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Analysis and Explanation of American Laws, Regulations, and Policies on Embryo Research and Genetic Research

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Abstract

The laws, regulations, and policies relevant to embryonic research and genetic research in the United States have separate histories. The United States has supported at the federal level genetic research – and bioethics on that research – yet the government has a history of not supporting embryonic research, in part due to the political nature of the abortion issue. Because of the difference in support, American laws, regulations, and policies on embryonic research and genetic research, research on stem cells wavers in the United States.

Keywords

Human Embryonic Research, Genetic Research, Human Stem Cell Research, US history of Research Regulation

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In the mid-1980s, the late Dr. Gary D. Hodgen used to say that when the "gene boys" got done, they'd have to get back to the cell. Little did he know how prescient his view was at the time. Hodgen, then chief of the pregnancy research branch at the National Institute of Child Health and Human Development (NICHD),[1] one of the National Institutes of Health (NIH) in Bethesda, Maryland, left in 1984 for the Jones Institute for Reproductive Medicine in Norfolk, Virginia.[2] His research at NICHD on *in vitro* fertilization was stalled because federal regulations on such research required review by a federal ethics advisory board. The Ethics Advisory Board (EAB) was set up in 1978 under the U.S. Department of Health, Education and Welfare (HEW)[3] and in 1979 issued its report on HEW support of research involving human *in vitro* fertilization and embryo transfer.[4] In that report, the EAB had separated for the first time funding for embryonic research from that for fetal research. The next year, 1980, the EAB was disbanded.[5] Thus began a moratorium on federal support of human embryonic research, one that changed the course of Hodgen's life, and that in effect continues today.[6] Human genetics research, however, has had no such moratorium. In fact, human genetics research has enjoyed significant support by the U.S. government.

This paper begins with the history of human embryonic research and federal government regulation. Next, the history of federal government involvement and support of human genetics research is presented in contrast. Following both sections is an analysis and explanation as to why the U.S. federal government has diverged on human embryonic research and human genetics research. The analysis and explanation uses three factors: cultural, political, and professional. How each one of those factors bears weight in American decision-making on human stem cells is discussed in the next section. Finally, a look at future problems with human stem cell research in the U.S. concludes this paper. At the end of

this paper are two appendices. One is an organizational chart of the U.S. federal government entities mentioned in this paper; the other is a timeline, showing the interaction between those entities.

Human Embryonic Research History

In the beginning, human embryonic research was the same as human fetal research, and human fetal research was the same as research on pregnant women.[7] The landmark U.S. Supreme Court case of *Roe v. Wade*[8] on abortion changed all that in 1973. Prohibitions against fetal research, in particular research using aborted fetuses, were passed.[9] Another change came with new developments in reproductive science. *In vitro* fertilization and embryo transfer led to the births of Louise Brown in the U.K. in 1978 and of Elizabeth Jordan Carr in the U.S. in 1981. The *in vitro* embryo was no longer *in utero* as the fetus, but now extracorporeal, on its own outside the body.

As mentioned earlier, the Ethics Advisory Board isolated federal funding for human embryonic research from that for human fetal research. This separation of funding actually created a mechanism for control over human embryonic research. At the federal government level, which supports most of the basic scientific research in the U.S., human embryonic research had for all intents and purposes stopped. Worldwide, research continued on the *in vitro* embryo, but in the U.S. only research which used animal models was supported by the federal government. Because of the moratorium, patients at American IVF (*in vitro* fertilization) clinics had become human research subjects, at the same time paying for that privilege.[10] The usual progression of basic research on animals to clinical research on humans had disappeared in reproductive science. Just as the human embryo had gone outside the

body due to *in vitro* fertilization, human embryonic research had gone outside the purview of the U.S. federal government.[11]

During the 1980s, three scientific developments greatly influenced human embryonic research. The first is superovulation, the chemical and hormonal stimulation of the growth of follicles in the ovaries to increase the number of oocytes available for ultrasound retrieval.[12] The second is micromanipulation, the use of tools at the microscopic level to manipulate the ovum and spermatozoan.[13] The third is cryopreservation of the embryo itself, which allows the manipulation of time and the accumulation of embryos.[14] *In vitro* fertilization had become an active process, rather than a passive one. With all this experimentation, the IVF clinic had firmly become the *de facto* IVF laboratory, and the IVF patient, or possibly the medical insurer, was now funding human embryonic research in the U.S.

