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Michaela Breen Salvo 19 April 2011

Times They Are A-Changin': The Convergence of Bioethics, Biotechnology and Biopolitics Within the Stem Cell Research Debate

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Abstract

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By Michaela Breen Salvo

Stem cell research has been one of the most controversial and politicized forms of biotechnology to come out of the 21st century. Since its emergence in the early 1990s, stem cell research, particularly embryonic stem cell research, has been the topic of heated political, religious, and philosophical debate. The issues debated, however, are far from modern. Choosing to focus on the post WW-II era, this paper recognized eight significant events in the history of bioethics. Through the lens of history, two predominant reoccurring ethical problems are highlighted: biomaterialism and definitions of life. Next, this paper attempts to give a biological background of the stem cell: its origins, the methods of cultivating it, and the politics surrounding its discovery and subsequent use. Finally, this paper engages and refutes several common anti-stem cell arguments. It proposes that biomaterialism is an inevitable reality and that definitions of life must change as biotechnology advances. This paper approaches the stem cell research debate from an interdisciplinary perspective, focusing not on history, philosophy, or biology but rather on how these three interact with each other and other disciplines to form a comprehensive understanding of this debate.

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“When you see something that is technically sweet, you go ahead and do it and you argue about what to do about it only after you have had your technical success. That is the way it was with the atomic bomb.”
—J. Robert Oppenheimer

Part 1

Introduction

American history texts focus almost exclusively on great men, great deeds, and great wars. Science and medicine however, are often overlooked, despite the critical role they play. They lurk in the background, rarely coming to the fore. However, as history cedes to the present, American society finds itself in a medicalized and technology dependent state where the boundaries between science and society are becoming increasingly blurred. Biotechnology has taken the spotlight as the gateway to the future of our society and consequently is the focus of public scrutiny. King among developing technologies is the stem cell, which is ripe with promise and risk. The stem cell has the potential to be the defining technology of the new millennium analogous to how the nuclear bomb defined the 1940s (and continues to define the present). The stem cell debate arises from new applications of old bioethical issues engendered by past biotechnologies. The key bioethical issues that will come to light time and again in this discussion are:

1. Biomaterialism and the Instrumentalization of Humanity.
2. Definitions of Life and Death
3. Unknown Consequences of Action and Inaction
4. Oversight/ Informed Consent
5. Political Involvement/Government's Role in Research

The following section will focus on a series of eight bioethical milestones spanning American history from WWII until the present. All of these milestones highlight at least one of the bioethical issues listed above. The repeated resurrection of these bioethical concerns throughout history demonstrates the evolving, dynamic nature of the problems. It is no surprise,

therefore that they continue to be present today. By examining the history of biotechnology, we can (hopefully) approach the stem cell research debate with open eyes and knowledge of our past shortcomings. With this goal in mind, we can only improve our ethical actions in the future.

The Atomic Bomb

In 1945, the face of science and research changed. At exactly 9:16 a.m., August 6, 1945 *Little Boy*, the first atomic bomb, exploded. The city of Hiroshima was incinerated under a cloud of smoke and fire that rose 40,000 feet into the August sky. Three days later, a plutonium bomb nicknamed *Fat Man* was dropped over the city of Nagasaki. The cumulative toll of death and destruction was surreal…incomparable to the power of any other individual weapon ever created.

Stepping into power on April 12, 1945 just a few months after the death of President Franklin Delano Roosevelt, President Harry Truman was quickly informed that the White House had a secret of astronomical proportions: it was called the Manhattan Project. President Truman was informed that a group of physicists had been working for three years to covertly create what is today one of the most deadly and horrifyingly efficient weapons in the history of the world: the atomic bomb.[1]

As American soldiers were landing on the shores of Normandy, White House officials predicted that the battle in the Pacific was far from over. The Secretary of War began drawing up a plan for the primary invasion of the Japanese islands to commence in October 1945 and the secondary invasion of Honshu. An estimated 100,000 American troops would have been killed if an invasion of Japan had become necessary, with an unknown number of additional casualties.

[1] Henry Stimson to Harry Truman. *American Experiences Truman Primary Sources.* PBS Online. (April 24, 1945).

These were likely the statistics that were presented to President Harry Truman and his main justification for using the atomic bomb. [23]

Debate still exists (within the historical community) about Harry Truman's culpability in the events that took place. It is unknown what number of casualties Truman estimated that the United States would incur (estimates range as high as 1,000,000) if forced to invade Japan. Also unclear, is whether Truman understood that Hiroshima was a civilian and not a military target.[4] However the most controversial and relevant debate topic surrounding Harry Truman is just how powerful he understood the atomic bomb to be. Many believe that Truman comprehended that the bomb would be formidable, but just how formidable is unclear.[5] This factor of the unknown is relevant to our debate today. Truman undoubtedly understood the atomic bomb would be powerful. Perhaps he even understood that the bomb would be the most powerful weapon yet created. However, what stunned the world was not the force of the bomb or the height of the

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[2] The numbers cited here come from the Encyclopedia Britannica. No one is certain of the exact estimates that were given to Truman. On separate occasions Truman claimed dropping the bomb prevented 250,000, 500,000 and 1 million U.S. casualties and untold Allied casualties. Realistic estimates range anywhere from 40,000 troops to 100,000 casualties that the US would have incurred.

[3] Hamby, Alonzo L. *Encyclopedia Brittanica Academic Edition.* <http://www.britannica.com/EBchecked/topic/712569/Trumans-decision-to-use-the-bomb>.

[4] Boyer, Paul. *Fallout*. (Columbus: The Ohio State University, 1998).
See also
Harry S. Truman Library "Papers of Harry S. Truman" Diary, July 17, box 333, President's Secretary's Files; July 16, "Ross, Mr. and Mrs. Charles G. (handwritten)" (1945).

[5] A confidential note from Colonel Stafford Warren estimates that the test bomb detonated with a force approximately equivalent to 10,000 tons of TNT and that a nearby family may have been exposed to radiation and required a follow up visit to ascertain any negative effects. Also notable is the message that Truman communicated to Stalin at Potsdam which stated that the US had "a new weapon of unusual destructive force." In his diary on July 25, 1945 Truman writes that it is "the most terrible bomb in the history of the world." He also writes, "it seems to be the most terrible thing ever discovered, but it can be made the most useful." Harry S. Truman Library, Papers of Harry S. Truman. Diary, July 17, box 333, president's secretary's files; diary, July 16, "Ross, Mr. and Mrs. Charles G. (handwritten)" box 322, president's secretary's files. via pbs.org

mushroom clouds; rather, it was the after-effects that the radiation blast had on the people of Japan in the days, weeks, and years following the attack.

Flash burns, the result of skin exposure to thermal radiation, left Japanese victims in agony for days before they died. Many that did not die from the burns quickly succumbed to complete organ failure, a direct result of radiation poisoning. Others survived several years only to find themselves riddled with cancerous tumors, to which radiation leaves its victims susceptible. Between 42,000 and 93,000 civilians were immediately killed in Hiroshima, a number that rises as high as 130,000 by the end of 1945. In Nagasaki, official death tolls range from 60,000-70,000 persons.[6] World was stunned by the immense power of the atom.

Interestingly, scientists were the first to recognize the effects of the bomb as a disturbing massacre as well as an enormous military success. It is unclear whether Truman or any of the scientists involved in the Manhattan project had any inkling that the effects of radiation from the bomb would be so dire and so long term. If so, we must question whether politicians, or any human, should have the power to inflict such cruelty. Equally, if not more terrifying, is the notion that scientists and politicians may have had no idea what horrors they were about to unleash. The traumatic effects of radiation poisoning at Hiroshima and Nagasaki on the world serve as an eerie warning to those who advocate the advancement of science at the expense of adequate ethical oversight.

While 85% of Americans initially approved of Truman's decision[7], prominent scientists worked hard to raise public debate about the ethics of the bomb. Gradually the public came to realize the consequences of the bomb, both for the Japanese and the rest of the world. Similar

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[6] atomicbombmuseum.org. "Section 3: Destructive Effects." <http://atomicbombmuseum.org/pdf/effects/Health%20Effects.pdf>

[7] Boyer, Paul. *Fallout*. (Columbus: The Ohio State University, 1998): 10.

destruction could be visited upon any nation; the advent of the nuclear bomb meant the potential for indiscriminate annihilation. J. Robert Oppenheimer is quoted as saying that when he received word that the bomb had detonated, his first thought was a quote from the Hindu Bhagavad Gita, "'Now I am become death, the destroyer of worlds.' I suppose [the scientists who worked on the bomb] all thought that one way or another."[8] The danger of the bomb was not a uniquely American concern; soon the USSR began to create and stockpile its own nuclear weapons. A nuclear arms race ensued over the next several decades, resulting in a worldwide collection of weapons capable of destroying the world many times over.[9]

The Manhattan Project contributed to the construction of the military/industrial/academic complex. Largely due to the need to develop military technologies, politics quickly began to play a critical role in scientific development. Scientists reached out to the public, calling for ethical oversight committees to review research protocols, thereby further conflating politics and science. "Government funding of American research and development (R&D) exceeded private industry funding until the 1980s and defense generally dominated R&D funding after 1945, especially from 1945 until 1963."[10] This meant that the American government could handpick which programs would advance (those related to victory in the Cold War) and which would remain in scientific obscurity (those of "pure" or non applied science). Students within the university were steered toward careers in the hard sciences while professors came under

[8] J. Robert Oppenheimer describes his reaction to the Trinity Test, (1965). <Atomicarchive.com/movies/movie8.shtml>.
[9] Boyer, Paul. *Fallout*. (Columbus: The Ohio State University, 1998): 10.
[10] Clark Northrup, Cynthia. *The American Economy: A Historical Encyclopedia* 1. (Library of Congress, 2003). 186.

increasing pressure to obtain government grants. Large universities became the machine through which the government fought the Cold War.[11]

Did the United States disregard the human dignity of the Japanese by using a predictably atrocious weapon on a defenseless people? Or were scientists and politicians unclear what the effects of their research would be? What is the role of politics and society in science today? Who, if anyone has the right to direct, regulate and appraise scientific research? These are all questions that stem from the atomic bomb. As time progressed, the American public developed sympathy for the victims of the bombings. The overarching question that arose was whether science and technology had overstepped both ethical lines and scientific knowledge to create a military Frankenstein in the name of progress—a claim that many people also apply to stem cell research.

Nuremberg

Following the end of World War II, the world was faced with a new dilemma: how best to rebuild and prevent another World War. Economic damages and the enormous death toll worldwide were reinforced by the horrifying images and stories that emerged from the Nazi concentration camps. The world was shocked at the bone-chilling accounts that liberated prisoners shared of their incarcerations under the Nazi regime. The world wanted retribution. Adolf Hitler, leader of the Nazi party, committed suicide when the defeat of the Nazi party was imminent. However, major players in the abuses that took place were captured by the Allied powers and moved to Nuremberg, where it was decided that they would stand trial for their roles in the atrocities committed.

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[11] Forman, Paul. "Behind quantum electronics: National security as basis for physical research in the United States, 1940-1960." *Historical Studies in the Physical and Biological Sciences* 18:1 (University of California Press, 1987): 149-229.

While the Nuremberg Trials raised fascinating questions of responsibility and humanitarian law, for our purpose one trial in particular requires further study: the Doctors Trial. The Doctors Trial was, in reality, an American Military tribunal, which, unlike the Trial of Major War Criminals, was solely overseen by American military personnel. Twenty-three German physicians and scientists were tried for experiments that they performed on prisoners.

The experiments were torturous; they included injecting prisoners with malaria, tuberculosis, and other infections to which German soldiers were susceptible. The prisoners were forced to endure hypothermia, high altitudes, and dehydration. Experiments involved forced sterilizations, attempted bone regenerations, and noxious gas reactions.[12] Still more patients were infected only to be executed and dissected so that German scientists could study the effects of infection on the body. The experiments were extensively documented and many of those documents were submitted as evidence during the Trial. The Trial found sixteen of the Nazi scientists guilty: seven were hanged and the other nine were sentenced to prison terms almost all of which were commuted.

Also disturbing was the Nazi promulgation of eugenics, a field that was developed primarily by British and American geneticists prior to the war. Nazi propaganda medicalized racism by accepting eugenics as a valid medical teaching. German medical textbooks taught that significant differences existed between the Jew and the Aryan; the Jew was considered the lower, less evolved race.[13] Moreover, eugenic attitudes leant credence to the Nazi euthanasia program, whereby those considered unworthy of life (including anyone of non-Aryan race as well as the

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[12] Cohen, Baruch C. "The Ethics of Using Medical Data From Nazi Experiments." *Jewish Law* (n.d.) <http://www.jlaw.com/Articles/NaziMedEx.html>.

[13] Biddiss, Michael. "Disease and Dictatorship: The Case of Hitler's Reich." *Journal of the Royal Society of Medicine* 90. (June, 1997).

physically and mentally handicapped, the elderly and the chronically ill) were killed in "acts of mercy."[14]

Similarly, Unit 731 was a covert unit of Japanese scientists who performed inhumane experiments on over 10,000 Chinese and Korean (and possibly American) POWs. The Japanese focused specifically on testing the effectiveness of biological warfare mechanisms such as the bubonic plague, anthrax and glanders.[15] Japanese experiments included vivisections without anesthetic, the removal of critical organs, and amputations with subsequent reattachments (in different corporeal locations) among other, equally gruesome practices. However, the actions of Unit 731 were unknown to the American public until 1980 when John Powell requested and published documentation of their crimes under the Freedom of Information Act.[16] The Japanese members of Unit 731 were given full immunity for their actions in return for their data on the effects of biological warfare reagents on the body.[17]

Following the conclusion of the Nazi Doctors Trial two very important questions arose: 1) what was wrong with the experiments that Nazi and Japanese doctors performed and 2) would it be ethically acceptable to use the data collected from the experiments? The idea of identifying what, precisely, was wrong with the Nazi experimentations seems a bit strange by today's ethical standards, but ethicists were at that time faced with the important task of analyzing where

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[14] United States Holocaust Memorial Museum.<http://www.ushmm.org/museum/exhibit/online/#propaganda>. See also:
Hitler, Adolf. "Fuehrer Euthanasia Authorization." *University of Western England*. <http://www.ess.uwe.ac.uk/genocide/mord1.htm>.

[15] Drea, Edward, Greg Bradsher, Robert Hanyok, James Lide, and Michael Petersen. *Researching Japanese War Crimes*. National Archives and Records Administration for the Nazi War Crimes and Japanese Imperial Government Records Interagency Working Group, (2006): 25.

[16] Ibid, 43.

[17] Ibid, 13.

humanitarian violations occurred. The conclusions that they came to implicate ongoing ethical concerns, which shape the stem cell debate today.

The first conclusion was that the medical experiments performed by Nazi doctors were ethically irresponsible because research subjects were treated exclusively as biomaterials and not as individuals. Biomaterialism is the notion that those naturally occurring cells, organs, organisms etc. can be used as we would use any other tool of scientific research. When this theory is applied to humans, it promotes a view of the body as a collection of individual components, each of which serve a specific research function without considering the person as a whole. For example, Nazi researchers often used their subjects as human vessels, to test developing immunizations and study the effects of disease and amputation on the body. Nazi exploitations of POWs, and the racist ideologies that they used to justify their actions, raise an important question: what it means to have human dignity and if that is a term decided by societal norms. Nazi ideology portrayed the Jew as subhuman and taught racism in, among other things, scientific texts. Were Nazi doctors who were raised to believe in racism accountable for their actions? The question is raised, not to justify their actions, but to encourage a contextual analysis. Definitions of life, personhood, and human dignity are, at least to some degree contingent upon the societal norms within which we are raised.

The second conclusion that was reached was that it was wrong that Nazi researchers failed to get the (uninfluenced) consent of their subjects to perform their experiments. In a world where paternalism had so long defined medicine, the Nuremberg Trials were a turning point for change. The creation of the Nuremberg Code (the informed consent model on which all informed consent doctrine is still based) was the first true call for patient participation and understanding of research procedures. The Code was unique in its defense of the quasi-sacred nature of the

human body and each individual's right to choose or refuse medical treatment. Biomaterialism and informed consent concerns would continue to influence the ethical conversation surrounding biotechnologies for the next 60 years.

