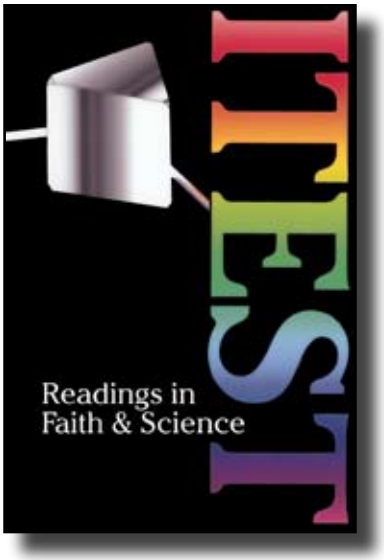

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Human Embryonic Stem Cell Research: Ethics in the Face of Uncertainty

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Human Embryonic Stem Cell Research: Ethics in the Face of Uncertainty

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Too often the opposing positions in the stem cell and cloning debate are presented in terms of the obviousness of their assertions made. Considering the complex nature of these controversial issues challenging our society, the reality is much less clear and certain. Therefore, the question addressed in this essay is: how might we best respond to the challenge of human embryonic stem cell research in the face of the uncertainties that pervade this issue?

Uncertainty is present in all aspects of this issue: scientific, medical, moral, religious and political. This essay begins with the areas of uncertainty that are perhaps most surprising and, hence, most vexing for those engaged in this public debate -- the scientific and the medical.

In order to appreciate more fully the scientific and medical uncertainties within stem cell research, it is helpful to put the science of the stem cell debate within a larger context of the current advances in molecular and cellular research. Stem cells are only one part of the rapidly expanding arena of molecular biology research. This arena includes such topics as genetic therapies, genomics, pharmacology, proteomics, and various types of cellular and tissue research.

(1) All of these research trajectories offer tremendous potential for advancing our scientific knowledge as well as the possibility of leading to new and exciting medical therapies and products. A couple of examples may help give a sense of the scope of these possibilities.

Much has been written both in academic journals and the popular press about the promise of human gene therapy. Until recently there has been little concrete evidence of the fulfillment of that promise, and, instead, some tragic and troubling research tragedy has occurred. (2) However, the latest results of some clinical trials employing gene therapies to treat immune system disorders indicate that the promise might be at least partially satisfied. (3)

In these clinical experiments, the researchers added a functioning gene to the cells of individuals who were diseased because of a genetic defect. The drawbacks to this approach include the problem of not being able to control where the new gene incorporates into a cell's DNA, and the problem of the mutated gene remaining in the cells. In the near future, researchers hope to address these problems by directly replacing or repairing the diseased genes. (4)

If the disease to be treated results from flaws in a region of DNA much larger than a single nucleotide or even a single gene, then researchers may try to employ artificial chromosomes to address the situation. In addition to a larger genetic carrying capacity, human artificial chromosomes would also have the advantages of maintaining a more stable number of the copies of a gene within a cell along with better control of long-term gene expression.(5) Using these genetic technologies to target both small and large genetic mutations, the physicians of the future may have much greater success in treating the genetic causes of many diseases.

However, if these genetic technologies can be used successfully to treat disease, might not they also be used to change the genetic constitution of a human being in order to alter that individual's physical or behavioral characteristics? Considering the fact that human beings share over 98% of their genetic sequence with chimpanzees, the question arises: would changing an individual's genetic constitution to include DNA sequences previously foreign to a human being change the nature of that individual? Is there an amount or kind of alteration that would

result in that individual no longer being human?

These examples from human genetic engineering have been used to show that the ethical challenges generated by cutting edge biotechnologies are very much the same as those raised by human stem cell research. An example from stem cell research will help to demonstrate this point.