In the meantime, the extracorporeal embryo became the focus of the bioethics debate on the moral and legal status of the embryo. This debates continues to influence laws, regulations, and policies on human embryonic research. As for the IVF clinics, the laws, regulations, and policies concern patients' issues, such as consumer protection, insurance coverage, and laboratory quality, in addition to the premier bioethics issue of informed consent.

Human Genetics Research History

Genetics research began at first with the hybridization of plants, and then animals.[15] The word **genetics** was coined much later, in the early twentieth century.[16] Just after the mid-twentieth century, the double helix structure of the genome was first described.[17] Exactly twenty years later after than, in 1973, the first scientific article on splicing genes was

published.[18]

Two of the authors of that article, Stanley Cohen and Herbert Boyer, applied from the federal government for the first patent on a gene in 1976.[19] That same year, Boyer, along with venture capitalist Robert A. Swanson, received the first state charter for incorporation of a biotechnology company.[20] Business interests, controlled by both the federal and state governments, began early on in human genetics research.

The importance of patents and genetics to business is illustrated by the turn of events following another landmark U.S. Supreme Court case, *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty.*[21] Ananda Mohan Chakrabarty "claimed patents to three things: the production of a type of bacterium, the material carrying that bacteria, and the bacteria themselves."[22] Ultimately, the U.S. Supreme Court ruled that living matter is irrelevant on the issue of subject matter patentability as long as the invention results from human interference and results in a genetically altered or manipulated product.[23] The U.S. Congress, the federal legislative body, was unhappy with that ruling. So in 1982 Congress created by law the U.S. Court of Appeals for the Federal Circuit, an intermediate federal appellate court with exclusive jurisdiction over patent cases, a court which controls the law on U.S. patents. Because of the court's exclusive jurisdiction and because patent law is federal, all cases in the federal district courts come to this intermediate court on appeal. If there is a further appeal, then it goes up to the U.S. Supreme Court, which does not take many cases to hear on appeal. Even so, because both the Supreme Court and the Court of Appeals for the Federal Circuit are appellate courts, meaning that they only hear cases involving legal issues, not factual ones, the Supreme Court has no choice but to remand or return any case it hears to the Court of Appeals for the Federal Circuit for further action.

Not too long after the *Chakrabarty* case, the U.S. federal government

became a more active participant in genetics, at this stage more properly genomic, research. Beginning at first with several independent origins,[24] the U.S. Department of Energy (DOE) started the Human Genome Initiative in 1986.[25] This initiative officially became the Human Genome Project in 1990, when DOE began working jointly with the NIH. Although both DOE and NIH are under the same branch of the federal government, the executive branch, each had a different reason for mapping the human genome, reasons that were consistent with their respective missions. The DOE had been studying radiation effects and human safety or tolerance levels for radiation. The NIH focused on health, including disease and prevention.

In 1989, the year before officially working with DOE, NIH created the National Center for Human Genome Research to facilitate this research endeavor. James Watson, co-discoverer with Francis Crick of the structure of DNA, became its first director. As director, Watson allocated five percent of the center's budget for research into the ethical, legal, and social implications of genetic research.[26] In 1997 when the center was elevated to the status of an institute, called the National Human Genome Research Institute (NHGRI), that budget allocation continued.[27] NHGRI is "the largest supporter nationwide of research into the ethical, legal and social implications of genetic research" through its Ethical, Legal and Social Implications Research Program (ELSI).[28]

In 1999, human genetics research suffered a much publicized blow with the death of Jesse Gelsinger in a nontherapeutic clinical trial at NIH-sponsored research at an American university.[29]