As a direct result of the trials, the Nuremberg Code was drafted, giving rise to the principle of informed consent.[18] The principle purports that no experiment can be done upon a human subject without the following:

> "1) Adequate disclosure of information, 2) patient freedom of choice, 3) patient comprehension of information and 4) patient capacity for decision making. By meeting these four requirements, three necessary conditions are satisfied: 1) that the individual's decision is voluntary; 2) that this decision is made with an *appropriate* understanding of the circumstances; and 3) that the patient's choice is deliberate insofar as the patient has carefully considered all of the expected benefits, burdens, risks and reasonable alternatives. *Legally*, adequate disclosure includes information concerning the following: 1) diagnosis; 2) nature and purpose of treatment; 3) risks of treatment; and 4) treatment alternatives."[19]

Unfortunately, the Nuremberg trials received very little press coverage within the United States, and the Nuremberg Code was not initially effective. A series of later events in U.S. medical history including the Tuskegee study, the Beecher publication, the Willowbrook hepatitis experiment, and the Jewish Chronic Disease Hospital experiment raised a public outcry and increased public awareness of medical paternalism and institutionalized racism. Informed consent was finally taken seriously in the United States a whopping twenty years after the

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[18] "Nuremberg Code" from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law. 2.10 (Washington, D.C.: U.S. Government Printing Office, 1949): 181-182. Via the Office of Human Subjects in Research.

[19] Ascension Health. <http://www.ascensionhealth.org/index.php?option=com_content &view=article&id=84&Itemid=171>.

Doctors Trial, when Institutional Review Boards (IRBs) were finally created.[20] Forcing doctors to fully educate their patients on risks, alternative treatments, and conditions meant that doctors could no longer ethically perform risky human experiments within the United States without consent.

The creation of IRBs was a profound step toward dismantling the paternalistic doctor-patient relationship. IRBs enlist community members as well as scientists to oversee and approve any protocol involving human subjects. They demonstrate, then and now, that doctors and researchers are not infallible and that they can be held ethically accountable to the public. Throughout the 1960s, when informed consent and IRBs were gaining prominence in America, the doctor-patient relationship became more mutualistic than paternalistic. Appreciation for autonomy caused "the model of mutual participation" to gain acceptance within the medical field.[21] As a result of informed consent, individuals today have a greater appreciation for patient and human rights; when informed consent policies are violated, public outrage ensues. The Nuremberg Trials were the first step toward creating a world that requires educated participation in one's medical care and balks at scientific progress at the expense of humanitarian concerns.

U.S. scientists began to debate in the 1960s whether it would be ethically permissible to use the data collected by Nazi doctors. On the one hand, the information could prove useful and with the advent of informed consent, such experiments could never again be performed. However, the experiments amounted to torture, and were performed on persons who could not

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[20] Dell'Oro, Roberto, and Corrado Viafora. eds. *Bioethics: A History of Bioethics International Perspectives*. (San Francisco: International Scholars Publications, 1996): 66-67.
See also
Fox, Renee C., and Judith P. Swazey. *Observing Bioethics*. (New York: Oxford University Press, 2008): 25-27.

[21] Kaba, R. and P. Sooriakumaran. "The Evolution of the Doctor-Patient Relationship." *International Journal of Surgery*. 5.1 Feb. (2007): 57-65.

refuse, thereby violating human rights. Dr. Henry Beecher eloquently argued against the use of the data, writing "this loss, it seems, would be less important than the far reaching moral loss to medicine if the data were to be published."[22] It was eventually determined that the data from the experiments was unreliable due to the effects of stress, the living conditions of the subjects, and the lack of controls. However these facts do not change the underlying ethical quandary: should science turn its back on potentially critical research because of unethical protocols?[23]

The Nuremberg Trials caused a change in the relationships between the doctor and the patient, the researcher and the subject. They marked the first step in the breakdown of paternalism that heretofore exclusively characterized the doctor-patient relationship. Following the atomic bomb, scientists requested ethical oversight of scientific research. IRBs were an initial step toward fulfilling that request. The question of whether unethically obtained data should be used by scientists raises the important dilemma of morality vs. progress. While morality succeeded and the data from the Nuremberg experiments was never used, the same cannot be said for the Unit 731 experiments, a fact that demonstrates a glaring inconsistency in governmental actions and policy. Informed consent laws and research oversight committees were both positive outcomes of the Trials and continue to affect nearly all bioethics dilemmas to this day. Further, concerns about biomaterialism, in this case the permissibility of human experimentation, were raised for the first time. The medicalization of Nazi political ideologies may imply that our understandings of life and human dignity are created, or at least influenced, by the societies in which we live. If so, this suggests that our own views may one day be

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[22] H.K. Beecher, *Ethics & Clinical Research*, (New England Journal of Medicine, June 1966): 1354-1360.

[23] Ibid.

considered equally monstrous. How we define life today in the United States and how we react to biomaterialism are critical to the frame of the stem cell debate.

Dialysis/Ventilators

Developed slightly before the ventilator, the dialysis machine challenged medicine in new and exciting ways. The dialyzer was created in 1945 by Dr. Willem Kolff as a means of treating (at least temporarily) those patients who otherwise would have died of acute kidney failure. Kolff, after WWII sent the blueprints for his dialyzer to the Peter Brent Brigham Hospital in Boston where it underwent significant alterations. Where Kolff's dialyzer had been unsustainable because it was impractical for long-term use, the new version was more efficient. The development of permanent shunt technology gave rise to the first dialysis center, known as the Seattle Artificial Kidney Center at Swedish Hospital. The dialyzer continues to be used today, albeit in an improved state from the original machine.[24]

However, the miracle of hemodialysis brought with it new baggage: redefining life and healthcare rationing. The dialysis machine was the first technology that could be used as a long-term substitute for a dysfunctional organ; one author even went so far as to call it the first artificial organ.[25] However calling a dialyzer an organ is, in itself, problematic, because although the machine completes the functions of an organ, it is not composed of living cells. It is an autonomous piece of technology, which mechanically substitutes for a non-functioning kidney. In a way, the dialysis machine is the inverse of the stem cell; it is a machine imitating life, as a

[24] Frezenius Medical Care. "History of Hemodialysis." <http://www.fmcag.com/files/Dialysis _Compact _2004_HD_History_english.pdf>. (2004).

[25] Project Bionics. "Artificial Organ History: A Selective Timeline." <http://echo.gmu.ed u/bionics/exhibits.htm>.

stem cell is a biomaterial imitating a machine.[26] Is a man with a dialyzer a human? A machine? A cyborg? Is he living? Is the dialyzer an organ or a machine? The hemodialysis machine marked the first technology (excepting perhaps the Iron Lung) that sustained life in a body otherwise incapable of living on its own. The line between the natural and the mechanical started to blur.

With the advent of dialysis machines the new bioethical buzzword became scarcity. The first bioethics committee was created to deal with the issue of just resource allocation. The creation of hemodialysis machines was (and is) expensive, and consequently, there were not enough machines to treat all of the 10,000 people in various stages of renal failure. Consequently, decisions had to be made regarding which patients would receive the expensive treatments. The first bioethics committee, nicknamed the God committee,[27] was created in Seattle in 1962 and consisted of seven citizens: a lawyer, a minister, a banker, a housewife, a state government official, a labor leader, and a surgeon. The committee took several factors into consideration when evaluating candidates for dialysis: marital status, dependants, age, sex, income, emotional stability, education, occupation, future potential, community service, etc.[28] The committee's attempt to ascertain the social worth of candidates angered and worried the

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[26] One might also wonder how dialysis machines were any different, ethically, from prosthetics. The difference lies in the function: improving quality of life (the function of the tools of the disabled) vs. sustaining life (the function of artificial organs). One could also question how dialyzers differ from insulin injections used by diabetics, as both are used to sustain life. Insulin at one time could only be obtained through other living organisms, such as the horse, from which it was taken, bottled, and distributed. Conversely the dialyzer is a completely artificial, man-made machine that is taking the place of a natural mechanism, the kidney. That is both what made it remarkable and led to ethical conflicts.

[27] Alexander, Shana. "They Decide Who Lives Who Dies: Medical Miracle Puts Moral Burden on Small Committee." *LIFE* 9 Nov. (1962): 102-125.

[28] Ibid.

American public as a whole.[29] The main role of the God committee involved evaluating life and personhood. Today, ethics committees are mandated in hospitals around the country. These ethics committees continue to be comprised of physicians as well as members of the community to help ensure fairness and objectivity.[30] Ethics committees, along with IRBs, represent the majority of local level oversight that physicians (or in the case of IRBs, researchers) must abide by. The concept of including community members in scientific discussions was somewhat groundbreaking and an idea that has resonated and influenced Embryonic Stem Cell Research Organization panels today.

Another biotechnology that developed parallel to the dialyzer was the ventilator. Varieties of ventilation technology have existed since the early 20th century, initially driven by the polio epidemic sweeping the United States. In 1927, scientists Philip Drinker and Louis Shaw developed the "Iron Lung," a massive tank respirator. The respirator consisted of an electric motor, two vacuum cleaners, and a pump that could adjust the internal pressure of the machine. The mechanism was invented to maintain respiratory function in children with acute onset polio. The researchers recognized that most childhood deaths from polio were the result of the virus paralyzing the chest and respiratory muscles and causing respiratory failure. However, those children who received respiratory aid until the viral attack passed (usually a week or two) generally regained full respiratory function and survived the virus.[31]

Ventilation technology was later enhanced as anesthesiologists began to use paralytic muscle relaxants and needed a means of more easily controlling respiration during surgery.

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[29] Smith, Harmon L. *Ethics and the New Medicine*. (Nashville: Abingdon Press, 1970): 101.
[30] Dell'Oro, Roberto, and Corrado Viafora. eds. *Bioethics: A History of Bioethics International Perspectives*. (San Francisco: International Scholars Publications, 1996): 22-24.
[31] Smithsonian National Museum of American History "The Iron Lung and Other equipment" <http://americanhistory.si.edu/polio/>.

Ventilators were and are required in emergency facilities across the country. Modern advancements in ventilator technology enable sustained respiratory function in trauma and coma patients.[32] The ventilator functions similarly to the dialyzer, keeping alive those patients that otherwise would be unable to survive. Ventilators, however, have led to many questions about how we define life and death. Since the advancement of ventilation technology "brain death" has become a new and vigorously debated category of being. One could, with the aid of a ventilator, remain in a coma, completely unresponsive, for the entirety of one's life. At what point does a breathing person cease to be "living?" Is it enough that a person's body is taking in and expelling air? Or does "life" imply a self-sustaining capacity? Is there a difference between being alive and possessing life? Physicians, bioethicists, lawyers and judges all struggled with the repercussions of this new category, attempting to define its parameters and interpret its shades of gray.[33]

The new reality was that hemodialysis and ventilation technology provided a means of mitigating previously deadly conditions. They raised questions of who was responsible for overseeing distribution. They challenged, and eventually rewrote, traditional definitions of life and death. Finally, they highlighted the ever shrinking gap between the mechanical and the natural. All these considerations are strikingly resurrected in the stem cell debate of today.

Transplantation

In 1954, in Boston, Massachusetts, the first successful kidney transplant operation was performed on two identical twins.[34] The event occurred shortly before the monumental discovery of histocompatability and the subsequent development of immunosuppressant drugs. The

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[32] Barash, Paul G., Bruce F. Cullen, Robert K. Stoelting, and Michael Cahalan. *Clinical Anesthesia*. (Philadelphia: Lippincott Williams & Wilkins, Wolters Kluwer Inc., 2009): 10.

[33] Bernat, James L. *Ethical Issues in Neruology*. (Philadelphia: Lippincott Williams & Wilkins, Wolters Kluwer Inc, 2008): 267-277.

[34] Dell'Oro, Roberto, and Corrado Viafora. eds. *Bioethics: A History of Bioethics International Perspectives*. (San Francisco: International Scholars Publications, 1996): 92.

discovery of histocompatability sparked further research that led to new classification systems of tissues.[35] These two factors combined led to an enormous increase in transplantation success rates. Since 1954, physicians and scientists have been working ardently to enhance transplant technology as well as to improve immunosuppressant drugs. Today we have successful heart, liver, pancreas, intestine, kidney, and lung transplants.[36] However, how these limited and precious organ resources are distributed is a complex, controversial process. Moreover transplantation again raises concerns of biomaterialism and shifting definitions of life and death.

A far cry from the original ethics transplant committee in 1954, today organ transplantation is a complicated practice involving computers, individuals, and luck. The contract for the organization of organ donations was given to a private organization, the United Network for Organ Sharing (UNOS), in an attempt to keep government bureaucracy out of the mix. UNOS compiles and maintains a national list of patients in need of organs, known as the Organ Procurement and Transplantation Network (OPTN).[37] UNOS also designates local Organ Procurement Organizations (OPOs) to facilitate the equal distribution of organs among various transplant centers.[38] OPOs compare patients on the list with organs as they are received. When an organ becomes available, the national registry will immediately narrow the candidates to those with close or similar blood types and antibodies. A transplant committee then considers geography and severity of need, though geography often trumps need.[39] Geography is critical

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[35] Ibid. 91.
[36] Gruessner, Rainer W., and Enrico Benedetti. *Living Donor Organ Transplantaion*. (McGraw Hill, 2008): 16-17.
[37] Ibid. 17.
[38] Menikoff, Jerry. *Law and Bioethics: An Introduction*. (Washington D.C.: Georgetown University Press, 2001): 487-493.
[39] Gift of Life Donor Program, http://www.donors1.org/patients/waitinglist/#1 and ARORA (Arkansas Regional Organ Recovery Agency), <http://www.arora.org/donorinfo/how_organ_transplanting_works.html>.

because organs need to be transplanted within several hours of harvesting or the donated tissue becomes unusable, though some organs maintain usability longer than others.[40]

The "brain death" conundrum again came to the fore in bioethical transplant discussions. Defining the moment of death was critical to physicians who needed to harvest organs for their transplant patients. Harvard Medical School compiled a report in 1968 that established the characteristics of brain death; since that time "brain death" by the Harvard Standard has been widely accepted by hospitals around the country. The criteria are that the patient 1) be unreceptive and unresponsive 2) should demonstrate no movement or breathing and 3) have no reflexes.[41] A patient who is brain dead according to the Harvard Standard is legally dead in the eyes of the hospital and is thereby a candidate for organ donation. Ethically, therefore, it is permissible to harvest organs from a breathing body, provided it has been shown that respiration is a result of a ventilator and not a functioning brain stem.[42] "Death," it seems, was re-defined by society and medical technology. This redefinition begs that definitive lines be drawn in the sands of the human dignity debate. Is the body so sacred that it should not be dismantled even to save the life of another? Should the preservation of human dignity, even in "death," trump the use of organs as biomaterials?

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[40] http://optn.transplant.hrsa.gov: For example, donated kidneys can last as long as 48 hours without implantation. However, in spite of their resilience, the list of people in need of kidney donations is substantially longer than that of people in need of a heart, lung, or pancreas. This is predominantly due to the impressive success and advancement of dialysis machines, which allow patients to function for years without a new kidney, though this raises concerns about quality of life.

[41] Ascension Health. <http://www.ascensionhealth.org/index.php?option=com_content &view=article&id=84&Itemid=171>.

[42] This should not be confused with a Persistent Vegetative State during which a patient loses higher brain function but retains non-cognitive functions such as breathing, circulation, and sleep patterns.

Other controversies stem from the use of live donors and the potential for organ farming. Bioethicists have struggled to reconcile the practice of harming a healthy person in order to help a sick one, though generally live organ donations are permissible provided the donor can function without the organ.[43] Should live donors be compensated for their services in the way that a sperm donor is for his semen? Modern biotechnologies such as stem cells could potentially form clones of our organs, completely eliminating organ shortages or the need for donors. However, organ cloning could potentially give rise to organ farming, for-profit organ production companies, and other autonomy crises.[44]

Organ transplantation has taken science far beyond the realm of man-made technology. Organs, for our purposes, were the first biomaterial. Organ donations raised questions of life and death, regulation and oversight committees, and informed consent laws. This melding of nature and technology marks the beginning of a new period of development, exploration, and ethics characterized by new, intimate, and individualistic forms of biotechnology like the stem cell.[45]

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[43] Gruessner, Rainer W., and Enrico Benedetti. *Living Donor Organ Transplantaion*. (McGraw Hill, 2008): 470.