In an experiment designed to investigate the emergence of reservoirs of neural stem cells in the developing fetal brain, Evan Snyder and Curt Freed directed research whereby cells from a neural stem cell line derived from a human fetal cadaver were implanted into the developing brain of a fetal bonnet monkey at approximately 12-13 weeks of gestation. After sacrificing the fetal monkey four weeks later, Freed and Snyder found that the human neural stem cells had migrated and incorporated into the fetal monkey brain. (6)

Though it was not the stated purpose of the experiment, these results pose serious questions about the uniqueness or significance of human nature. If human beings are considerably interchangeable with other animals on a cellular and/or genetic level, then how might that reality affect our concepts of our selves? If we now have the ability to interchange genes, or cells, or even tissues and organs with other animals, then at what point does an addition of non-human parts make a human being something or someone else? Already researchers add human DNA and human cells to animals. In light of these realities, one could try to frame the question of human nature in terms of percentages of human DNA, cells, or genes expressed in a given animal. This approach, I would argue, is not likely to succeed because such quantification cannot encompass the complexity and richness found in our concepts of human nature.

The above experiment with human neural stem cells in fetal monkey brains is particularly relevant to these questions about human nature because arguments are often presented that focus on the human brain as the physiological basis for what makes human beings special or unique. If cells from humans and other animals can be mixed early in development and still form a functioning brain, then does it -- will it -- should it matter what percentage of a brain is made up of human cells? Perhaps, instead, research will indicate that the timing of a genetic or cellular manipulation during organismal development is more important than the amount of material inserted? Whatever the case may be, brain experiments mixing cells from different species will certainly add to the challenges scientific research is raising to our commonly held concepts of what it means to be human, and what makes humans special -- if anything.

In light of these challenges, and the troubling ramifications they may have for our moral frameworks and ethical reasoning due to their unsettling effects on our beliefs and concepts about human nature and human value, one could easily ask why it is that such research is being done at all? In order to answer this question well, at least a cursory understanding of stem cell research is required.

First of all, what are stem cells? The concept of stem cells is used to help explain how it is that a multicellular organism, such as a human being, can begin as a single cell and yet develop into a complex creature made of trillions of cells, that come in thousands of different types, which form hundreds of different tissues and organs, that provide the physiological basis for all our abilities and characteristics. In addition, many of the cells we require to function die during the course of a lifetime and need to be replaced. Stem cells are the source of these replacement cells. Hence, stem cells are considered to be special cells that can multiply to create and replace the many cells of our bodies, and at the same time replace themselves so that we continue to have some stem cells throughout our lives. (7)

From this understanding of stem cells one can easily project several important goals for research using these amazing cells. Often these goals are grouped into three categories: basic research in human development, safer and more specific drug development, and therapies to repair or replace damaged tissues and organs. (8) The basic research is obviously significant because scientists want to understand better how human beings develop from a single cellular structure to the complex structure of an adult body. In addition, since stem cells function to replace the cells we lose in daily life, basic stem cell research may help answer questions about disease, injury,

and aging.

The goal of safer and more specific drug development is one that might be less obvious to the public at large. The idea here is to use stem cells from different individuals to grow cells, tissues, or perhaps even organs. Then instead of, or in addition to, testing drugs on animals or generic human cell lines which may not represent accurately or precisely the reactions of a target human tissue, the cells or tissues grown from different individuals can be tested for the efficacy and toxicity of various drugs. From such research, companies might get a much better idea of which individuals would benefit more from which drugs, and which individuals should avoid which drugs, even before clinical trials with human subjects are begun.

Eventually, the goal of this research is to develop products and therapies that would allow physicians to more directly, efficiently and effectively replace and repair the cells, tissues, and organs of an individual that may have been damaged or destroyed. This medical approach is now being promoted as "regenerative medicine." (9) In the public debate surrounding the stem cell issue, it is most often this goal of using stem cell research to regenerate tissues and organs that receives the greatest attention. Some additional distinctions concerning different types of stem cell research will help to clarify why this is the case.

The distinction most often used in the current stem cell debate is between "embryonic" and "adult" stem cells. "Adult" stem cells is something of a misnomer, since they are found in various tissues from the time of fetal development until death. "Embryonic" stem cells are those derived from the inner cell mass of a "blastocyst." "Blastocyst" is the term for a certain stage of human organismal development that is within the broader eight week period of embryonic development. The blastocyst is a hollow sphere of cells with a cluster of cells inside. The embryonic stem cells are derived from this inner cluster, and are obtained by breaking open and thus destroying the blastocyst. Since the procurement of embryonic stem cells results in the destruction of embryos, this process is highly contentious in our society where many hold the position that human lives deserve protection from destruction for research purposes even, or especially, during this early stage of development.