The parents of Gelsinger, a minor at the time of his initial involvement in the clinical trial, had not been informed about prior results from scientific trials using animals. The research involved "gene therapy," a misnomer because the technique was not therapeutic, but experimental gene transfer. As HHS Secretary at the time Donna E. Shalala said,

"What's at stake is the integrity of research, public confidence in that research and the integrity of the institutions as well as researchers all around the country."[30] She went on, "Take notice" ··· "Investigators and institutions need to know that when they deviate from accepted practices, there are consequences."[31] Consequently, NIH tightened its regulations on patient safety in nontherapeutic clinical trials.[32] After the setback of the Gelsinger death and regulatory changes resulting from it, human genetics research, and research on the non-scientific implications of that research, continued flourish under the U.S. government.

Three Factor Analysis and Explanation

There are three reasons why the U.S. federal government has diverged on human embryonic research and human genetics research. Those three reasons are cultural, political, and professional, and contained within them are strands of ELSI.

The first reason: cultural

The cultural reason chiefly concerns the distinction between human and animal. This distinction goes back to 1760 in science when Carolus Linnaeus divided life into three kingdoms: animal, human, and mineral. Those kingdoms were further divided into phylum, class, order, family, genus, and species. This taxonomy of classification today continues, even though some scientists have proposed new kingdoms based on genetics.[33] The distinction between human and animal goes back even further in the Judeo-Christian religion. In the Bible, God gives man (human) dominion over the animals, and because man is made in the image of God, many believe that human life is sacred.[34]

In the Judeo-Christian culture, because human life is distinct from animal life and because it is sacred, the bioethical issue of the status of the embryo is huge. One question is, when does the embryo become a person? Is this a biological event, at conception when the male and female chromosomes from the spermatozoan and the ovum respectively complete combination? In that case, an in vitro embryo has attained personhood. Or is it another biological even, such as birth? Complicating this is the question of ensoulment, or when does an embryo acquire a religious soul. Moral debate on the status of the embryo varies between religions too.[35]

Then there is the legal status of the embryo. If the human embryo *in vitro* is a person, what rights are accorded to it? What duties and responsibilities are owed to it? In colonial America, if a woman who was sentenced to death for a crime was found to be pregnant, then she was allowed to live until she gave birth, because the fetus had not committed any crime.[36]

The second reason: political

The legal status of the embryo spills over into the next reason, political. First, as background, one needs to understand the tripartite nature of the U.S. government. Three branches − the legislative, the executive, and the judicial − make up the federal government. The legislative branch makes national laws through the U.S. Congress, which is composed of the Senate and the House of Representatives. The largest, the executive branch, which is headed by the American president, executes or carries out those laws. The smallest, the judicial branch, is a hierarchy of federal courts throughout the country, with only one at the top, the U.S. Supreme Court. The judicial branch interprets those laws enacted and executed in accord with the U.S. Constitution, the supreme law of the

land. Unlike the legislative and executive branches, which are elected, the Supreme Court justices are appointed for life. So, despite its size, some consider the judicial branch the most powerful, because of this life tenure and resulting independence from the electorate.

The Constitution lays out a framework for a federal government, a government that works through a series of checks and balances between the three branches mentioned above. The Constitution also respects in the legislative branch equality for each state (each state gets two Senators in the Senate) and respects population size for each state (each state gets a number of Congressional members proportionate to the state's population). In addition, the Constitution's first ten amendments, commonly referred to as the "Bill of Rights," respect the individual person. This respect for the individual is key to the working of a democracy. The individual is given notice of any abridgment or loss of rights and allowed an opportunity to be heard. Also, the elections of representative officials constitutes another way an individual can be "heard" in the federal government.

But as important as the results of an election is the process for determining how the vote comes out. Consensus means that all agree. A majority vote means that a minority does not agree. Therein lies both the problem and the strength of the federal government in regard to human embryonic research and human genetics research. Getting a majority vote, much less a consensus, is difficult in Congress, which represents all fifty states. Members of Congress vote as representatives of their electorate, an electorate that encompasses all persons. Consequently human embryonic research has never really succeeded because Congress, which under the Constitution controls all money or appropriations, cannot reach a majority vote over such any controversial issue involving human embryos. Unlike the legislative branch, which has difficulty in reaching a majority vote, the executive branch can

relatively easily make changes, simply due to the fact that it is headed by one person, the U.S. President. But a problem still exists with funding, because Congress controls the entire budget for the executive branch.