[44] The autonomy question comes into play when one ponders if it would be ethically permissible to create a clone that lacked functional consciousness, to keep as a "spare" when one or more of our organs began to fail. Do the same problems exist if you are only cloning an organ as opposed to an entire functional body?

[45] I hope to establish through this paper two individual forms of biotechnologies: the man-made and the biomaterial. While we push forward wholeheartedly with the mechanized, we sometimes question the viability of the naturally occurring.

I mentioned earlier with kidney dialyzers that one of the interesting aspects of this machine is that it is a piece of factory assembled technology that hopes to replace a functional living corporeal part. Conversely, donated organs are themselves a form of technology, but differ in that they are naturally occurring. Consequently, legal as well as moral questions are constantly arising about organ transplantation. Where few would argue that an automated external defibrillator should not be used on a patient in ventricular fibrillation, many would hesitate to volunteer a piece of their liver to a cirrhosis patient. The way that we consider these technologies is fundamentally different and stems from their origins.

Perhaps the next phase of scientific technology is the hybrid of these two, which is the man-made natural technology, a unique derivative of synthetic biology. Such SynBioTech will

Abortion

While abortion is neither new nor a modern phenomenon, the institutionalization, politicization, and legalization of abortion within the United States is. "As soon as bioethical issues appeared in the form of enticing public challenges around 1970, some political leaders identified themselves with the important issues they addressed."[46] As the radical 1960s were drawing to a close, Second Wave feminism was just getting started. Feminists brought reproductive rights into the public eye through lobbies, rallies, and speakouts drawing in the support of civil liberties groups and even clergy.[47] By June of 1970 the country's abortions laws were as follows:

> "The State of New York passed the first Abortion on Demand Law (24-week limit), [and] it became the 16th state to allow abortion. Due to an extremely loose interpretation of "mental health," California also had de facto abortion-on-demand. Alaska and Hawaii had liberal laws. Laws in the other 12 states, which included Arkansas, Colorado, Delaware, Georgia, Kansas, Maryland, Mississippi, New Mexico, North Carolina, Oregon, South Carolina and Virginia, were very restrictive, typically allowing abortion only for pregnancies due to assault rape, incest and life of the mother as well as for severe fetal handicap."[48]

On January 22, 1973, the United States Supreme Court handed down a decision that limited the power of the State to deny women abortions: Roe v. Wade. In Roe v. Wade, the Court ruled that a woman's right to control her own body is protected under the Due Process Clause of the

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prove to be both powerful and useful in the future when it reaches a capacity that improves upon, rather than imitates, the natural. I leave that discussion for a later time and instead group Synthetic Biology as one of the ultimate examples of the biomaterial.

[46] Dell'Oro, Roberto, and Corrado Viafora. eds. *Bioethics: A History of Bioethics International Perspectives*. (San Francisco: International Scholars Publications, 1996): 93.

[47] Boston Women's Health Book Collective. *Our Bodies, Ourselves for the New Century*. (Touchstone, 1998).

[48] McAdam, Thomas. *The McAdam Report*. <http://www.mcadamreport.org/Abortion.html>.

Fourteenth Amendment. The Due Process Clause, the Court ruled, gives a woman the right to terminate her pregnancy without interference from the State, through the first trimester. However, the Court also ruled: "for the stage subsequent to viability the State, in promoting its interest in the potentiality of human life, may, if it chooses, regulate, and even proscribe, abortion except where necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." The Court defined viability as the point at which the fetus is "potentially able to live outside the mother's womb, albeit with artificial help."[49]

Under Roe v. Wade, government programs such as Medicaid funded up to one third of all first trimester abortions from 1973-1976. In 1976, feminists lost a critical battle in the right-to-life movement: the Hyde Amendment, which banned Medicaid from funding abortions henceforth. The result was an enormous population of women (predominantly of color) who did not have access to abortion procedures because of the prohibitive costs. While feminists attempted to establish low cost abortion centers around the country, unsubsidized abortions were extremely expensive and demand was growing exponentially.[50] The abortion question gave rise to many highly politicized, controversial and divisive public debates. Two platforms emerged out of the debates, the pro-life and the pro-choice. These groups still exist and influence reproductive debates today, including the stem cell research debate. Aborted fetuses are one of the biomaterials from which researchers can harvest stem cells. Researchers, abiding by informed consent laws, need the permission of both parents to harvest the stem cells from a fetus, a problematic approach in a nation where women may decide, alone, to obtain an abortion.

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[49] Menikoff, Jerry. *Law and Bioethics: An Introduction*. (Washington D.C.: Georgetown University Press, 2001): 54-62.

[50] Boston Women's Health Book Collective. *Our Bodies, Ourselves for the New Century*. (Touchstone, 1998).

Why does the Court have the right to define life? What happens if neo-natal technologies develop that allow a fetus to be viable earlier than the end of the first trimester? What role should the government (Federal or State) play in regulating and funding scientific technologies, especially when they involve the human body and issues of free will and human dignity? Should women be able to donate the stem cells from their aborted fetuses to researchers without the consent of their partners? How has the abortion divide affected the future of reproductive technologies? These questions are at the heart of bioethics and today's stem cell controversy.

Genetics

Friedrich Miescher discovered nucleic acids (then called nucleins) in the late 19th century but their significance was not appreciated at the time of their discovery. Several years later, Gregor Mendel, a scientist best known for his experiments with pea plants, demonstrated that certain traits were inherited in groups and could be passed down across generations; he called these inheritance packages "genes." It was not until 1944, however that the world began to appreciate the crucial nature of the gene. The Nobel Prize website detailing the history of the double helix sums up the epiphany that began the field of genetics as follows:

> "For a long time the connection between nucleic acid and genes was not known. But in 1944 the American scientist Oswald Avery managed to transfer the ability to cause disease from one strain of bacteria to another. But not only that: the previously harmless bacteria could also pass the trait along to the next generation. What Avery had moved was nucleic acid. This proved that genes were made up of nucleic acid."[51]

[51] "The Discovery of the Molecular Structure of DNA - The Double Helix". Nobelprize.org. 5 Dec. (2010). <http://nobelprize.org/educational/medicine/dna_double_helix/readmore.html>.

In fact, the power of genetics was so revered that a movement emerged (as noted earlier) and continues to exist both in the United States and abroad that advocates the practice of eugenics.[52]

Over the course of the next decade, scientists began to understand deoxyribonucleic acid (DNA). They learned that it is composed of four nucleotides: adenine, thymine, guanine, and cytosine, which are evolutionarily conserved. The field of genetics gained significant momentum when (the now-infamous) James Watson and Francis Crick proposed in 1954 the double helix model that we now understand to be the structure of DNA.[53] Throughout the 1970s, scientists within the United States continued to successfully unravel the mystery of DNA; they discovered plasmids, restriction enzymes, and DNA ligases, all of which helped them to better understand the role DNA replication plays in inheritance. In 1972, the first recombinant DNA strand was created, a game-changer in the field of genetics.[54] With this discovery, DNA crossed the boundary between theoretical material and biomaterial, a reality that terrified many. As a result, recombinant DNA technology was halted in 1974, when a group of researchers petitioned the National Academy of Sciences to create a committee to examine the bioethical issues of recombinant DNA technology. Unwilling to pass judgment without further discussion, the

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[52] Literally translating to "good creations," eugenics was the practice of controlling human reproduction so as to propagate a certain race or trait over others considered to be inferior. While the most common example of a eugenic society is Nazi Germany, many people overlook the United States' own forced sterilization practices. We could, some feared and some hoped, eventually perfect the genetic code, weeding out the "inferior" genetic material and directing society's evolution. However, the pedestal onto which genetics was eventually raised cast into shadow political, social, and economic factors. Society became (and continues to be) obsessed with the "genetic fix," whereby tweaking, removing, or adding to the genetic code scientists can solve all of our "genetic ailments." Evidence of the biomedicalization of society's problems can be seen in our pursuit of the heart disease gene or the obesity gene, and our fixation with developing pharmaceutical fixes while neglecting to take note of social, environmental, political, and economic factors.

[53] Smith, George P. *The New Biology: Law, Ethics and Biotechnology*. (New York: Plenum Press, 1989): 15.

[54] Grace, Eric S. *Biotechnologies Unzipped: Promises and Realities* 2 (Washington D.C.: Joseph Henry Press, 2006): 31-32.

committee recommended the stay be extended until an international conference could be had. The result was the Asilomar Conference of 1975.[55] The conference represented a major foray into the sphere of public debate. It established several recommendations and guidelines by which scientists performing recombinant DNA research should operate. It demonstrated that public discussions and evaluations do not mean the death of research.

It was not until 1976 that the first practical application of genetics became a reality in the form of Genentech, the first genetic engineering company to use recombinant DNA technology to create pharmaceuticals.[56] By 1978, Genentech had successfully used recombinant gene technology to create human insulin via bacterial plasmids.[57] The molecule at the very heart of human life, DNA, was the biomaterial that scientists snipped, unzipped and recombined to create unique organisms. DNA had officially become a biomaterial.

In 1981, only three years after the founding of Genentech, researchers discovered human oncogenes (genes that cause cancer). Gene mapping, the process of locating where on a chromosome a specific gene is located, became a crucial technique used by geneticists. Due to these two advancements, genetics changed; it was no longer a purely intellectual endeavor. Instead it was the puzzle that, when solved, would reveal the cure for cancer and countless other conditions. Two years later in 1983, the gene for Huntington's Disease (HD) was mapped and cloned, making it possible to accurately predict if an individual would succumb to HD. [58] In 1988 the Department of Energy and the National Institute of Health created the Genome Office at the

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[55] Berg, Paul, et. al. "Summary Statement of the Asilomar Conference on Recombinant DNA Molecules". *Proc. National Academy of Science.* 72: 6. June (1975): 1981-1984.

[56] Carmen, Ira H. Cloning and the Constitution:An Inquiry into Governmental Policy Making and Genetic Experimentation. (Wisconsin: University of Wisconsin Press, 1985): 61-110.

[57] Access Excellence Resource Center. *The National Health Museum.* <http://www.accessexcellence.org/RC/AB/BC/1977-Present.php>.

[58] Lane, Jo Ann. Access Excellence National Health Museum. (1994). <http://www.accessexcellence.org/AE/AEPC/WWC/1994/geneticstln.php>.

National Institutes of Health (which later became the National Center for Human Genome Research), commencing a thirteen-year effort to map the human genome in its entirety. The Human Genome Project, as it was colloquially dubbed, was directed by James Watson who allocated three percent of the project budget to the formation of an ethics committee to study the ethical ramifications of gene sequencing.[59] [60] The project concluded successfully in 2003. The sequencing of the human genome, the advances in the field of genetics and new gene mapping technologies together raise a series of bioethical questions about genetic discrimination, tailor made drugs, and the reach of individual privacy laws.

Genetics once again became the center of controversial debate with the advent of advanced cloning procedures. Cloning is the genetic technique whereby an exact DNA replica of an organism is produced. The cloning debate was initiated by the birth of Dolly the sheep in 1996, the first mammal to be successfully cloned. To create Dolly, scientists removed the nucleus from an adult sheep's somatic breast cell and implanted it in an irradiated egg cell, thereby inducing cleavage and embryo formation. The implications of Dolly were not lost on bioethicists or the American public. "The revelations of Dolly's creation unleashed a worldwide torrent of print and electronic media coverage with a profusion of commentaries from assorted experts in fields including ethics, religion, law, biomedical science and medicine."[61] The potential of human clones raised national alarm, especially concerns about human dignity. Bioethicists feared that cloning would breed an inevitable loss of free will, autonomy, and

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[59] Gert, Bernard et al.. "Morality and the New Genetics: A Guide for Students and Health Care Providers.". (Boston: Jones and Bartlett Publishers,1996).

[60] By 1989, DNA fingerprinting was used by law enforcement agencies in murder, immigration and paternity cases. This development gave serious, court-approved credence to the field of genetics.

[61] Fox, Renee C., and Judith P. Swazey. *Observing Bioethics*. (New York: Oxford University Press, 2008): 85.

privacy.[62] American society balked at the thought of an unoriginal person and the psychological and biological hardships that person would endure. It is not enough that an embryo have sufficient DNA to form a human person. Life as we define it, it seems, is tied inexplicably to our need to be unique.

With Dolly's early death at the age of six (sheep typically live to ten or twelve), cloning was even further demonized as unsafe. If scientists could not understand the biological consequences of cloning, how could it ethically be used? Some outlandish thinkers have even recommended the creation of human clones (or even organ clones) strictly for the purposes of harvesting organs. The idea is widely rejected, as it is drenched in human dignity and non-malfeasance violations. It would, however, eliminate the need for organ rationing and account for the inadequacies of the transplantation system. Can scientists move forward, manipulating genetic codes that they do not understand? More importantly for all of us, should they?

The genetics movement continues to highlight our main stem cell themes. First and foremost what did/does the study of genetics mean for society's definition of life? Is life merely a random genetic sequence? Are we really no more than our DNA? As the study of genetics gained traction, so too did the ideas and fears of eugenics. The role of genes is proving to be larger and more complex than scientists have thus far been able to unravel. This complicated discipline raises fears of all the unforeseeable consequences associated with that unraveling. However, geneticists are working hard to understand what the function of each and every human gene is. Who is to say we will ever have all the answers? Genetics also initiated one of the first and most effective public dialogues on bioethics: the Asilomar Conference. Asilomar

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[62] For a more in depth look at cloning and its bioethical concerns see *Cloning and the Constitution*, *Observing Bioethics*, *Biotechnology Unzipped*, *Biotechnology: Our Future as Human Beings and Citizens* Chapter 5

demonstrates that regulation need not mean the end of research. Finally, and perhaps most importantly, genetics represents yet another institutionalization of biomaterialism, which raises questions of human sanctity. If we can ethically splice and recombine our DNA and genetic code, why not use stem cells for research?

IVF

In vitro fertilization is closely linked with, and some might consider it to be a subset of, genetics. The *in vitro* fertilization process is completely removed from the host organism. The first documented IVF success in mammals came in 1959 by scientist Michael Chang. Then, in 1978, two British scientists successfully produced the first human IVF baby, Louise Brown.[63] The first United States IVF baby was born shortly thereafter, in 1981, when scientists Howard and Georgeanna Jones altered the techniques formerly used in the UK. The new techniques that the Jones' used became the foundation for modern day IVF. In 1999, over thirty-five thousand babies were "conceived" using assistive reproductive technologies. Today, the IVF procedure can be summed up as follows:

> "Typically a woman's ovary produces one egg per month. Physicians who specialize in IVF use fertility drugs to stimulate a woman's ovaries to produce multiple eggs. Eggs are then retrieved during an office procedure in which a needle is inserted into the ovary through the vagina. The eggs are then mixed with sperm in order to allow fertilization. After a period of growth and observation in

[63] Heilbron, J. L. *The Oxford companion to the history of modern science.* (Oxford University Press: New York, 2003): 422.

> the laboratory, a number of fertilized eggs, now known as embryos, are returned to the uterus of the woman who will carry the pregnancy."[64]

While originally developed to treat female infertility, IVF is now thought of as the solution to male infertility as well. Advancements in the form of pre-implantation screenings allow scientists to weed out those embryos that may contain undesirable traits such as Down's syndrome. Scientists ability to "play God" by selecting for specific traits or genders raises memories and fears of a new eugenics movement. Screenings allow parents to select for specific genders; a practice that many fear could lead to sexist selections.[65] Some communities such as the Deaf community fear the discovery of a gene that causes deafness because IVF couples might then be able to select against embryos that would produce a deaf child.[66] Will IVF screening technologies lead to a genocide of the handicapped and socially undesirable? [67]

While the wonders of IVF have undeniably helped many infertile and non-traditional couples have children, IVF raises a host of ethical issues. Men (and more recently women) are paid for their gamete donations, a practice that is relatively unchallenged legally despite strict laws prohibiting the sale of body parts. Payment for biomaterials further distances them from the "bio" segment of their name, moving them more toward the realm of commercial technology. Should biotechnologies and

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[64] Encyclopedia of Children and Childhood in History and Society <http://www.faqs.org/childhood/In-Ke/In-Vitro-Fertilization.html >.