If obtaining human embryonic stem cells is so controversial, then why would anyone want to do it? The answer to this question requires our returning to the above description of stem cells and human development. Since it is known that the human body begins development with the fertilization of an egg with a sperm, it can be concluded that all the different cells of an individual had their beginning in a single fertilized egg. Similarly, scientific evidence indicates that all the different cells of our adult bodies arise from some of the cells in the inner cell mass of the blastocyst. Using this information, researchers conclude that these embryonic stem cells must be able to make any human cells or tissues one might need for research or therapy. Therefore, some researchers wish to use these embryonic stem cells to recapitulate what goes on during normal and/or abnormal human development.

Basically, then, the public debate concerning human embryonic stem cells revolves around weighing the good of doing this scientific research, with the primary goal of medical benefit, against the harms involved in doing research on human embryos. Having listed the benefits of this research above, I now turn briefly to the harms involved.

The most obvious, and probably the most broadly contentious, harm cited in the public debate is the destruction of the human embryo. This issue becomes exacerbated when proposals are made for intentionally creating human embryos, either by in vitro fertilization or by nuclear transfer techniques (cloning), in order to destroy them for their embryonic stem cells. At issue here is the value -- moral, legal, social, etc. -- societies are to acknowledge in or give to human embryos. The different arguments made concerning the value of human embryos range from claiming that they should be treated basically the same as any piece of human tissue to claiming that they should be treated basically the same as any human person. Since much has already been written across this broad spectrum, I wish to address only one aspect of the debate that highlights the uncertainty involved in this issue -- the ambiguities encountered in this debate concerning the term "embryo."

In order to support the claim that human embryos should not have protections similar to those held by human

subjects in general, it is often argued that the relatively high rate of embryo loss in early pregnancy (with some estimates at 50% (10)) indicates that embryos should receive a lesser moral and legal status than human subjects in general. (11) Otherwise, it is asked, why do not societies and cultures encourage the ritual mourning of the loss of these embryos, and why do they not advocate for greater medical interventions to save these human lives? Prescinding from an analysis of differing traditions concerning the appropriate response to death early in human development, one can, instead, evaluate the importance of this argument by focusing on the ambiguity, or even equivocation, inherent in this argument with respect to the use of the term "embryo."

When arguing about the ethical status of a human embryo, the underlying reality about which one is arguing can be described as that stage of human development we all transited on our way to our current stage of human development, whatever that may be. In other words, we are discussing human embryos in the context of what we ourselves once were. This context is not the same as the scientific one that undergirds the statistics about human embryo losses in early pregnancy. Such statistics might readily include abnormal growths, such as complete hydatidiform moles. (12)

Though hydatidiform moles may have characteristics similar to embryos as described above, these growths are not developing along the trajectory of a human organism. Rather, these growths are disorganized in their development to the extent that they may require surgical removal in order to prevent them from becoming life threatening cancers. The question then arises: in light of the possibility of non-embryonic pregnancies, how many of these pregnancy losses are actually human embryos of the type of which we envision in our ethical debates? Once again, it appears that we are confronted with significant uncertainty. Since our scientific conceptualizations of an embryo may not match the embryo conceptualizations employed in our ethical analyses, the relevance of the argument regarding the percentages of embryos lost in pregnancy may be only minimal at best with respect to the human embryo research debate.

This problem of uncertainty in arguing about the ethical status of embryos fits within the larger context of uncertainty about human nature described earlier in this essay. It is not surprising that there is difficulty in defining the beginnings of human life, if it is indeed becoming more difficult to define human life itself due to our rapidly increasing scientific information. From this larger context, these uncertainties in the definition and understanding of embryos and human life may help to explain the impasse currently experienced in the human embryo research debates. If different, and even contrary, understandings of the beginnings of human life are being used in this public debate, then without extensive clarifications resolution of this contentious issue may be improbable, if not impossible. And if we cannot reach resolution on the status of the human embryo, how will we as a society address the coming dilemmas surrounding our concepts of human life or human nature?