The third reason: professional

The third and final reason is professional, specifically the professional standards of the scientist. Scientific research differs from clinical research, which in turn differs from clinical care. Clinical care revolves around the medical needs of an individual patient. Clinical research, although it includes clinical care, concerns a specific disease or condition, not an individual patient. Scientific research, also called basic research, does not bother with specifics. The goal of scientific research is to discover.[37]

Scientific researchers, including those in human embryonic and human genetics research, share a certain *esprit de corps* based on trust and communication among themselves. The centerpiece of this trust and communication is the peer-reviewed scientific article.[38] The date of first publication of a discovery is akin to striking gold. The gold here is respect and honor within the professional field, and hopefully a patent.[39] But respect and honor are conditioned upon reproducible results by other laboratories, which validate the discovery and further the field.[40]

In order to reproduce results, and especially to make a discovery, all scientific researchers need access to three things: trained personnel, laboratory equipment, and basic materials. And, all of those three things need funding. In the U.S., both human embryonic research and human genetics research suffer from lack of access to basic materials. This lack of access to basic materials is something that those two fields of research share in common with human stem cell research.

Human Stem Cell Research

Stem cell research involves cells from either adult or embryonic cells. When those cells are human cells, ELSI issues abound. However, those issues are neatly summed up in three words: sources, access, and funding.

In the U.S., human adult stem cell research has something of a precedent in the California Supreme Court case of *Moore v. Regents of the University of California*.[41] John Moore, a leukemia patient, believed that his continuing visits with his doctors over years were for further medical treatment. Instead, the doctors were using his cells to develop a cell line, which was then patented. The court allowed him to sue under informed consent, because a doctor must "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."[42] This case reverberates in discussion of informed consent in research.

A second issue with adult stem cell research concerns genetic information and privacy. The issue of privacy arises between the genetic donor and other family members, related or not by biology or marriage. The genetic donor is also worried about the privacy of his or her genetic information usually in a civil context, such as medical or life insurance, or in a criminal context, such as identification. Consequently, be it fear or mistrust, people are reluctant to donate cells for research because of the use or misuse of their genetic information, not because the research is genetics research or stem cell research.

With human embryonic stem cell research, the case is just the opposite. It's not the later use of the genetic information that is the problem, but rather how the cells are initially obtained from an embryo. In order to have the most potential or pleuripotent embryonic stem cells, the cells must come from the inner cell mass of an embryo *in vitro* and

prior to the stage of implantation, usually between seven and fourteen days after conception. In the U.S., the problem here is a cultural one, the bioethical issue of the moral status of the embryo. The cultural problem becomes a political one, because of the representative nature of American democracy.

The above paragraphs discuss problems with sources of cells for stem cell research in the U.S. The two other problems for stem cell research in the U.S. are access and funding. In 2001, when President George W. Bush limited federal funding for human embryonic research to the sixty cell lines then in existence, he simultaneously limited U.S. stem cell researchers to access to cell lines and access to federal funding.[43] Then in June 2007, as Bush issued an executive order to expand research into alternative sources of pluripotent stem cells, he vetoed a Congressional vote to use embryonic stem cells for research.[44]

Federal funding for human embryonic stem cell research is prohibited by what is called the "Dickey Amendment." Representative Jay Dickey in the U.S. House of Representatives originated this amendment, which is a rider to an appropriations bill. Starting in 1995 and continuing since then, the Dickey Amendment prohibits HHS from using funds for creating human embryos for research or for doing research where human embryos are destroyed.[45]

As a consequence of this void in federal research funding, frustrated voters are taking action at the state level. The first state is California, which approved Proposition 71, the California Stem Cell Research and Cures Initiative, in 2004.[46] The following year, the California Institute for Regenerative Medicine (CIRM) was established.[47] CIRM has approved more than $614 million in research grants and claims to be "the largest source of funding for embryonic and pluripotent stem cell research in the world."[48] Other U.S. states awarding grants are Connecticut, Illinois, Maryland, New Jersey, New York, and Wisconsin.[49]