[65] Gajilan, Chris A.. "Gender Selection a Reality, but is it Ethical?." *CNN*, 17 Nov. (2005).

[66] Mundy, Liza. "A World of Their Own." *The Washington Post*, sec. W. 31 March (2002): 22. Also see
Davis, Lennard J. "Deafness and the Riddle of Identity." *Chronicle of Higher Education Review*, Jan. (2007).

[67] Carmen, Ira H. *Cloning and the Constitution: An Inquiry into Governmental Policy Making and Genetic Experimentation*. (Wisconsin: University of Wisconsin Press, 1985): 84-87.

mechanical technologies be viewed in the same light? Or should biomaterials be given a certain degree of reverence due to their natural occurrence?

Perhaps most obviously, IVF again challenges traditional definitions of human life. Is an embryo created in a lab, but never implanted, a life? Is it even a potential life? And what can we say about the creation of extraneous embryos? Fertility clinics often harvest multiple eggs for the purposes of IVF. Those embryos that are not implanted are frozen to preserve them. [68] However, what should be done with the embryos that couples decide they do not want? Should they be disposed of? Donated to science? The discovery of stem cells further complicates that issue by questioning if we may harvest stem cells from embryos in the name of progress.

Synthetic Biology

Synthetic biology raises serious moral questions linked inextricably to stem cell research. While there is no real "start date" per se, synthetic biology is tied closely to the evolution of genetic engineering. The 1970s boom in recombinant DNA technology was the precursor to the field of synthetic biology. In the 1990s, DNA sequencing technologies became available and genome sequencing projects presented scientists with the complete genetic codes of numerous organisms. Subsequently, scientists created machines whereby they could synthesize DNA.[69] In 2005, engineer Drew Endy, then an engineer at MIT, set out to revolutionize biological engineering. Endy called for the creation of a biological standard and from this concept the BioBrick emerged. BioBricks are synthetically constructed segments of code, created in DNA

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[68] Bellomo, Michael. *The Stem Cell Divide: The Facts, the Fiction, and the Fear Driving the Greatest Scientific, Political, and Religious Debate of our Time*. (New York: AMACOM, 2006): 51-52.

[69] *New Directions: The Ethics of Synthetic Biology and Emerging Technologies.* Presidential Commission for the Study of Bioethical Issues. Dec. (Washington D.C: 2010): 47-55.

synthesizers, which are made to fit together in the same way as LEGO blocks. Endy's idea of the BioBrick utilizes open source technology; MIT researchers created an open public database of BioBricks for synthetic biology researchers. Endy is also responsible for initiating the annual undergraduate and high school international Genetically Engineered Machine (iGEM) competition. This prestigious competition has encouraged young students to familiarize themselves with and utilize the BioBrick database as well as open source forums, to create genetically engineered organisms.[70] Since its evolution synthetic biology has seen an unusual rise in the popularity of open source forums and Do It Yourself research (DIY). DIYSynBio raises concerns about regulation and public safety while standing as a striking example of public engagement with research.[71] As recently as 2010, synthetic biologist Craig Venter completed the creation of the first self-replicating synthetic bacterial genome. While Venter is insisting he is the first to create synthetic life, others are skeptical. "He has not created life, only mimicked it," says David Baltimore a geneticist at CalTech. Venter's synthetic sequence could not survive without a host bacterium.[72] His creation, however, elicits the question of whether a synthetic genome is the equivalent of synthetic life.

Understanding exactly what constitutes synthetic biology is complicated. The President's Commission for the Study of Bioethical Issues reported in December of 2010 that true synthetic biology aims "to create new biochemical systems or organisms with novel or enhanced

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[70] Keller, Evelyn Fox. "What Does Synthetic Biology Have to do with Systems Biology." *Biosocieties.* (London School of Economics and Political Science, 2009): 291-302.

[71] Hessel, Andrew. "Protocells, Precautions and Open-Source Biology" *The Ethics of Protocells: Moral and Social Implications of Creating Life in the Laboratory.* Ed. Mark A. Bedau and Emily C. Parke. (Cambridge: MIT 2009).

[72] Wade, Nicholas. "Researchers Say They Created a 'Synthetic Cell'" *The New York Times* 20 May (2010): 1-3.

characteristics."[73] However, does synthetic life truly need to have a novel function? "Engineered organisms will be increasingly understood as machines—their design, function, and evolution completely knowable, unlike the organisms of the natural world," maintains Andrew Hessel. [74] Dr. Evelyn Fox Keller addresses the question of "what is synthetic biology?" by comparing it to systems biology. Synthetic biology marks "this shift from conceptual to material reconstruction… systems biology never promised to put a real-world Humpty Dumpty together again."[75] Synthetic biology seems to assume it knows enough from systems biology to start creating. The adopted mantra of the synthetic biology community is "what I cannot create, I do not understand." However, SynBio researchers seem to be ignoring the fact that the mantra does not necessarily work the other way around. In other words, while it may be true that the inability to create implies a lack of understanding, the act of creation is no longer contingent upon complete understanding—on a biological or deeper ethical level.

The ethical concerns that the field of synthetic biology has generated are very similar to those raised by its contemporary issue: the stem cell debate. The first is a question of regulation. Who will be in charge of making sure that researchers do not cross moral boundaries and will that regulation come on a local, state, or federal level? This conundrum is exacerbated by the prevalence of open-source and DIY science. The second problem involves the high stakes of the research. No one can say what the consequences of synthetic biology will be. Just as synthetic biology may generate the cure for cancer or create new, efficient biofuels, it may also give rise to

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[73] *New Directions: The Ethics of Synthetic Biology and Emerging Technologies.* Presidential Commission for the Study of Bioethical Issues. Dec. (Washington D.C: 2010): 36.

[74] Hessel, Andrew. "Protocells, Precautions and Open-Source Biology" *The Ethics of Protocells: Moral and Social Implications of Creating Life in the Laboratory.* Ed. Mark A. Bedau and Emily C. Parke. (Cambridge: MIT 2009):185.

[75] Keller, Evelyn Fox. "What Does Synthetic Biology Have to do with Systems Biology." *Biosocieties.* (London School of Economics and Political Science, 2009): 292.

deadly new organisms. What does synthetic biology mean for life as we know it? What implications does Dr. Venter's claim to have created life by manufacturing DNA hold? Is there a difference between creating a life and creating an individual, and what are the implications for stem cell developments?

Ethical Conclusions

It is important to take from this extensive history that the five predominant ethical issues closely associated with stem cell research are not unique to the stem cell debate. Rather, we can trace their development by studying bioethical milestones, a tactic that also links these issues with other bioethical concerns raised along the way (like eugenics, doctor-patient relationships, rationing, etc.). Milestones discussed include the atomic bomb, the Nuremberg Trials, kidney and dialysis invention, organ transplantation, abortion, genetics, IVF technologies, and synthetic biology. These eight historical landmarks predominantly focus on the five paramount concerns in the stem cell research debate: political involvement, regulation, consequences, biomaterialism, and definitions of life. Examining the evolution of these issues via their re-emergence throughout history will help us to appreciate the shifting nature of ethics. We can also attempt to foresee ethical problems that may arise and construct regulatory or ethical bodies in an effort to waylay them.

The role of government and politics in science begins largely with wartime technology. The Manhattan Project represents the unprecedented degree to which the government began to invest in science. With the "success" of the atomic bomb, the federal government began pouring money into scientific R and D, handpicking those projects the government wanted to see succeed. The Nuremberg Trials also introduced government into a novel role: that of the ethical judge. Foreign governments were able to stand in judgment and punish those individuals who

violated human rights. In addition, the Nuremberg Trials serve as a warning, demonstrating the consequences of allowing racist political dogma to intrude into science. The next shift in the role of the government (in the examples reviewed) came during the abortion debates and reproductive wars of second wave feminism. The Courts as well as the State and Federal legislatures became regulators of the body, dictating what women could and could not do during pregnancy. State legislatures continue today to pass laws further limiting the abilities of women to obtain abortions. The government once again attempts to serve as the judge deciding which medical procedures are elective and which are necessary. As a result of these decisions procedures such as IVF and abortion are not eligible for federal funding and are not covered under Medicaid, while kidney dialysis, for example is fully funded for the entirety of a patient's life.

Government involvement concerns go hand-in-hand with regulation. In the aftermath of the atomic bomb, researchers were among the first individuals to call for regulation. Post-WWII, the Nuremberg code was created and informed consent laws gained prominence internationally, though not in the United States. It was not until many years later (the 1970s) that the U.S. first began to develop IRBs, which review research protocols in an attempt to reinforce informed consent laws. In 1962, the first bioethics committee was created; a group of non-scientists who were tasked with determining which individuals would receive rare kidney dialysis treatments. Since that time, hospitals have voluntarily embraced bioethics committees to review ethical questions raised in the course of medical practice. A critical component of those committees is the community members who still participate and bring new, non-scientific concerns and perspectives to the table. Transplantation gave rise to the first highly organized regulation system, which operates privately and primarily at the local level to justly allocate organs. Along with the increase in genetic research, there was a concomitant increase in regulatory oversight.

Interested parties convened at a conference, Asilomar, to discuss and draw up a series of ethical guidelines for recombinant DNA researchers, setting the bar for ethics and community involvement. Finally, calls are being made today for similar ethical guidelines to restrict synthetic biology research. Thus far, there is no established system for regulating synthetic biology and the unique challenges associated with DIYSynBio and open-source forums.

Ethics committees are essential to evaluating our next ethical dilemma: the unknown consequences. In science, and particularly scientific research, the consequences of action (and inaction) are often unpredictable. When President Truman decided to detonate the atomic bomb in August of 1945, he did so (hopefully) after carefully evaluating the consequences of both his action (Japanese deaths) and his inaction (prolonged war, American deaths). However, the effects of radiation poisoning at the time of detonation were relatively unknown,[76] and the historical documentation is unclear about how much Truman knew or understood about radiation poisoning or if that information would have altered his decision to bomb. Such decisions involve weighing one result against the other and then coming to an ethical decision about the best path. Synthetic biology finds itself in a similar situation, one that Bedau and Triant have dubbed "deciding in the dark.[77]" The potential for synthetic biology to create something incredible is as great as its potential to create something catastrophic. Similarly, choosing not to pursue synthetic biology research may save the world from flesh eating mutant bacteria or it may deprive the world of a cure for cancer. These decisions require careful and comprehensive consideration.

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[76] There had been several incidents where nuclear plant employees were accidentally exposed to high levels of radiation and died.

[77] Bedau, Mark A and Mark Triant. "Social and Ethical Implications of Creating Artificial Cells." *The Ethics of Protocells: Moral and Social Implications of Creating Life in the Laboratory.* Ed Mark A. Bedau and Emily Parke. (Cambridge: MIT Press , 2009): 39-45.

Decision-making does not end with whether or not to conduct research: it is also tied to definitions of human life. Hemodialysis machines and ventilators introduced society to a new concept: prolonged life despite organ malfunction. Prior to the invention of these instruments, organ failure usually caused death. These new biotechnologies forced society to deal with a new reality: perpetual human dependence upon a machine. The advent of the organ transplantation age required a new evaluation of the definitions of life and existence. In order to harvest functional organs via new transplantation techniques, scientists developed a new subset of death: "brain death." Death, and by extension life, became intimately linked to thinking and brain function. The notion that one could physically live but mentally die—and define that as death—was revolutionary. The genetics movement further changed how we, as a society, define life. The first change was the sudden rise in biomedicalization. Many social woes or abnormalities became attributed to our genetic make-up and genetic determinism became a prominent ideology.

Equally interesting was how people pushed to differentiate themselves from other animals, as science proved that genetic sequences are conserved across species. Questions arose as to what actually constitutes human life, since our genetic make-up is largely the same as "lower" life forms. Reluctant to allow our very existence to be boiled down to A, T, G, and C, current thought purports that perhaps the key to defining humanity lies in the division between physical life and personhood…between being and being human.

Defining human life took a new turn with the passage of Roe v. Wade. Deciding when life begins and, further, when it is accorded full human legal protections, was an immensely challenging task that fell to the Court. The Supreme Court declined to clarify when exactly life begins, choosing to focus instead on when a fetus' rights supersede those of its mother. Each state has independently passed its own abortion laws, which vary significantly in how and when

they define the beginning of life. Therefore, a fetus may have full legal human rights in one state and be considered biological property in another. Without an agreed upon standard point at which an embryo/fetus is considered human life it is that much more difficult to determine what constitutes its death. Whether living embryos should be accorded the same rights as living, thinking, fully developed adults is a question answered affirmatively and negatively largely depending on the geography of the questioner. IVF technologies further complicate this question, challenging what exactly it is that makes fertilization so sacred. If scientists create embryos in Petri dishes, are they creating new life? Synthetic biology will soon force society to once again reevaluate what it means to be human. As synthetic biology works to create unique organisms, we must question whether these synthetic organisms should be attributed any less dignity than ourselves. Physically, these creations will be made of the same molecules arranged in similar but improved versions of our own.

Regardless of what we determine constitutes human life—the physical or something deeper—the way we value the physical nature of the body itself is changing. Prior to the detonation of the atomic bomb, doctors and patients engaged in typically paternalistic relationships, whereby patients had no understanding or say in their treatment. However, following concerns raised by both nuclear fallout and Nuremberg, the doctor-patient relationship shifted and patients became more autonomous. Informed consent laws dictated that human beings could no longer be used as unwitting guinea pigs. The human body shifted away from being defined as a research tool. However, with the advent of hemodialysis and the ventilator, the human body became the forum in which to test and refine life-sustaining technologies. Biotechnologies were developed to mimic the functions of the body, in a way paying homage to the original defective pieces. Organ transplantation carried that homage a step further.

Recognizing that there is no substitute for the original, scientists began to use the organs from the deceased to save the living. Organs were the first biomaterials: naturally occurring technologies. Everything in genetics stemmed from the ultimate biomaterial: DNA. The challenge became to study and eventually manipulate the genetic code. Recombinant DNA technology is based almost solely on biomaterials. At the heart of the abortion debate was the fear that fetuses might be undesirable biomaterial, and as such expendable without moral qualms. IVF technologies went a step further demonstrating we could use existing biomaterials (gametes) to produce original and immensely powerful new biomaterials (embryos). Finally, synthetic biology proposes that it is possible to artificially create biomaterials. If these biomaterials are created using DNA reconfigured in unnatural sequences, does that just make them materials? What does the evolution of biomaterials mean for the ethics of the body, human dignity, and life as we know it?

The NIH issued a report in 1994 that recognizes the potential of human embryo research, particularly stem cell potential, and unknowingly opened Pandora's Box.[78] IVF clinics became a proverbial Wal-Mart for researchers in need of discarded embryos from which they could harvest stem cells. The implications of stem cell research when combined with new genetics techniques raised a host of ethical fears in the media and public. The stem cell debate continues today, emphasizing five ethical conundrums. Understanding how these issues have developed over time, may better enable us to predict where they will go next. The face of science is certainly

[78] Ruse, Michael, and Christopher Pynes. eds. *The Stem Cell Controversy* 2nd Ed. (Amherst, New York: Prometheus Books, 2006): 51.

changing, and ethics must change with it; in the words of Dr. Richard Clarke Cabot the time has come for "ethics and science to shake hands."[79]

Part II

Stem Cells: The New Biomaterial:

It has been called the wonder cell and the gateway to the future but what actually is the stem cell and what makes it so incredible? Since the creation of the first human stem cell line in 1998, stem cells have been heralded as the cure for all that ails the human race, be it Alzheimer's, Parkinson's, heart disease, degeneration, diabetes or aging. Yet for all their promise, stem cells have yielded very few results. The reason why lies somewhere between science and politics. As I hoped to show in the previous section of this paper, biopolitics is a relatively new phenomenon in the United States, truly gaining traction during the World Wars. It was not until the mid to late 1940s that the United States government proclaimed science to be the gateway to advancement, success and the future. History since that time has been marked by significant scientific and technological achievements, culminating now with the age of the stem cell. We are in a time where science challenges conventional definitions of humanity through its progress. However, the interdependence between science and politics and, more importantly social identity, has opened the door to political and judicial intrusions into research, shown beautifully through the lens of the stem cell research debate. "Never before has a debate about a specialized laboratory practice been the occasion for passionate cultural division that surfaced in

[79] Cabot, Richard Clarke. *The Meaning of Right and Wrong.* (The Macmillan Publishing Company, 1936): 9.

three presidential campaigns and many state elections, before completing its latest adventure in the judicial system."[80] Stem cells have engendered a controversy.