I have argued elsewhere that the answers to these profound questions will require a revitalization of the philosophical anthropologies that undergird our ethical systems as well as our concepts of health, disease and human nature. (13) This revitalization will likely entail broad interdisciplinary and intercultural dialogue, and, hence, some length of time. Still, as our society currently wrestles with these more fundamental questions, one needs to inquire what our society is doing now to address the debate concerning human embryonic research in spite of the contentiousness and uncertainty surrounding this issue?

In one sense, this dilemma is not new for us, for as a society we have already decided that, in light of past abuses such as the research performed on African-Americans or the mentally disabled, it is sometimes best to limit what science and technology can do in order to better serve what is good for society. (14) In light of the harms caused to people in the name of scientific or medical progress, our society, and others around the world, have created guidelines and agencies to protect human research subjects from undue risks and harms. (15) This protection of human research subjects is an ongoing process, with new revelations and investigations regularly being reported by government commissions and by the media. (16) The controversies surrounding human embryo research not only involve the debate over the status of human embryos, but also include other human subject issues such as the procurement of human eggs in large numbers as might be required by nuclear transfer research and technology.

(17) From within this current context of protections from undue research risk and harm, how is our current system of public ethical reflection responding to the human embryo research predicament?

One response to this contentious social issue has been for various organizations to gather panels of experts to investigate, analyze and evaluate the issue with the goal of generating recommendations for actions to be undertaken by governmental and/or other agencies. In general, the arguments and recommendations formulated by these expert panels have been reflective of or employed by many who are engaged in the broader public debate, especially with regard to legislation that has been or is to being addressed on both the state and national levels. The arguments that have been made in support of human embryo research often fall into two primary categories, referred to here as arguments from "need" and "number." (18) A brief analysis of these arguments will reveal the uncertainties inherent in them, and, consequently, their insufficiency to serve as justifications for pursuing this socially contentious research.

Addressing the argument of the need for human embryo research, it is important to recall that, as was observed in the beginning of this essay, the diseases suggested as likely targets for human embryonic stem cell research are also being targeted by researchers using other approaches, such as genetic therapies, drug development and adult stem cells. It may well be the case that for many patients the treatments for their illnesses may come more quickly from research avenues other than human embryonic stem cell research, and that these alternative treatments may even be better than any treatment derived from human embryonic stem cell research.

In response to this uncertainty as to what line of research might yet prove most successful in meeting the medical needs of people afflicted with severe or fatal diseases, proponents of human embryo research have argued that all scientifically sound lines of research should be pursued simultaneously, so that we have the best chance of discovering what will work as soon as possible. From a scientific perspective, this approach makes the most sense. In science, when there is uncertainty, one does all the research indicated to gain the desired knowledge and understanding. However, as was observed above, what is best for science is not always best for a society and its members. Some lines of research may be restricted or banned regardless of their scientific appeal in order to protect the well being of a society. Research that is as controversial and contentious as human embryo research must have reasons to justify its pursuit that are as ethically compelling as the harms it creates.

At this point in the debate, human embryo research proponents often turn to the second argument cited above and emphasize the incredible number of people who could potentially benefit from such research. These proponents can point to the uncertainty inherent in all this biological research and argue that no society should deny all these people who suffer from severe and fatal diseases the potential benefits of this research, even if the research is controversial and contentious within a given society. Associating this research with the substantial societal value of medical healing gives this argument significance.

There is, however, a fundamental flaw in this argument that undermines its power and claim. The flaw in this argument lies in its assumption of a direct correlation between scientific or medical advance and medical benefit for those who need it. The realities of health care systems both in our own society and around the world argue against this assumption. With respect to health care in the United States, we need to acknowledge that, even if treatments from human embryonic stem cell research are the first to be proven successful, many if not most people who need these treatments will not get them.

Evidence of the accuracy of this bleak assessment of our health care system is found in the December 2001 report of the President's Cancer Panel. Though great strides have been made in cancer research during the past three decades of our war on cancer, the Panel concludes, "In short, our health care system is broken, and it is failing people with cancer and those at risk for cancer -- all of us." (19) Worldwide the situation is much more bleak, considering that millions of children die each year from a lack of clean water, not to mention inadequate access to minimal health care technology. (20) Therefore, just because many people in the world might tragically share a devastating disease, such as diabetes or Parkinson's, one cannot conclude that this tragedy will be resolved by breakthroughs in research. The greater tragedy is that only a relative few will enjoy the benefits of many of our

medical research advances. The argument from number does not fit our social reality.