Three states (Iowa, Massachusetts, and Missouri) affirm the legality of human embryonic stem cell research.[50] But six states (Arkansas, Indiana, Louisiana, Michigan, North Dakota, and South Dakota) ban studies with the destruction of human embryos.[51] Only Arizona bars state funding for embryonic studies.[52]

Conclusion

President-elect Barack Obama is expected to issue an executive order lifting President Bush's restrictions on funding for research using human embryos.[53] Congressional leaders have also said that they will push a stem cell research bill, now twice vetoed, through Congress. If both of those happen, then the problem of access to embryonic stem cell lines, and possibly research using human embryos, along with the problem of federal funding for such research, will go away, at least for the time being. However, given the economic conditions at the present, the question remains about how strong the U.S. research will be, or become, in human embryonic stem cell research and genetics research, when states like California fund their own research and when federal funding in real terms is falling while countries like South Korea, China, and Japan are increasing theirs.[54]

Postscript

At the time this article was written in November 2008, Barack Obama had been the U.S. President-elect for less than a month. Today, March 9, 2009, less than 100 days as President, he did sign an Executive Order, titled "Removing Barriers to Responsible Scientific Research Involving

Human Stem Cells" that allows federal funding for research on human embryonic stem cells, thus overturning the ban under former President George W. Bush. In conjunction with that signing, President Obama also signed a Presidential Memorandum on Scientific Integrity, because in order to make policy decisions, the public must trust the science upon which those policies are based.

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Appendix A:

Abbreviated Organizational Chart of U.S. Federal Government Entities in Three Branches

Branch	*Levels within the Branch (based on indentation)*				
	1	2	3	4	5
Legislative	U.S. Senate, headed by the U.S. Vice President				
	U.S. House of Representatives, headed by Speaker of the House				
Executive	President of the U.S., head				
		Department of Health and Human Services (HHS) (formerly Department of Health, Education, and Welfare, HEW)			

National Institutes of Health (NIH)
National Human Genome Research Institute (NHGRI)
National Institute of Child Health and Human Development (NICHD)
Reproductive Sciences Branch
(formerly Pregnancy Research Branch)

Judicial
Chief Justice of the U.S. Supreme Court, head
U.S. Supreme Court (highest appellate)
U.S. Courts of Appeal (appellate - questions of law only)
U.S. District Courts (trial - questions of fact and law)

Appendix B: Timeline

1953 DNA structure first described by James Watson and Francis Crick
1973 U.S. Supreme Court decides abortion is legal, *Roe v. Wade*, January 22, 1973
1978 First IVF birth in the world - Louise Brown, born July 25, 1978, in England
1981 First IVF birth in the U.S. - Elizabeth Jordan Carr, born December 28, 1981
1989 James Watson is named the first director of the National Center for Human Genome Research (NCHGR) at NIH - ELSI program funding begins
1990 Congress votes to override the moratorium on human embryo research, but President George H. Bush vetoes that vote
1993 President Clinton lifts the ban
1994 Human Embryo Research Panel favors research, but President Clinton overrides the panel
1995 The first Dickey Amendment banning embryo research is passed by Congress
1996 Dolly, the first cloned mammal - born July 5, 1996, in Scotland
1998 James Thomson publishes "Embryonic Stem Cell Lines Derived from Human Blastocysts" in *Science*, November 6, 1998
1998 John Gearhart publishes "Derivation of pluripotent stem cells from cultured

human primodial germ cells" in the *Proceedings of the Academy of Sciences* 95: 13726-13731

2001 President George W. Bush's Remarks on Stem Cell Research on August 9, 2001 allows federal funds to be used for research only on the sixty then existing stem cell lines

2005 California establishes its own Institute for Regenerative Medicine

2007 President Bush's Executive Order on June 20, 2007, expands approval of stem cell lines in ethically responsible ways