Every cell in our bodies stems (no pun intended), ultimately, from a stem cell. Now scientists are looking to harness the power of that cell, experiment with it, and learn to manipulate it. Many people are uncomfortable with science (or perhaps more accurately scientists) having such an intimate and invasive hand in the future of human development. To understand the dilemmas surrounding stem cell research (mostly embryonic and germ stem cell research) we must first understand the stem cell: what it is, how it is created, what its potential is and what has happened in the stem cell debate thus far.

Development

Stem cells are extraordinary for several reasons: Self-renewal, infinite growth, and potency. When a stem cell undergoes (single-parent) reproduction it produces two daughter stem cells, at least one of which remains undifferentiated. Given the right environmental conditions, stem cells can reproduce infinitely, forming millions of other stem cells. Finally, stem cells are unique in their ability to differentiate, ie become new types of cells. Most cells that we possess are somatic cells (committed or specified non-gametes). This means that these cells are programmed to be, for example, muscle cells. Muscle cells are extremely different in form and function from, for example, nerve cells. Both however derive from stem cells. Cells differentiate via a complex network of genes, transcription factors and signaling proteins that, together, indicate a specified type of cell. The chemical signals that a cell produces and interacts with determine its identity.

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[80] Moreno, Jonathan D., John M. Nolan, Patrick M. Taylor, Emad U. Samad, Suy Anne R. Martins, and Stephen G. Brozak. "Long Shadow of the Stem-cell Ruling." *Nature* 467 (2010): 1032

To debate the pros and cons of stem cell research one must have at least a cursory understanding of human development. Important terms include development, differentiation, potency, blastocyst, and embryo. In order to clarify the terms and concepts being discussed a general overview of human development as it pertains to stem cell research is as follows: Humans are mammals, meaning that 1) they reproduce sexually and 2) mothers undergo internal fertilization followed by the internal development of their offspring. The human body is composed of trillions of cells, but generally cells are grouped into two categories: the somatic cells and the gametes. Gametes, also known as sex cells or germ cells, are unique in that they only contain 23 chromosomes (Most human nuclei have 46 chromosomes). Chromosomes are thread like structures, located in the nucleus, that are composed of DNA and support proteins. A key to human evolution and individuality is a process known as recombination, which occurs during fertilization.

Fertilization occurs when the sperm cell (the male gamete) locates, penetrates and inserts its nucleus into the egg cell (the female gamete). Because each gamete contributes only 23 (not 46) chromosomes, the nuclei must fuse to create a full complement of human DNA. The new cell that they form is known as a zygote, from the Greek word meaning "to join." The zygote has half the DNA of the mother and half the DNA of the father (See Figure 1). With a fully intact 46-chromosome nucleus, the zygote begins to prepare for cell division by beginning chromosomal replication.[81] During the process of replication, the DNA from the female and male gametes undergoes a phenomenon known as genetic recombination.

[81] Grace, Eric S. *Biotechnology Unzipped: Promises and Realities*. (Washington, D.C.: Joseph Henry, 2006): 9.

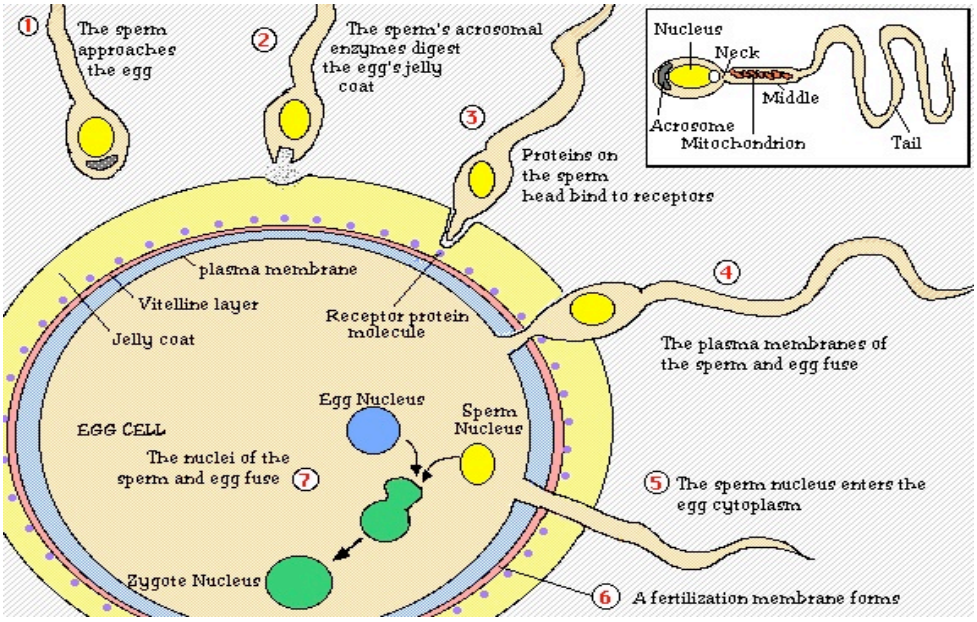

Figure 1: Fertilization

This figure depicts the process of human fertilization. The sperm moves toward and penetrates the egg. It then injects its own nucleus, which fuses with that of the egg, forming a zygote. [82]

During chromosomal replication (when the chromosomes begin to replicate in anticipation of division), the chromosomes of a cell pair up. Sometimes, as these pairings occur, genetic information is transferred from one chromosome to the other or translocated (moved) to another part of the chromosome (see Figure 2). The variations in the location of genetic information along the chromosome account in part for each individual's unique genetic sequence. Throughout the course of an organism's adult life, most cells continue to replicate and reproduce (skin cells for example).

However, sometimes when cells detect that chromosomal mutations (changes in DNA) have occurred that will hamper cell function or the health of the organism they under go

[82] Davidson University. Molecular Biology Bio306, Fertilization. (2005). http://www.bio.davidson.edu/Courses/Molbio/MolStudents/spring2005/Champaloux/fourth.html

apoptosis (cell suicide) or inactivate the cell cycle (reproduction process) in that mutant cell,[83] a feature that is important when weighing the dangers of adult stem cell research.

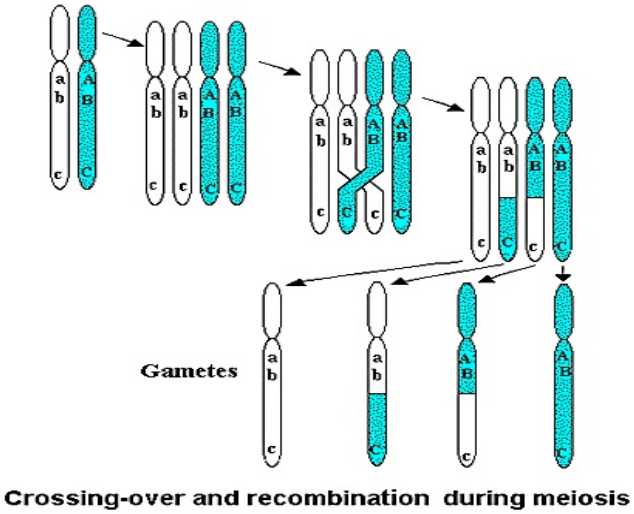

Figure 2: Replication and Recombination

This figure shows the process of chromosomal replication and recombination. The chromosomes pair up in anticipation of cell division. They then replicate, forming copies. During the replication process recombination occurs, and the genes from the blue and white chromosomes switch locations. [84]

After the zygote is formed, it begins to travel down the fallopian tube toward the uterus. Simultaneously, the zygote enters a rapid cycle of mitotic (asexual) cell divisions known as cleavage, during which the cells created (blastomeres) replicate but do not increase the size of the zygote. The embryo, the term for the fertilized cell (between fertilization and its development

[83] Rand, David. "Lecture 4: Mutants Linkage and Recombination." Lecture Biomed 48: Evolutionary Biology. Brown University Biomedal Center Room 139. (Providence, RI) Lecture.

[84] "Crossing Over and Recombination During Meiosis." National Health Museum adapted from Morgan T.H., Sturtevant A.H., Muller H.J., and Bridges C.B., "The Mechanism of Mendelian Heredity." (1915).

into a fetus), on days 3, 4, and 5 divides into 2, 4 and 8 blastomeres, respectively (See Figure 3).

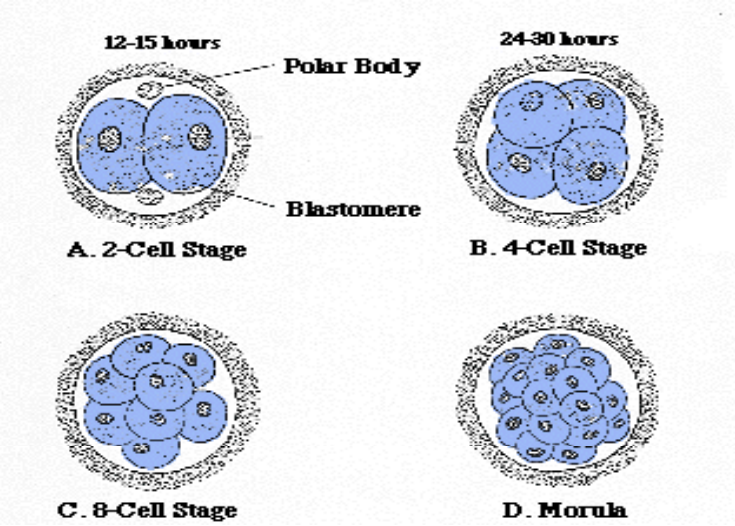

Figure 3: Early Embryogenesis

The figure above shows the early stages of a cleaving mammalian embryo. The embryo first begins to divide, the divisions then become asymmetric, and finally the embryo undergoes compaction and forms a morula.

[85] Blastomeres are totipotent stem cells and, thus, the first group of stem cells that could potentially be used by scientists for hESC research. A stem cell is an un-determined cell that self-renews but also can give rise to other, differentiated cell types.[86]

As development progresses, cells become determined and then differentiated; a process that explains why all the different cells in your body contain the same DNA and yet develop and function differently. Determination means that a cell has received genetic instructions (so-to speak) from various environmental sources such as transcription factors and signaling proteins that commit the cell to a particular fate. After the point of a cell's determination, the cell will carry out its instructions, even if transplanted into a different location. Which stage in the development process stem cells are harvested from dictates how potent they are, i.e. how able they are to form various cell types (how un-determined). Totipotent cells have the highest degree

[85] "Early Embryo, Cleavage, and Blastocyst Formation." http://lifeandloveinthepetridish.blogspot.com/2010/06/ivf-7-day-6-blast-results.html

[86] Appendix A: Early Development . In *Stem Cell Information*. (Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2009).

of pliability. They can form any cell in the human body.[8788]

Following the 8-cell stage, the embryo begins to change form. It becomes a blastocyst around day 5, a structure with a hollow center cavity, a collection of cells known as the inner cell mass and a collection of cells that ring the cavity know as the trophoblast. Cells of the inner cell mass will go on to form the embryo proper, while cells of the trophoblast will develop into the extra-embryonic membranes (placenta, amniotic sac, etc). Cells of the inner cell mass are pluripotent stem cells, meaning that they have the potential to form some, but not all, cell types. This is the most common stage from which scientists remove stem cells from the embryo. Back inside the mother, the embryo continues to move toward the uterus, finally implanting in the uterine wall approximately 8-9 days post-fertilization. Between 8 and 9 days post-fertilization the inner cell mass differentiates into the epiblast and the hypoblast.

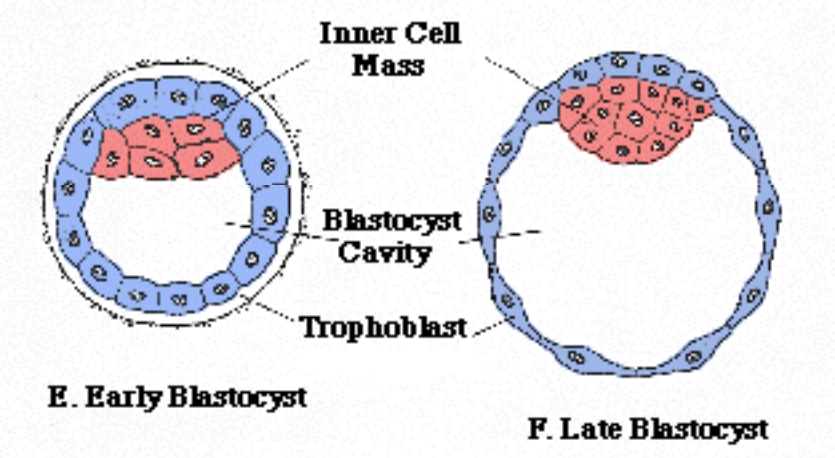

Figure 4: Blastocyst Formation

Figure 4 depicts a blastocyst both in the early and late stages of development. The figure clearly displays the inner cell mass, the trophoblast, and the blastocyst cavity. Researchers use the pluripotent

[87] Please note the sections cited in the endnotes pertain specifically to mouse development. However, for our general knowledge purposes, this information is both parallel to human development and sufficient.

[88] Wolpert, Lewis. *Principles of Development*. 3rd ed. (New York: Oxford UP, 2007). Sections 3.4,3.9,3.10,3.12,3.13, 3.20

> stem cells of the inner cell mass most often for embryonic stem cell research. [89]

On approximately the 15th day post-fertilization, the cells within the embryo differentiate into 3 germ layers, cells in each of which are beginning to differentiate to a particular fate: endoderm (the gut), mesoderm (muscle, bone, heart, lungs etc.) and ectoderm (skin, hair, nervous system etc.).[90] Differentiation is when physical changes occur in the shape and intra-cellular environment that make cells *terminally* (at least in humans) different from one another and committed to a particular fate.

While embryonic stem cells arise anywhere between 2 and 7 days post fertilization researchers can harvest human germ stem (hEG) cells between 5 and 8 weeks into the development process from the gonadal ridge. These germ stem cells are pluripotent. The transfer from the embryonic to the fetal stage of development occurs approximately 8 weeks post-fertilization. All of the major organ systems will have finished developing by the end of the embryonic stage and by the first week of fetal development, all will have begun functioning. Fetal stem cells can be obtained from aborted fetuses during any point in fetal development. These stem cells are found in the fetal blood, pancreas and neural tissues.[91]

Finally, it is important to note that stem cells continue to live and work in the adult human throughout its lifetime. Stem cells can be found in the blood, organ linings, skin, muscle, bone, and neural tissues. These stem cells are differentiated in so far as they only create specific cell types. For example, hematopoietic stem cells give rise to both bone marrow and peripheral blood cells but cannot produce muscle or neural cells because the signaling proteins that

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[89] "Early Embryo, Cleavage, and Blastocyst Formation." http://lifeandloveinthepetridish.blogspot.com/2010/06/ivf-7-day-6-blast-results.html

[90] Appendix A: Early Development . In *Stem Cell Information*. (Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2009).

[91] Ibid. 1-13.

hematopoietic stem cells produce are different than those required by muscle or neural cells. These stem cells do, it seems, have a lifespan.[92] Research with adult stem cells have shown that they cease division (exit the cell cycle) much sooner than stem cells harvested from earlier periods of development.[93]

Potency

Stem cells can be found in the human body at all stages of development, from embryo to adult. However, not all stem cells are created equal. Research has shown that as stem cells age, they lose some of their plasticity, or potency, as it is referred to in the scientific realm. The youngest stem cells, embryonic, are totipotent. This means that they can create any cell, including a germ cell or the cells that make up the extra-embryonic membranes (EEMs). Germ, fetal, umbilical, and certain embryonic stem cells are all known as pluripotent, meaning they can give rise to any cell in the three germ layers but do not have the ability to form EEMs. Finally, later stage stem cells such as those obtained from adults often have much narrower potentials; they are only multi-potent, meaning that those obtained from bone marrow, for example, are limited to the formation of blood cells. Each type of stem cell has its own benefits and its own detriments. While adult stem cells are hard to find, cannot differentiate widely, and stop replicating sooner, it is easier to predict how they will differentiate. While embryonic stem cells have the greatest amount of plasticity, they involve obtaining and destroying an embryo and researchers have yet to truly harness their developmental capabilities. The great advantage to using early stage stem cells (umbilical, fetal, or embryonic) is that they seem to replicate for

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[92] Stem Cell Basics: What are the similarities and differences between embryonic and adult stem cells? . In *Stem Cell Information*. (Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2011).