At this juncture, it is critical that the arguments from uncertainty presented above be applied precisely. These arguments have been made to call attention to the flaws in the reasoning often presented in support of human embryonic research. These arguments do not argue against the pursuit of medical advances *per se*. These arguments do, however, place scientific and medical research in the larger context of the good of societies in general. The National Bioethics Advisory Commission acknowledged the importance of this context and the consequent requirement for greater justification than normal in pursuing scientific research that is socially contentious. (21) Therefore, if the justification for proceeding with the destruction of human embryos for research rests even in part on these claims of need and number, then this justification is flawed and requires rethinking.

The evidence and analysis put forward in this essay attest to the pervasiveness of uncertainty in all of the aspects of the human embryo research issue. This uncertainty, it has been argued, even undermines the proposals for pursuing this research put forth by some of the expert panels commissioned to address this issue.

How then should society proceed? The arguments of this essay suggest two responses that could be implemented immediately within the current circumstances of our society. First, in recognition of the need for research into stem cell biology in order to understand better its promises and perils for future societal decisions, governmental support should be increased for stem cell research using animal models and non-embryonic human stem cells. This response would achieve scientific progress without raising especially contentious social and ethical concerns.

Second, in recognition of the vast numbers of people, within our own nation and around the world, who suffer from severe and lethal diseases or injuries, the findings and recommendations for improving health care proposed by expert groups such as the President's Cancer Panel and the World Health Organization should receive at least the same level of attention and action as has been expended on human embryo research.

Endnotes

1. The National Center for Biotechnology Information has websites that provide an overview of many of these technologies and internet links to other resources explaining these technologies. See both http://www.nebi.nlm.nih.gov/About/primer/index.html, and http://www.nebi.nlm.nih. gov/About/outreach/index.html.

2. See, Somia N, Verma IM, "Gene therapy: trials and tribulations," *Nat Rev Genet*. 2000 Nov;1 (2):91?9; and Teichler Zallen D, "US gene therapy in crisis," *Trends Genet*. 2000 Jun;16(6):272 - 5.

3. Rosen FS, "Successful gene therapy for severe combined immunodeficiency," *NEngl J Med*. 2002 Apr 18;346(16):1241?3; and Hacein-Bey-Abina S, Le Deist F, Carlier F, Bouneaud C, Hue C, De Villartay JP, Thrasher AJ, Wulffraat N, Sorensen R, Dupuis-Girod S, Fischer A, Davies EG, Kuis W, Leiva L, Cavazzana-Calvo M, "Sustained correction of X-linked severe combined immunodeficiency by *ex vivo* gene therapy," *NEngl J Med.* 2002 Apr 18;346(16):1185-93.

4. Gene replacement could involve techniques known as homologous recombination while gene repair could be done using techniques that correct a mutation by replacing the single letter (nucleotide) that is misspelled in the DNA. For example, see Richardson PD, Augustin LB, Kren BT, Steer CJ, "Gene repair and transposon?mediated gene therapy," *Stem Cells*. 2002 Mar;20 (2):105-18.

5. Willard, HF, "Artificial chromosomes coming to life," *Science.* 2000, 290:1308-9.

6. Ourednik V, Ourednik J, Flax JD, Zawada WM, Hutt C, Yang C, Park KI, Kim SU, Sidman RL, Freed CR, Snyder EY, "Segregation of human neural stem cells in the developing primate forebrain," *Science*. 2001 Sep 7;293(5536):1820-4

7. For background on stem cell biology and the perspective of the National Research Council committee on stem cell research see their report, "Stem Cells and the Future of Regenerative Medicine" which can be found online at http://www.nap.edu/books/0309076307/html/.

8. See the NIH stem cell primer webpage, http://www4.od.nih.gov/stemcell/figure5jpg.

9. "Stem Cells and the Future of Regenerative Medicine," note 7.

10. For more on miscarriage and its causes see the March of Dimes website at http://www. modimes.org/ HealthLibrary/334_592.htm.