NOTES

1. Now named the Eunice Kennedy Shriver National Institute of Child Health and Human Development.
2. Jeffrey L. Fox, "Scientist quits NIH over fetal rules," *Science* 223(March 1984) : 916.
3. Now the U.S. Department of Health and Human Services (HHS).
4. U.S. Department of Health, Education, and Welfare, Ethics Advisory Board, *Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer* (Washington, DC: U.S. Department of Health, Education, and Welfare, 1979)
5. The Office of Science and Technology Policy directed HHS to do this despite federal regulation promulgated by HHS. Office of Technology Assessment, "Lessons from the Past," in *Biomedical Ethics in U.S. Public Policy*, Chapter 2, 11. http://www.princeton.edu/~ota/disk1/1993/9312/931204.PDF
6. Jonathan D. Moreno, "The End of the Great Bioethics Compromise," *Hastings Center Report* 35 no.1 (January-February 2005) : 14-15.
7. An embryo is defined to be "[i]n humans, the developing organism from the time of fertilization until the end of the eighth week of gestation, when it is called a fetus." http://stemcells.nih.gov/StaticResources/info/popups/glossary.html
8. *Roe v. Wade* (410 U.S. 113)
9. For instance, Missouri, "Manslaughter, when - Murder, when - Civil damages, when - Use of fetus for research or experimentation prohibited," *Missouri Annotated Statutes*, Section 188.035, 1974; Massachusetts, "An Act prohibiting

experimentation on human fetuses," *Massachusetts General Laws Annotated*, Chapter 112, Section 12J, 1974.

10. "[T]he federal government not only does not regulate the field (of IVF), but puts next to no money into it ··· leaving most fertility research in the hands of private clinics." NIH human embryonic stem cell scientist Mahendra Rao. Cynthia Fox, *Cell of Cells; The Global Race to Capture and Control the Stem Cell* (New York, NY: W.W. Norton & Co., 2007), 377.
11. *Ibid*.
12. S.G. Hillier et al., "Superovulation strategy before in vitro fertilization," *Clinics in Obstetrics and Gynaecology* 12 no.3 (September 1985) : 687-723.
13. A. Laws-King et al, "Fertilization of human oocytes by microinjection of a single spermatozoon under the zona pellucida," *Fertility and Sterility* 48 no.4 (October 1987) : 637-642.
14. H. W. Michelmann and Nayudu P., "Cryopreservation of human embryos." *Cell and Tissue Banking* 7 no.2 (2006) : 135-141.
15. Robert Cook, "A Chronology of Genetics." 1937 *Yearbook of Agriculture*, pp. 1457-1477. [Republished electronically by Electronic Scholarly Publishing http://www.esp.org at http://www.esp.org/foundations/genetics/classical/holdings/c/rc-37.pdf]
16. Letter from William Bateson to Adam Sedgwick dated 1905, digitally reproduced at http://www.junkdna.com/ipgs_staged/early_history.html
17. J.D. Watson and Crick F.H.C., "Molecular structure of nucleic acids," *Nature* 171 (April 1953) : 737-738.
18. S.N. Cohen et al., "Construction of biologically functional bacterial plasmids *in vitro*," *Proceedings of the National Academies of Sciences* 70 no.11(November 1973) : 3240-3244.
19. S.N. Cohen et al., "Process for producing biologically functional molecular chimeras," U.S. Patent 4,237,22, granted on December 2, 1980. Available at: http://patft.uspto.gov/netahtml/PTO/srchnum.htm
20. That company, Genentech, was founded on April 7, 1976, in California. http://www.gene.com/gene/about/corporate/history/timeline.html
21. (447 U.S. 303) 1980.
22. Susan Cartier Poland, "Genes, patents, and bioethics - Will history repeat itself?" *Kennedy Institute of Ethics Journal* 10 no.3 (September 2000) : 269.