[93] Silva, H. and Conboy, I.M., "Aging and Stem Cell Renewal." StemBook, ed. The Stem Cell Research Community, *StemBook* 15 July (2008). http://www.stembook.org.

longer amounts of time, as opposed to adult stem cells, which only replicate for a short amount of time before they exit the cell cycle permanently.[94] Using adult stem cells in research is ill advised because adult cells run a greater risk of having been exposed to mutations, morphogens, or carcinogens over the course of one's life that could seriously affect their productivity and safe use.

Types

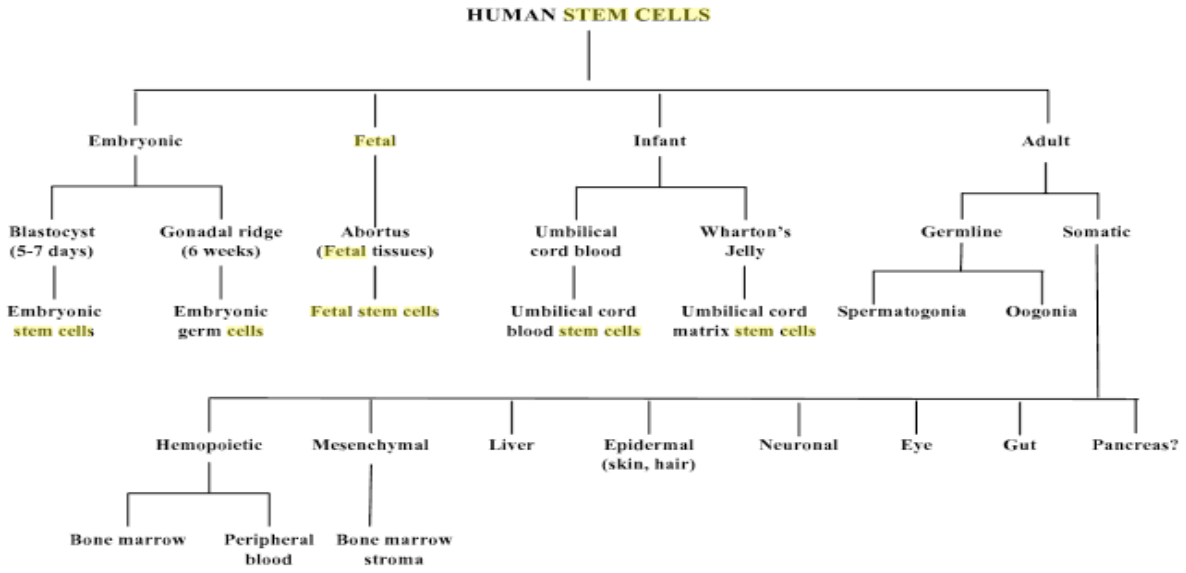

Figure 5: Stem Cell Types

The figure above serves to highlight most of the various types of human stem cells. There are, however several types of stem cells that are not included on the chart most notably include totipotent cells derived from a compacted morula, those formed by somatic cell nuclear transfer, and induced pluripotent cells.[95]

Stem cells come in several different levels of potency and from several different sources as demonstrated above in Figure 5. In order to fully appreciate the stem cell debate, which

[94] "What Are Stem Cells?" *Library of Congress Home*. 23 Aug. (2010).
[95] Bongso, Ariff, and Eng H. Lee. "Stem Cells: Their Definition, Classification, and Sources." *Stem Cells: From Bench to Bedside*. (Hackensack, NJ: World Scientific, 2005): 4

revolves mainly around embryonic and fetal stem cells one must be familiar with some of the alternatives.[96]

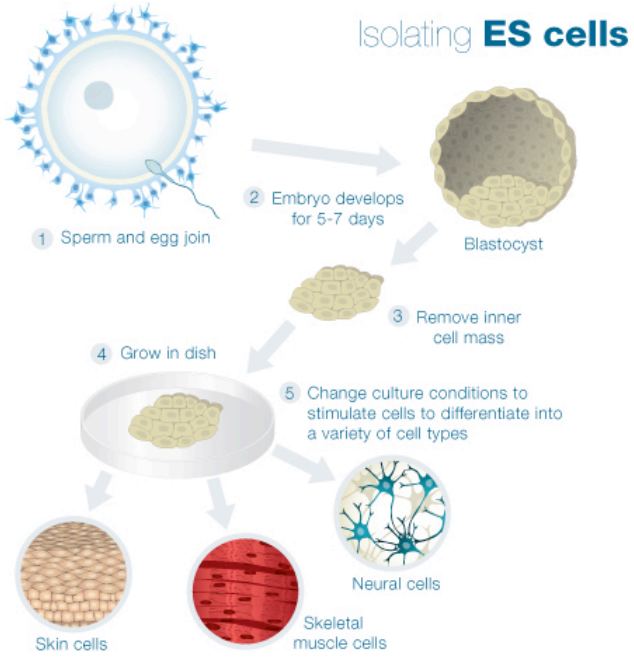

Figure 6: Isolating Embryonic Stem Cells

The figure above demonstrates generally where embryonic stem cells are derived from and the cells they subsequently form.

[97] 1) The earliest form of stem cell is the hES or human embryonic stem cell. This stem cell is totipotent: it has the potential to give rise to every cell in the body, including EEMs such as the placenta. Totipotent cells are difficult to obtain because they are few in number. You may only obtain totipotent hES cells from a zygote or an embryo in (up to an 8 cell-stage embryo) cleavage. Scientists would, in the case of the 8 cell-stage embryo, separate the 8 stem cells and use each to create a unique stem line. Embryonic stem cells can be obtained from naturally fertilized or IVF embryos.

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[96] "What Are Some Different Types of Stem Cells?" *Learn.Genetics™*. (The University of Utah and National Institutes of Health, 2002). and "Stem Cell Quick Reference." *Learn.Genetics™*. (The University of Utah and National Institutes of Health, 2011). and Lakshmipathy, Uma, Jonathan D. Chesnut, and Bhaskar Thyagarajan, eds. *Emerging Technology Platforms for Stem Cells*. (Hoboken: John Wiley and Sons, 2009), and Bongso, Ariff, and Eng H. Lee. "Stem Cells: Their Definition, Classification, and Sources." *Stem Cells: From Bench to Bedside*. (Hackensack, NJ: World Scientific, 2005): 1-13.

[97] Genetic Science Learning Center. "Stem Cell Quick Reference." Learn.Genetics 9 Feb. (2011).

2) The second type of human stem cell, also known as the hES cell, comes from slightly later in the developmental process—those derived from the blastocyst. As the human embryo develops, it takes the shape of a sphere with a hollow center and a dense mass at one end. That dense tightly packed group of stem cells is known as the inner cell mass displayed in Figure 6 (right). This mass will give rise to the embryo. Also located within the blastocyst is the trophoblast, a series of cells lining the blastocoel that have the exclusive ability to give rise to EEMs such as the placenta. Stem cells derived from the blastocyst stage cannot give rise to extra-embryonic membranes and are therefore pluripotent.

3) A third type of stem cell is the human embryonic germ cell (hEG). HEG cells are taken from the gonadal ridge of the developing embryo between 5 and 7 weeks post fertilization. HEG cells are pluripotent but are not frequently used by stem cell researchers, due to the difficulty of harvesting them. Harvesting hEG cells does not require the destruction of the embryo.

4) A fourth type of stem cell is the fetal stem cell. After approximately 8 weeks of development the blastocyst becomes known as a fetus. Fetal stem cells are derived from various fetal tissues. Scientists obtain multipotent fetal stem cells from aborted fetuses.
Using tissues from aborted fetuses is an extremely controversial topic, as is (even more so) the concept of creating a fetus strictly for research purposes.

5) Finally, for our consideration purposes, are adult stem cells. Such cells can be found in many different areas of the body. Anyone who has ever broken a bone or donated blood knows that cells regenerate damaged tissues and the wound “heals.” An organic system like our skin could not function without the constant regeneration of epidermal cells, considering we shed

over 5 million skin cells a day.[98]Adult stem cells are found in many places but have, undergone differentiation. For example, a human adult muscle stem cell would not, of its own accord, produce skin cells; it will always create new muscle cells when induced. Whether scientists can manipulate adult stem cells to make them pluripotent is an important factor in the stem cell debate.

6) As recently as 2007, scientists discovered a new way to create pluripotent stem cells: by reversing the differentiation process in somatic cells. Think, for example, of a newt. When a newt loses its tail or leg, a stump known as a blastomere forms. From this blastomere, a new limb grows. This is possible because of reverse differentiation. To form a limb the cells of the limb must differentiate. Differentiation involves changes in the cell shape and internal chemistry. Therefore to *re-grow* a limb, a newt must reverse or overcome what was always considered *terminal* differentiation. Researchers have discovered a set of 4 genes that are active in stem cells but not in differentiated cells. By activating and inhibiting certain genes via a complex cocktail of reprogramming factors, as seen above in Figure 8, scientists succeeded in reversing the fate of terminally differentiated cells in mice. This technique was later successfully used in 2008 to create induced pluripotent cells from human somatic cells.[99]

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[98] Most of this cell replacement comes from cell division of already determined skin cells. However in cases of severe damage epidermal stem cells also contribute to healing.

[99] Bongso, Ariff, and Eng H. Lee. "Stem Cells: Their Definition, Classification, and Sources." *Stem Cells: From Bench to Bedside*. (Hackensack, NJ: World Scientific, 2005): 8.

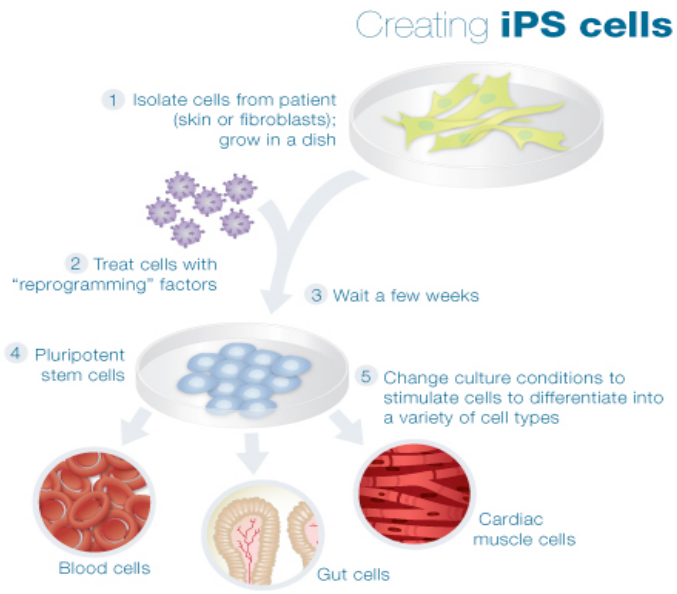


Figure 7: Procedure for creating iPS cells

The above diagram explains, very basically, the process of creating iPS cells from previously determined somatic cells. The cells are collected, exposed to reprogramming factors and allowed to interact, causing them to regain potency. [100]

Method

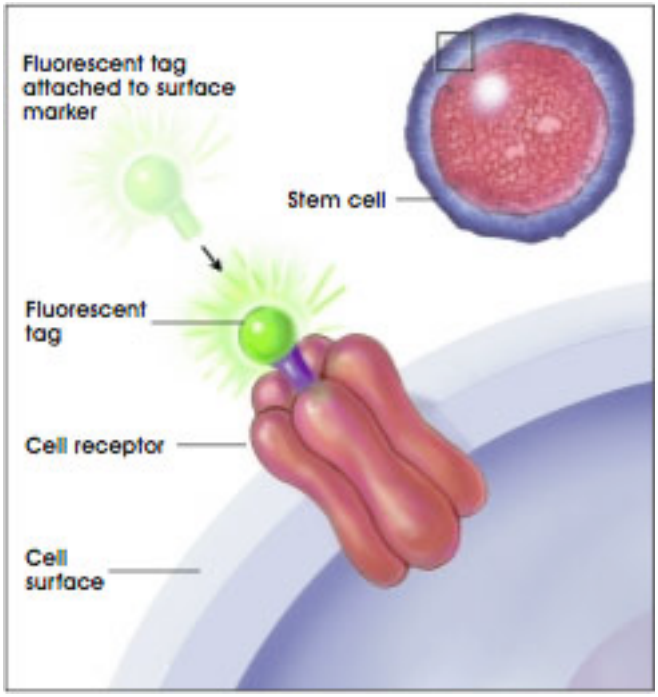
The amount of time and precision required to create a stem cell line is important to the stem cell debate and the marketability of stem cells as an FDA approved therapy. Often unsuccessfully, scientists follow a series of techniques to make one stem cell reproduce and form millions of undifferentiated offspring. The process, however, is far from simple, and provides multiple opportunities for failure. While the techniques have changed slightly in the last few years they largely remain the same and are detailed very basically here:

Pre-implantation human embryonic stem cells are isolated from IVF embryos and spread over a medium in a Petri dish. The inner surface of the Petri dish culture contains a feeder layer of mouse embryonic skin cells that cannot divide. The purpose of the mouse cells is to give the

[100] Ibid.

stem cells a surface to latch onto as well as to release nutrients into the medium.[101] Not all plated stem cells survive, in fact many die, differentiate, fail to reproduce, or develop genetic abnormalities. Those that reproduce without mutations form daughter stem cells, which spread out and cover the Petri dish. The cells are then separated, re-plated, and subcultured. This is the beginning of a cell line but only after the cells have undergone many "passages" or re-platings are they known as an "embryonic stem cell line." [102]

Figure 8: Fluorescent Tagging



The above figure is a diagram from the National Institutes of Health, which depicts a stem cell marker and the florescent tagging technique that researchers may use to identify a stem cell.[103]

Determining that the offspring of the original stem cells are also themselves stem cells is difficult. Scientists must rigorously test to be assured that the offspring meet "stem cell requirements." One of the primary tests that scientists perform is visual; the cells must, under the microscope, appear healthy and undifferentiated. The cells must also produce the proper transcription factors, proteins that regulate gene activity, (such as Oct4 and Nanog), which maintain the undifferentiated state of a stem cell.

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[101] Lakshmipathy, Uma, Jonathan D. Chesnut, and Bhaskar Thyagarajan, eds. *Emerging Technology Platforms for Stem Cells*. (Hoboken: John Wiley and Sons, 2009): 11.
[102] Ibid, 20-21.
[103] Winslow, Terese. (2001). via Appendix E: Stem Cell Markers . In *Stem Cell Information*. (Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2009).

Scientists look for "markers" found on embryonic stem cells using florescent tags. These tags are specially programmed to only adhere to stem cell markers. Using florescent tags, scientists can separate stem cells from other types of cells. This works by feeding the group of cells through a needle, one cell at a time. A laser then assigns electronegativity to those cells with the florescent protein. The electronegative stem cells are then pulled, magnetically, into a container, while the rest of the cell types continue onto a separate refuse container.[104]

Daughter stem cells' chromosomal arrangements must remain undamaged when compared to the mother cell. The cells must be able to be re-grown after being exposed to manipulations such as freezing and re-plating. Finally, the cells must be pluripotent. Scientists test potency by inducing differentiation and watching to see if a cell forms each of the three germ layers (endoderm, mesoderm, and ectoderm). Alternatively, scientists may inject an immunosupressed mouse with the offspring cells and then search for a teratoma. Teratomas are cystic tumors that contain 1 or more germ layers. The presence of a teratoma indicates the ability to differentiate.[105]

Differentiation is induced when stem cells are allowed to group together, causing a cluster effect to take place and embryonic bodies to form, which then self-induce into neuron bunches, muscle cells etc. However, by merely allowing cells to cluster, scientists have no way of knowing which differentiated cells the stem cells will form. In an effort to eliminate this inefficient method of differentiation, scientists are attempting to perfect a new technique known as directed differentiation. Directed differentiation is exercised when scientists alter the medium

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[104] Appendix E: Stem Cell Markers . In *Stem Cell Information.* (Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2009). And Lakshmipathy, Uma, Jonathan D. Chesnut, and Bhaskar Thyagarajan, eds. *Emerging Technology Platforms for Stem Cells*. (Hoboken: John Wiley and Sons, 2009): 56.

