability, access, distribution, quality, cost and ownership of any cell lines that may eventually prove useful. The commercial possibilities already promoted by biotechnology companies will attract interest among investors, who will be entitled to some return on their investment. The costs of research and development will have to be returned through the price of cell transfer treatment. If stem cells should prove to be effective, the high cost of treatment will become a moral issue. Disproportionate access based only on ability to pay cannot be just in the case of a life-saving or curative treatment. Government subsidies for the economically less advantaged will be necessary. In the current commercialized climate of American health care, assurance of justice in distribution will surely become a matter for legislative action.

This question of distributive justice is especially acute in stem cell research since the cells available for federal funding come from predominantly European and a small number of South Asian sources.
This is a small representation of the ethnic diversity of our world. The research currently permitted may not be transferable and consequently may be unavailable to many ethnic groups in the U.S. and the world. Yet on the basis of equity and justice as well as humanitarian grounds, it would be unjust not to make these benefits available to all.

The problem of ability to pay is linked to the limited sources from which existing cell lines have been drawn. They derive from “excess” embryos resulting from in vitro fertilization, a costly process denied to the poorer members of our society. If it turns out that stem cells can be engineered to reflect the unique qualities of the humans who donate them, then the economically less fortunate will again be left out. The same problem arises when embryos are cloned to meet the specification of the donors for cells of a particular type. Custom-tailored stem cells will likely be costly and well beyond the means of the poor.

These questions will become particularly acute should there be a shift in our health care system to one of universal entitlement. Legislators will be heavily involved in establishing principles of fair distribution and access. Justice and fairness are not intrinsically matters of expediency and some concept of social justice must be evolved for access and payment when truly effective biotechnologies appear.

The question of monopoly already looms as a genuine issue. One corporation, for example, controls the rights over many of the stem cell lines now eligible under President Bush’s plan for federal funds. The same corporation, Geron of Menlo Park, California, owns commercial rights to the technology that produced Dolly, the first cloned sheep, as well as rights to telomerase. Telomerase is an enzyme that can restore the telomere to full length in vitro and seems to extend the age of cells. Inhibiting telomerase might be useful in inhibiting growth in cancer cells. Geron at present is making little or no profit on these possibilities, but its CEO Thomas Okarma says his company aims “...to dominate the market.”

Further, the patent on embryonic stem cells is held by the University of Wisconsin Research Foundation, and Geron Corporation holds commercial rights to six cell types and seeks to exercise its options over twelve more. Okarma expresses a view not rare among investigators in this field, “I am not apologetic for our intellectual property. We paid for

17. Id. at 11.
it, we earned it and we deserve it." To what extent does this frank assertion of property rights over biological material conflict with what is owed in justice to individuals and society? Who really "owns" the cell lines from a "donated" embryo?

Geron also has plans for "therapeutic cloning," creating new embryos from a patient's own cells to obtain stem cells specific to the donor, thus avoiding the dangers of immuno rejection. Another company, Advanced Technology of San Francisco, has been formed to compete with Okarma. Clearly, the question of how much can be left to the market and how much is to be controlled in the public interest already presents itself. In a nation already commodifying health care, the likelihood of extension of commodification to human cells is unfortunately high. The fact that Geron Corporation also has its own "ethics committee" is not at all reassuring. Money, profit and ethics are not natural allies.

All of this is now in the private sector, which is not covered by President Bush's recent decision. Ethical and legal constraints are at the moment not available to protect either the embryo or the public interest. Indeed, those who work within President Bush's constraints, like NIH and University investigators with federal grants, look to private industry and research to supply the cell lines they believe they need to continue their research. One need only mention these facts to appreciate how complex and intermingled are the ethical, scientific and socio-political issues we as a nation must face.

In a recent update, the National Institute of Health expressed confidence that patenting of new discoveries would not affect research. However, it mentioned neither the ethical status of such patenting nor of its impact on the public interest. Are stem cell research and the products it generates simply commodities? Or are there humanitarian and human rights dimensions that are being ignored in pursuit of the principles of utility and market economics?

Important as these considerations may be, they leave aside the question of whether there can be two standards of morality: one for the private sector and one for the federally funded sector. If it is morally wrong to create new embryos to obtain stem cells on federal grants, how can it be morally permissible to do so with private funds? This is a rather extreme example of the difficulties created when morality is left entirely to social convention or convenience.

18. Id.
Very serious questions will arise in the realm of professional ethics. Currently, this field, which deals with the obligations of physicians and other health professions, is already in flux with many calling for a “new” ethic. What will the professional obligations be of physicians who see a grave moral problem in providing treatments obtained from embryonic stem cell research dependent on destruction of the embryo?

This question will become intensely debated if stem cell treatment becomes genuinely effective. The pressure on physicians to make stem cell treatment available will be enormous. Must physicians be “value neutral” as some contend and submerge their personal ethical beliefs and provide treatment simply because they are physicians? Is it even possible to be “value neutral” in this arena? Will compliance with a socially accepted treatment be a condition of licensure regardless of the physician’s personal beliefs? What will be the impact on this question of universal health care entitlement if this becomes a policy? Will physicians morally opposed to the destruction of embryos be barred from practice or even entry into medical school?

The same questions will apply to religiously sponsored hospitals and other health care institutions. Will Catholic hospitals, for example, be allowed to receive public funds or reimbursements if they do not provide a full range of services? Will a choice have to be made between religious sponsorship, institutional integrity and survival? Will dissenting hospitals and physicians be limited to caring for those who share their beliefs only?

These issues touch on the much deeper question any policy must face in a morally pluralist society. How are we to live peaceably and protect the human rights of all citizens when we are “moral strangers”, i.e. members of communities whose ethical and or religious beliefs do not permit certain compromises? Stem cell research is a paradigm case of the kind of questions that will also rise with the actualization of some of the promise of the genome project, human cloning and biological innovations as yet unimaginable.

These are some of the inter-related and intermingled questions which confront our society and which will generate demands for public policies, regulations, legislation and accountability. They are inter-related in the nexus of science, ethics and politics. Clearly, in the real world, these issues are not so easily dissectible. Yet if they are to be examined, the nature of each must be recognized and a proper balance struck between them.

In striking a balance, the ethical considerations should guide both the use of science and the economic and political uses of that science. This means that decisions may move more slowly than interested parties, patients, biotech companies and scientists desire. If anything is clear in the
example of stem cell research, it is that haste, overselling of results and political pressure can lead to more conflict rather than less. The debate has only begun. All of the general public will be either victims or beneficiaries of our collective deliberations. Let us hope that they are morally sound, scientifically correct and politically just.