23. *Ibid*., 270.
24. Charles R. Cantor, "Orchestrating the Human Genome Project," *Science* 248 (April 1990) : 49.
25. http://lowdose.tricity.wsu.edu/timeline.htm
26. Larry Thompson, "Background paper on internal educational activities at the National Human Genome Research Institute," June 10, 2002. Under section "Ethical, Legal and Social Implications (ELSI) Projects" available at: http://www.genome.gov/10005291
27. *Ibid*.
28. Although both NIH and DOE fund their own ELSI programs, the NIH spending has been for a greater amount. See OTA, fn. 5, p. 8, Box 2A, at: http://www.princeton.edu/~ota/disk1/1993/9312/931204.PDF
29. Rick Weiss and Nelson Deborah, "Penn settles gene therapy suit; University pays undisclosed sum to family of teen who died," *Washington Post*, November 4 , 2000, p. A4.
30. Marc Kaufman, "Clinical trial sanctions urged; HHS plans to tighten controls to protect patients in tests," *Washington Post*, May 24, 2000, p. A2.
31. *Ibid*.
32. *Ibid*.
33. Fabien Burki et al., "Phylogenomics reshuffles the eukaryotic supergroups," *PloS ONE* 2(8): e790 doi:10.1371/journal.pone.0000790 Published 29 August 2007.doi:10.1371/journal.pone.0000790
34. "And God said, Let us make man in our image, after our likeness: and let them have dominion over the fish of the sea, and over the fowl of the air, and over the cattle, and over all the earth, and over every creeping thing that creepeth upon the earth." *The Holy Bible*, Genesis I:26, King James Version.
35. National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research; Volume III, Religious Perspectives* (Rockville, MD, June 2000) Available at: http://www.bioethics.gov/reports/past_commissions/nbac_stemcell3.pdf
36. "The writ *de ventre inspiciendo*, to ascertain whether a woman convicted of a capital crime was quick with child, was allowed by the common law, in order to guard against the taking of the life of an unborn child for the crime of the mother." *Union Pacific Railway Co. v. Botsford* (141 U.S. 250, at 253)

37. Fox, fn. 10, p. 335. Cardiologist Emerson Perin, at the Texas Heart Institute at St. Luke's Episcopal Hospital, is quoted as saying, "Our objective is to help people get better. Those guys who work only with rats, they get so lost in the world of "Is, Isn't.'"
38. National Academy of Sciences, *On Being a Scientist: Responsible Conduct in Research* (Washington, DC: National Academies Press, 1995), 27. "Publication and Openness." pp. 9-12.
39. "The potential gold mine that gene-hunters ultimately seek is a patent." Erramouspe, Matthew. "Staking patent claims on the human blueprint: Rewards and rent-dissipating races." 43 *UCLA Law Review* 961 (1996), reprinted in part in Lori B. Andrews et al., *Genetics: Ethics, Law and Policy*, 2nd ed (St. Paul, MN: Thomson/West, 2006), 207.
40. *Ibid*.
41. 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991)
42. Susan Cartier Poland, "Landmark legal cases in bioethics," *Kennedy Institute of Ethics Journal* 7 no.2 (June 1997) : 202.
43. For the text of his speech, go to:
    http://www.whitehouse.gov/news/releases/2007/06/20070620-8.html
    http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html
44. For the text of his speech, go to:
    http://www.whitehouse.gov/news/releases/2007/06/20070620-8.html
    http://www.whitehouse.gov/news/releases/2007/06/20070620-8.html
45. (Sec. 128) Prohibits any funds made available in PL 104-91 form being used for: (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research under applicable Federal regulations. Available at:
    http://thomas.loc.gov/cgi-bin/bdquery/z?d104:HR02880:@@@L&summ2=m&
46. http://www.cirm.ca.gov/
47. *Ibid*.
48. *Ibid*.
49. http://www.stateline.org/live/details/story?contentId=270951

50. *Ibid*.
51. *Ibid*.
52. *Ibid*.
53. Jonathan Weisman, "Obama is likely to use executive power to halt drilling, fund stem-cell work," *Wall Street Journal*, November 10, 2008, p. A6.
54. Peter N. Spotts, "Asia trumping US on science R&D," *Christian Science Monitor* 100 (October 10, 2008) : 3.