[105] Ibid, 56.

or the chemicals that the stem cells are exposed to in an effort to obtain specific desired types of differentiated cells. Directed differentiation is an emerging technique but, if perfected, may be another step in the direction of treating degenerative diseases such as Parkinson's, MD, and heart disease. [106]

Political Playing Field

The political debate surrounding stem cell research is just a small branch of a recent historical phenomenon known as biopolitics. The term biopolitics has several meanings and definitions that it has acquired over time and so at this time I should qualify that I use biopolitics according to Somit's fourth approach to the concept: "issues of public policy raised by advances in biology."[107] Ethicist Jonathan D. Moreno writes, "seen in the light of other incidents, and cultural and political factors, the torturous tale of hESC research in the United States is but a more emphatic example of an emerging 'biopolitics'.[108] While the author goes on to argue that modern biopolitics emerged in the 1970s with the recombinant DNA debate, true biopolitics dates back to World War II. When the government began contracting with universities, demanding new military technologies in exchange for work, pay, and the chance to pursue interesting scientific research (thus beginning in earnest the military-industrial-academic complex), it changed the way politics and science interact.[109] Science came to depend upon government funding and through those funds progressed in leaps and bounds. Politicians discovered that the projects they chose to fund, more often yielded promising results and those

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[106] Ibid p 204, Stem Cell Basics: Introduction. In *Stem Cell Information*. (Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2009).
[107] Somit, Albert. "Biopolitics" *British Journal of Political Science* 2: 2 April (1972): 210.
[108] Moreno, Jonathan D., John M. Nolan, Patrick M. Taylor, Emad U. Samad, Suy Anne R. Martins, and Stephen G. Brozak. "Long Shadow of the Stem-cell Ruling." *Nature* 467 (2010): 1031-033.
[109] Clark Northrup, Cynthia. *The American Economy: A Historical Encyclopedia* 1 (Library of Congress, 2003): 186.

projects that were not well funded went nowhere. So an interdependent relationship developed;[110] scientists relying upon politicians for work, and politicians on scientists for results on the coat tails of which they could ride safely through reelections. Politicians slowly began incorporating scientific technologies into their platforms, some vowing to stop them and others to fund them. The stem cell battle is largely divided down common political lines; social liberals want it while social conservatives do not. The Right to Life movement, which sprung to life in the heat of biopolitical abortion debates of the past two decades, is a staunch opponent of hESC research. Stem cell lobbyists and proponents fear the loss of invaluable time, money, and resources while stem cell opponents fear the loss of moral accountability, and damage to the very definition of humanity. And so, just as the nuclear bomb, organ transplantations, recombinant DNA research, IVF, contraceptives, and abortion all faced their time at the crux of biopolitical battles, so too does stem cell research.

In 1993, Congress and President Clinton made history via the National Institutes of Health Revitalization Act, which gave the NIH direct authority to fund human embryo research for the first time. The NIH established a panel of scientists, ethicists, public policy experts, and patients' advocates to consider the moral and ethical issues involved in embryonic stem cell research and to determine which experiments should be eligible for federal funding. In 1994, this NIH Human Embryo Research Panel made its recommendations—among them, that research involving the destruction of "extra" embryos from fertility clinics with the express purpose of obtaining stem cells, should be eligible for federal funding.[111]

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[110] Forman, Paul. "Behind quantum electronics: National security as basis for physical research in the United States, 1940-1960." *Historical Studies in the Physical and Biological Sciences.* 18:1. (University of California Press, 1987):149-229.

[111] Dunn, Kyla. "The Politics of Stem Cells." *NOVA: The Politics of Stem Cells*. 1 Apr. (PBS, 2005).

However, the new era of government funded stem cell research was not to last. In 1995, Congress shifted to a Republican majority. Shortly thereafter in 1996 Republican Representatives Jay Dickey and Roger Wicker drafted a rider which they attached to P.L. 104-99 in section 128. The rider, which has been attached to every Labor, HHS, and Education appropriations act since that time, remains largely the same. It precludes human embryonic stem cell research from receiving federal funding. The original text states:

> SEC. 128. None of the funds made available by Public Law 104–91 may be 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 on fetuses in utero under 45 CFR 46.208(a)(2) and 42 U.S.C. 289g(b).[112]

The statute then goes on to define a human embryo as any organism that is not protected as a human subject but is derived from of one or more human gametes and is created by fertilization, parthenogenesis, cloning or any other method involving gametes. However, the evolving sophisticated techniques of research may one day provide a loophole by creating an embryo through reverse differentiation or currently unknown techniques. [113]

In 1998 James Thomson of the University of Wisconsin and John Gearheart at Johns Hopkins University successfully created the first human embryonic stem cell lines (groups of cells all deriving from the same origin). In 1999 the Clinton administration's legal counsel found a loophole in the Dickey-Wicker Amendment: While national funds could not be given to labs

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[112] Balanced Budget Downpayment Act, I, Pub. L. No. 104-199, § 128, 1.10 Stat. 34 (first enactment of Dickey-Wicker amendment), (1996).

[113] "Cloning: Dickey Wicker Amendment." *Genetics and Public Policy Center*. (The Johns Hopkins Genetics and Public Policy Center, 2010).

that derive human stem cells from embryos (thereby destroying the embryos), they could certainly fund the labs that experimented with the stem cells themselves. Therefore funding could, and did, go toward embryonic stem cell research.[114] Meanwhile the NIH worked to set up ethical frameworks within which stem cell researchers would be required to operate in order to receive funding.

When President George W. Bush took office in January of 2001, he ordered the NIH to cease funding all hES research, pending a government review of the Clinton legal decision. In addition he ordered the NIH to stop reviewing grant applications for researchers hoping to pursue stem cell research. On August 9, 2001 Bush stated in his first nationally televised presidential address that, in an effort to discourage the destruction of any further human embryos, he was limiting government funding to the 22 already existing human stem cell lines;[115] any lines produced after that date would not be eligible for funding.[116] Those lines, which became known as the Presidential stem lines, were, many scientists believed far from sufficient to allow stem cell research to progress to its full potential.

Representatives and Senators from both sides of the table urged President Bush to reconsider and expand the number of embryonic stem cell lines that he would agree to fund.[117] In 2004 the State of California passed Proposition 71, which allocated 3 billion dollars to the

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[114] Ibid.

[115] Scientists were concerned that embryonic stem lines that came into contact with the mouse cells might be contaminated. All 22 Presidential stem lines were cultured using mouse epithelial cells and so, for many years, the only ESC lines that researchers could experiment with were potentially contaminated.

[116] Bush, George. "Position on Stem Cell Research." Crawford, TX. 9 Aug. (2001) via Washingtonpost.com

[117] Office of Legislative Policy and Analysis. 107th Congress. http://olpa.od.nih.gov/legislation/107/pendinglegislation/15stem.asp.

funding of hESC research.[118] Nobel Laureates threw their names and support behind Democratic presidential challenger John Kerry, citing Bush's interference with stem cell research as their motivation. Even President Bush's own NIH director testified before Congress that reversing the policy would benefit scientific progress. In 2005 and again in 2006 a bipartisan bill that would lift the federal ban on new lines passed in both the Senate and the House but was vetoed by the President.[119] On June 20th 2007, President Bush issued Executive Order 13435 which granted the NIH permission to resume reviewing grants and to allocate federal funds to researchers promising to use "ethically responsible techniques" to study hESCs. In addition, Bush prohibited the funding of projects that would destroy or harm embryos or obtain them from labs that did.[120]

When President Barack Obama took office in 2009 he repealed Bush's executive order with an executive order of his own. Executive order # 13505 removed most of the Bush moratoriums, though it still prohibits the funding of "cells or of ESCs derived from embryos created for research purposes."[121] In addition, although the Obama administration made eligible for funding those stem cells that were to be discarded by IVF clinics, it must still abide by Dickey-Wicker. However with Obama's Executive Order the floodgates opened and government money began to pour into hESC research. In 2009 the FDA approved the first hESC clinical trial, which uses an embryonic stem cell derived therapy for patients with spinal cord injuries.[122]

The most recent chapter of the saga began on August 23, 2010 when Federal Judge Royce C. Lambert issued a preliminary injunction against federal funding of hESC research on

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[118] Robertson, John A. "Emrbyo Stem Cell Research: Ten Years of Controversy." *Law, Medicine, and Ethics* 38.2 (2010):196

[119] Dunn, Kyla. "The Politics of Stem Cells." *NOVA: The Politics of Stem Cells*. 1 Apr. (PBS, 2005). <http://www.pbs.org/wgbh/nova/body/stem-cells-politics.html>.

[120] Exec. Order No. 13435, 3 C.F.R. (2007).

[121] Exec. Order No. 13505, 3 C.F.R. (2009)., Robertson, John A. "Emrbyo Stem Cell Research: Ten Years of Controversy." *Law, Medicine, and Ethics* 38.2 (2010): 196.

[122] Ibid, 191.

the grounds that it violated Dickey-Wicker. The judge claimed that "If one step or 'piece of research' of an E.S.C. research project results in the destruction of an embryo, the entire project is precluded from receiving federal funding,"[123] On September 9th, 2010 a federal appeals court in Washington DC overturned the injunction, a decision that was again upheld on September 28th of the same year. However, the reality that hESC research can be discontinued so suddenly shows all to clearly the danger political interferences pose to scientific progress.[124]

Federal oversight however is a different matter. Whether IRBs are qualified or even have the right to make decisions regarding hESCs is debatable. After all, the human embryo, much like the human fetus, is not according to the law, a viable human subject. IRBs were created to review all research proposals involving human subjects. Therefore embryo related research might fall outside of their jurisdiction. The National Research Council Institute of Medicine of the National Academies created, in 2005, a report entitled of Guidelines for Human Embryonic Stem Cell Research. These guidelines have been accepted by most major research institutions in the United States and by the states as they have begun to deal in hESC regulation. The committee established ethical guidelines that became the standard for stem cell researchers, universities and institutions.

ESC guidelines dictate: 1) all major institutions should create Embryonic Stem Cell Research Organizations (ESCROs) composed of both public citizens and scientific experts in a number of fields; these committees will be responsible for determining the ethical permissibility of hESC research 2) IRBs will be responsible for assuring adherence to informed consent laws as well as procurement methods 3) the establishment of stem cell line banks should be undertaken

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[123] Harris, Gardiner. "U.S. Judge Rules Against Obama's Stem Cell Policy." *The New York Times.* 23 Aug. (2010) sec. A: 1.

[124] Harris, Gardiner. "Stem Cell Financing Ban Ends, For Now." *The New York Times.* 10 Sept. (2010), sec. A: 14.

with meticulous documentation 4) a national body should be established to review, revise and oversee these guidelines.

Since that time the National Academies have updated their guidelines several times. Additionally, the NIH has become involved in the development of oversight. The NIH issued its own set of hESC guidelines in July 2009 and has since created a committee to review and select stem cell lines that are eligible for federal funding (those in adherence with Dickey-Wicker). The NIH guidelines only apply, however, to those researchers receiving federal funding. As such, the National Academies have revised their own guidelines to be used in tandem with the new NIH guidelines, in an effort to regulate all hESC research.[125]

Part III

The Great Debate:

The stem cell research debate is nearly as complicated as the technical procedures involved in the research itself. On one side there are radical conservatives, on another are radical liberals and in between, the rest of us find ourselves wading through the inconsistencies of federal and state laws, media reports, moral justifications, false promises, and doomsday scenarios. Not only are politicians politicking, but also religious leaders are pushing from their pulpits, scientists from their lab benches, ethicists through their writings, lawyers and judges from the courts, and academics from their classrooms. The goal of this section will be to present and refute all of the arguments against stem cell research as I see them. I support the use of fetal and embryonic stem cells as well as the creation of stem cells for research purposes. Official opponents of stem cell research include the Roman Catholic Church, the National Association of

[125] *Final Report of the National Academies' Human Embryonic Stem Cell Research Advisory Committee and 2010 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research*. (Washington, D.C.: National Academies, 2010).

Evangelicals, the Southern Baptist Convention (which, it should be noted, does not represent the sentiments of all Baptists), the National Right to Life Committee, and an assortment of politicians, theologians, and pro-life supporters. Those encouraging the research include, notably, all denominations of Judaism, the Presbyterian Church, the United Church of Christ, the Methodist Church, the Alzheimer's Association, The Christopher Reeve Foundation, The Michael J. Fox Foundation, The National Parkinson Foundation, and various scientists, pro-choice advocates, and politicians.[126]

The state of debate in the U.S. is so convoluted that it is hard to determine what existing federal laws permit and prohibit. Roe v. Wade rules that the State does not have a compelling interest to override a woman's right to privacy until the 24th week of pregnancy. President Bush's 2004 Unborn Victims of Violence Act allows for any "child in utero" to be considered a legal victim if injured or killed during a federal crime of violence. The act then goes on to define a child in utero as a member of the *Homo sapiens* species, at any stage of development that is carried in the womb. These contradictory laws make it legal for a woman to abort her fetus up until 24 weeks and simultaneously give the fetus and the embryo (at any point in development) full legal human rights of protection.[127] In addition, 35 states in the United States have unborn victim homicide laws.[128] It seems, that according to federal and the majority of state laws, mothers are given an exception to commit legal homicide. One might question why it matters who terminates a fetus or embryo if the result is the same; why it is sometimes murder and other

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[126] "Religious Groups' Official Positions on Stem Cell Research." *Pew Forum on Religion & Public Life*. 17 July (Pew Research Center, 2008). <http://pewforum.org/Science-and-Bioethics/Religious-Groups-Official-Positions-on-Stem-Cell-Research.aspx>.

[127] Unborn Victims of Violence Act aka Lacy Peterson's Law. H.R. 1997, 108 Cong. (2004) (enacted).

[128] "State Unborn Victim Laws." National Right to Life Committee, 25 Feb. (2011). <http://www.nrlc.org/Unborn_victims/Statehomicidelaws092302.html>.

times abortion. This is a compelling commentary on the state of existing federal laws and their contradictions. It exemplifies the desperate need for a clear definition of human personhood and, further, the dangers of political inconsistencies with regard to scientific policies.

Fetal Stem Cells

The first controversy that we will discuss surrounds fetal stem cells—stem cells taken from fetal tissue of aborted fetuses. Parameters set forth by the 1998 Human Fetal Tissue Transplantation Research Panel[129], dictate that the decision to abort a fetus must occur separate from the decision to donate fetal stem cells. Therefore the ethics of fetal termination should not be considered when deciding the ethical permissibility of harvesting fetal stem cells. These fetuses, which otherwise would be disposed of, have no potential for development or growth at the time of harvesting because they are slated for destruction.[130] Additionally, fetuses are, quite literally under the law, the biological property of the women who carry them and as such the women have exclusive decision-making rights over the fetus.[131] Further, a mother may decide to donate the fetus' stem cells without legal qualms, as she is the individual charged with making medical decisions on the fetus' behalf.

However, for those like Catholic theologian Richard McCormick who are uncomfortable with biomaterialism and therefore believe "that the fetus is a fellow human being and ought to be

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[129] National Bioethics Advisory Commission. *Ethical Issues in Human Stem Cell Research*. (Rockville, MD: National Bioethics Advisory Commission, 1999): 46.

[130] We will revisit the notion of potential development later in the paper when discussing embryonic potential.