11. For two examples of this type of argument see *American Journal of Bioethics* 2(1) 2002, Jeffrey Spike, "Bush and Stem Cell Research: An Ethically Confused Policy," p. 45, and Robert Baker, "Stem Cell Rhetoric and the Pragmatics of Naming," p. 53.

12. For more on molar pregnancies see http://www.modimes.org/HealthLibrary/334_591.htm.

13. "Philosophical Anthropologies and the HGP," in *Controlling Our Destinies: The Human Genome Project from Historical, Philosophical Social and Ethical Perspectives*, edited by Phillip R. Sloan; Notre Dame University Press, 2000.

14. Adil E. Shamoo and Joan L. O'Sullivan, "The Ethics of Research on the Mentally Disabled," in *Health Care Ethics: Critical Issues for the 21st Century*, eds. John F. Monagle and David C. Thomasma, Gaithersburg, MD: Aspen Publishers, Inc., 1998.

15. Guidelines for protecting human research subjects are found in such reports as the World Medical Association's "Declaration of Helsinki," and the U.S. "Protection of Human Subjects," *Code of Federal Regulations* 45 CFR 46, revised March 8, 1983. As well as RAC, OPRR, etc.

16. Examples of current events include the Virginia Governor's apology for forced sterilizations (http://www. governor.state.va.us/*Press_Policy/Releases*/May2002/May0202.htm), and recent Navy bioweapon exposures reports (http://www.cbsnews.com/stories/2002/05/24/national/ main510079.shtml).

17. Andrew Pollack, "Use of Cloning to Tailor Treatment Has Big Hurdles, Including Cost," *New York Times* (December 18, 2001).

18. Though many examples of these basic arguments can be found in the transcripts of Congressional and state legislature hearings, one can find the arguments from need and number clearly stated in the following documents from three of the highest profile expert panels assembled to date: American Association for the Advancement of Science and the Institute for Civil Society report, "Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research" (http://www.aaas.org/spp/dspp/sfrl/projects/stem/report. pdf), National Bioethics Advisory Commission report, "Ethical Issues in Human Stem Cell Research, September 1999" (http:// bioethics.Georgetown.edu/nbac/pubs.html) and the National Research Council and Institute of Medicine report: "Stem Cells and the Future of Regenerative Medicine (2002)" (http://books.nap. edu/books/0309076307/html/R1.html).

19. President's Cancer Panel report (Dec. 2001), "Voices of a Broken System: Real People, Real Problems," p. 2 (http://deainfo.nci.nih.gov/ADVISORY/pcp/video?-summary.htm).

20. World Health Organization, "Children's Environmental Health" (http://www.who.int/peh/ceh/ index.htm).

21. NBAC report, note 18, p. 52?3.

QUESTIONS

The author asks at the beginning of this article, "How might we best respond to the challenge of human embryonic stem cell research in the face of the uncertainties that pervade this issue?" He then goes on to list these uncertainties citing the "scientific, medical, moral, religious and political"

Taking each of these categories of "uncertainty" discuss each in the light of biotechnological development and its affect on the individual and on human beings in society in general. What are some of the "promises" of cures from stem cell research? What are some of the caveats of this research?

Reliable research shows that human beings share over 98 percent of their genetic sequence with chimpanzees. What, therefore, makes a human being different from a chimpanzee? Discuss. Where does this distinction or difference lie in the human being? What does it mean to be human?

The author notes that stem cell research may help answer questions about disease, injury and aging. List some of the benefits of stem cell research in the area of drug therapies. List some of the drawbacks of such research. What are some of the differences between so-called "adult stem cells" and embryonic stem cells? Cite some of the arguments for using adult stem cells for research purposes; conversely, cite some of the arguments against such research.

Should Government be involved in setting guidelines for any kind of stem cell research? Who should fund such research? Government? Private industry? Individuals? Discuss the pros and cons of funding research and the impact of such funding on society.

The author recommends in the final section of his paper that, although much attention is being given to stem cell research, there is a real need for funding in other areas of research as well, for example improving health care, care for the aging and so on. Would it be better to concentrate our efforts and dollars into one aspect of research -- stem cell -- or would it be better to allocate funds and resources more generally to a variety of research endeavors? Support your argument --pro or con -- with examples.

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