[131] This is the moral consequence of Roe v. Wade, which overrides the States ability to prohibit abortions. In the Roe v. Wade decision the Courts acknowledge that fetuses do not have the same legal rights as born persons and, more, that a woman may choose to terminate her fetus, if for any reason she does not wish to carry the pregnancy to term.

treated…exactly as one treats a child,"[132] John Robertson at UT Austin law school, has the answer. Robertson draws a comparison between fetal stem cell donation and harvesting organs from a murder victim. While Robertson concedes too easily that the degree of humanity is the same between an adult and a fetus, a fact I am admittedly uncomfortable with, his argument works well here. Robertson argues that, even if you staunchly oppose abortion and hESC research on the grounds that life begins at conception, you cannot oppose fetal stem cell use. Doing so, he contends, is like arguing that you should refrain from taking organs from a murder victim.[133] While the death of the murder victim is a tragedy, if the victim's family consents to the donation of his organs so that some good may come of his death, who could claim it is unethical?

The National Bioethics Advisory Commission's 1999 report on the ethical questions raised by stem cell research addresses the concern that fetal stem cell donations would, through indirect causal responsibility, attribute an unacceptably positive outcome to abortion procedures. "Some argue that the benefits achieved through the routine use of fetal tissue will further legitimize abortion and result in more permissive societal attitudes and policies concerning elective abortion."[134] There are two responses to this concern: 1) abortion itself carries an innate series of benefits that women deem sufficient to warrant termination and 2) allowing the donation of fetal stem cells will only add an additional benefit to a long list of those already in existence.

The monetary gains made by physicians who perform abortions should be considered a

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[132] McCormick, R. *Experimentation on the fetus: Policy proposals*. (1976). via Appendix to *Report and Recommendations: Research on the Fetus.* National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (Washington, D.C)

[133] Robertson, John A. "Ethics and Policy in Embryonic Stem Cell Research." *Kennedy Institute of Ethics Journal* 9: 2 (Johns Hopkins University Press, 1999): 109-136. via *The Stem Cell Controversy: Debating the Issues*: 136-38.

[134] National Bioethics Advisory Commission. *Ethical Issues in Human Stem Cell Research*. (Rockville, MD: National Bioethics Advisory Commission, 1999): 46.

positive outcome of abortion. The physician experiences a logically good outcome both by making money and, in some circumstances, by helping a woman out of an unwanted pregnancy. Additionally, the physician's compensation may influence him or her to perform abortions more often. However, surely no one would argue that physicians performing abortions should not be compensated. Similarly, there is always a set of circumstances that cause a woman to consider abortion in the first place: she does not want her body to change, is enrolled in school, the father has no money to pay child support, the conception was an accident to begin with, she is in a life-threatening situation, the fetus is discovered to have a terrible disease or disfiguration, she was raped etc. In all of these situations, the woman considers having an abortion for concrete logical reason(s). By terminating her pregnancy the woman is liberated to continue living her life as planned and, thus, a good outcome is achieved. Individual benefit must inherently come of this decision, as rational beings are naturally inclined to make decisions in their own self-interest.[135]

NBAC argues further that the decision to pursue a career might just as easily be the tipping point for a young woman deciding if she should have an abortion. However the solution is not to prohibit women from having careers.[136] Stem cells are no different. If a woman has decided to abort her pregnancy, then she has already determined that the benefits to herself, her health, and her life, outweigh the act of termination. Once that decision is made, there is no additional harm in having a physician or researcher ask if she would donate the fetus' stem cells to research.

If one looks at the abortion statistics in the United States today, one would find that an overwhelming majority of procedures are performed on women under the age of thirty. In 2008,

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[135] Christensen, Robert J. "The Nature of Decision Making." *Journal of Cooperative Extension* Spring (1968): 23-28.

[136] National Bioethics Advisory Commission. *Ethical Issues in Human Stem Cell Research*. (Rockville, MD: National Bioethics Advisory Commission, 1999): 47.

1.21 million abortions were performed and in 2010 18% were performed on teenagers, 33% in women in their early to mid twenties, and 24% in women in their mid to late twenties.[137] These statistics indicate that a large percentage of women who decide to terminate their pregnancies are young. The numbers could indicate that social attitudes and preparedness are the factors that explain the age gap. In fact, according to the Guttmacher Institute:

> "The reasons women give for having an abortion underscore their understanding of the responsibilities of parenthood and family life. Three-fourths of women cite concern for or responsibility to other individuals; three-fourths say they cannot afford a child; three-fourths say that having a baby would interfere with work, school or the ability to care for dependents; and half say they do not want to be a single parent or are having problems with their husband or partner."[138]

In addition, there have thus far been no statistics that indicate that permitting fetal stem cell donations increases abortion rates. While, as NBAC says, it is impossible to prove that stem cell donation will *never* be the tipping point for conflicted pregnant women, it is no different from the other social criteria that weigh into the decision to abort (job, age, ambition, finances, education, etc.). We do not try to mitigate the other social circumstances that affect a woman's decision-making process. Therefore, if we outlaw fetal stem cell harvesting on the basis of not wanting to assign a positive outcome to abortion, we are also ethically obligated to mitigate *all* of the social factors that might weigh into the decision to terminate, a proposal that is simply not possible.

Finally, some might argue that fetal stem cells are not the mother's to donate but again I would turn to Robertson's comparison to organ donation. For a moment, we can assume that the

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[137] Jones RK, Finer LB and Singh S, *Characteristics of U.S. Abortion Patients, 2008*. (New York: Guttmacher Institute, 2010).

[138] Finer LB et al., "Reasons U.S. Women Have Abortions: Quantitative and Qualitative Perspectives." *Perspectives on Sexual and Reproductive Health*, 37:3. (2005): 110–118.

fetus is a human person equal to an adult. Even if such a claim were true, Next of Kin laws dictate that parents may make medical decisions for their incapacitated children including a) terminating life support thereby letting the individual die and b) donating the organs of the individual to other needy patients or research.[139] One could argue that, in keeping these two scenarios parallel, the mother has made the decision to terminate her fetus' life sustaining treatment and is also entitled to donate her fetus' stem cells to research. The mother, like the relative of a dying patient, assumes decision-making power for the fetus and as such can decide if donating fetal stem cells is permissible or not.

Fetal stem cell donations would not be problematic, except for their association with abortion, which remains a contentious issue. Fetal stem cells are biomaterials obtained from the tissues of aborted fetuses. However, harvesting fetal stem cells from a fetus is done once the fetus is removed from the womb, indicating that all the mechanisms the fetus requires to survive (the placenta, cell wall, umbilical cord etc) have been detached from the mother. Without these enabling structures, the fetus cannot survive. Moreover, fetal stem cells are harvested from fetuses that are headed for waste bins. The decision to donate fetal stem cells is made separately from the decision to terminate a fetus. Women have the right to donate fetal stem cells on behalf of their fetuses, much in the same way that Next of Kin Laws allow individuals to make organ donation decisions for incapacitated dying loved ones. Abortion provides a good outcome for several people involved in the process. Those benefits are derived from an array of social circumstances and may lead a woman to decide the benefits of an abortion outweigh the costs. It is impossible to mitigate all of the social factors that would attribute a positive outcome to abortion. In fact, statistics indicate that social factors, such as the financial costs of raising a

[139] Each state has its own laws regarding advanced directives and next of kin. For more information on your own state you can visit http://www.hrc.org/issues/transgender/7935.htm.

child, influence many women's decisions to have abortions today. However, we do nothing to eliminate financial concerns of pregnant women, and similarly we should not prohibit fetal stem cell harvesting on the basis of protecting women. There is nothing that indicates that allowing fetal stem cells to be used as biomaterials for research will increase abortion rates any more than allowing organs to be donated increases the amount of euthanasia in hospitals.

Embryonic Stem Cell Research

At last we come to the crux of the debate: the use of embryonic stem cell research. Embryonic stem cells are most controversial because 1) they are harvested from blastocysts, the moral standing of which is even more obscure than the fetus, 2) harvesting hES cells leads to the destruction of the embryo, 3) these embryos are "spares" left in IVF clinics by couples attempting IVF and will most likely be destroyed (as of right now stem cells created specifically for research purposes will not receive federal funding), and 4) scientists agree that stem cell research has enormous potential to cure many forms of disease. More, underlying the debate is the question of life—what it is, when it begins, and how far scientists should probe into its origins. The ever-increasing sophistication of technology has led to deeper and more intimate studies of the stuff of life. When the sonogram and X-ray machines were invented physicians and patients could see inside bodies and better connect with the unseen processes of development. When ventilators and dialysis machines came along, society was forced to accept machinery as life sustaining and re-evaluate what constitutes the end of a life. When organ donation became a successful and acceptable technique, medicine was forced to accept that biomaterials could be used as forms of life-sustaining technologies. Today, the stem cell debate goes one step further, challenging scientists to manipulate a biomaterial to eliminate diseases and improve quality of life. How far is too far for research?

However the biggest question and problem in this debate is the fundamental question: What constitutes human life? Renee Descartes wrote in Principles of Philosophy "ego cogito, ergo sum," a famously quoted belief that purports that thought characterizes humanity and personhood. However, with no intention of slighting Descartes, science and technology have evolved somewhat since his time and thought is no longer a sufficient indicator of human life. Today, medical imaging technologies and scientific studies of systems biology have led us to tenuous moral grounds, whereby we have difficulty identifying at which point life begins and, further, what constitutes human personhood. A school of thought known as biological reductionism asserts that organisms are only the sum of their parts. By deconstructing (or, in the case of synthetic biology, constructing) organisms process-by-process and molecule-by-molecule, we create life. However most religious organizations, including most relevantly the Jewish and Catholic faiths reject the notion that human personhood is solely a complex series of chemical processes. Rather, most faiths advocate the existence of something greater, a soul, which could almost be seen as an emergent property of life. It is the existence of, or more precisely receiving of, this soul that worries religious anti-stem cell activists.

Why Stem Cell Research should not be banned.

There are four core arguments against the use of human embryonic stem cells in research: alternative forms of stem cells exist, the consequences of the research are uncertain, embryos are human persons, and Instrumentalization is dangerous for humanity. There is also an assumption associated with these protests that the embryo is sacred or at least that there is a large (ethical) cost associated with destroying it. I will give each claim a thorough and complete summary before refuting each systematically.

The first concern, that alternate, less controversial, forms of stem cells exist, is absolutely true. However, as discussed earlier, these alternatives to embryonic stem cells (adult, fetal, and umbilical), are often less malleable, and more difficult to control. In addition, these cells have potentially been exposed to contamination in the forms of signaling proteins, toxins consumed by the mother and/or the self, genetic mutations and point mutations that change the genetic code of the stem cells from their original form to a more destructive form. That is to say that throughout the course of a cell's life, it is exposed to environmental factors that alter the original state of the cell's genetic code. Take for example the skin cell. Skin is constantly exposed to harmful rays from the sun, which have been shown to eventually damage the DNA of epidermal (skin) stem cells. When these cells replicate, their altered DNA is passed on to their offspring. In many cases these alterations do nothing, but in some cases the mutation is the starting point for cancer.[140] Accidentally using an adult cancerous stem cell in stem cell therapy would be devastating to an immunocompromised patient. Adult stem cells are difficult to locate, and while they differentiate more predictably, they have lost the ability to differentiate as widely as their embryonic predecessors. It is important to advance the research being done on all of these types of stem cells but thus far no true alternative to the hES cell has been discovered.

Research on iPS cells—stem cells created by reversing the differentiation process of somatic cells—while still in its infancy, has great potential to advance the field of stem cell research. However, iPS cells are derived from adult somatic cells that may have been exposed to mutagens and carcinogens, and their use is potentially dangerous. In addition, I fail to see how, ethically or logically, iPS cells should differ from hES cells. If anything, iPS cells should be more disturbing to anti-hES cell research individuals because their creation inherently

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[140] Epstein, John H., and Stephen Q. Wang. "UV Information." The Skin Cancer Foundation, (2011). <http://www.skincancer.org/understanding-uva-and-uvb.html>.

demonstrates that embryos (potentially living persons by their own arguments) can be created out of any cell in the body. If one were to follow this train of thought to its logical conclusion, every cell in the body would be a potential embryo and therefore too sacred for research.

The argument that all of the benefits and consequences of stem cell research are unknown is also absolutely true. Dubbed by Bedau and Triant "deciding in the dark," we are faced with the rather scary (but all too common) conundrum of being unable to predict the future of this research. What is more, our inability to predict what might happen leaves society paralyzed in the face of current decision making models, through which we assign values to various outcomes and tally the score to make the best decisions. Scientists cannot guarantee that within ten years we will have more cures, or even more knowledge about stem cells, than we do now. However, without stem cell research, we can be certain that scientists will never know the answers, an "opportunity cost" or "harm of inaction" that Bedau and Triant say is often overlooked.[141] It seems that, when it comes to finding cures for illnesses like heart disease and Parkinson's disease, searching for answers is preferable to not. Further, the vast majority of cures are discovered only after years of research and knowledge of both pathology and anatomy (let alone knowing how to work the technologies!). Even if scientists, through years of research, determined what exactly *causes* cancer, they would be unable to use stem cells as an *instrument* of cure without understanding how stem cells work and can be used. It would be like trying to put together a machine without an instruction manual. "New technologies give us new powers, and these powers make us confront new choices about exercising the powers. The new responsibility," writes Bedau and Triant, "to make these choices wisely calls on a variety of

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[141] Bedau, Mark A. and Mark Triant. "Social and Ethical Implications of Creating Artificial Cells." *The Ethics of Protocells: Moral and Social Implications of Creating Life in the Laboratory*. ed. Mark A Bedau and Emily C. Parke. (Cambridge: The MIT Press, 2009): 39-45.

virtues, including being courageous when deciding in the dark. We should be prepared to take some risks if the possible benefits are significant enough and the alternatives unattractive enough."[142] However, Bedau and Triant seem prepared to advocate the jump-right-in, reactive ethics approach that has so often failed society in the past. They discuss what a mistake they believe the Moratorium letter (written to halt recombinant DNA research in Massachusetts) and subsequent Asilomar Conference to have been, citing James Watson's own written disgust with the halting of research. They fail, however, to note Watson's professed interest and support of eugenics and of the good that came of Asilomar as far as community involvement. In fact, Asilomar is often placed on a pedestal as a shining example of responsible evaluation and review of research procedures. Ethics cannot afford to be laissez-faire when it comes to cutting edge research and technology. Critics of hES cell research are right to raise questions of potential consequences and viable alternative forms of research. However, when it comes to stem cell research, such pauses and considerations have already been taken and the potential benefits have been found to largely outweigh the potential risks (or at least the ones we can foresee). One cannot demand that scientists definitively study diseases, understand their causes, and declare and demonstrate that stem cells can cure those diseases, all without giving those scientists the opportunity to understand and explore the potentials of stem cells themselves.

Third is the assertion that the embryo is a human person and its active termination violates the sanctity of human life. However, it is unclear what exactly constitutes a life: physical qualities or the possession of a soul. Catholic leaders have come to the conclusion that ensoulment occurs at conception, citing the Holy Scripture as "proof." The first passage comes from Exodus 20:13 and reads "Thou shall not kill." Those same Church leaders ignore Exodus

[142] Ibid, 45.

21:22-24: "If men who are fighting hit a pregnant woman and she gives birth prematurely but there is no serious injury, the offender must be fined whatever the woman's husband demands and the courts allow. But if there is serious injury [i.e. to the woman], you are to take life for a life...wound for wound." This second Exodus passage illustrates the inconsistencies in the texts of the Bible, as the death of a woman's fetus does not receive equal punishment to the murder of the woman herself. The next passage reads: "Before I formed you in the womb I knew you; before you were born I set you apart" Jeremiah 1:5. However, the Church fails to take the writing in context—that is, that Jeremiah is *specially* known as a prophet of the Lord, but perhaps that connection to the Lord is unique to his role as a prophet. Finally is the story from the Gospel of Luke 1:41 that when Mary and Elizabeth meet, Elizabeth's fetus leaps in her womb.[143] However, Luke's gospel could alternatively be interpreted so far as to say that fetuses are capable of movement, not that they necessarily are ensouled. These three passages make up the entirety of divine authority, as far as Catholics are concerned.

Additionally, Church leaders have written their own works that have influenced the position of the Catholic Church. The first is "On Embryonic Stem-Cell Research: A Statement of the U.S. Conference of Catholic Bishops" which notes that the embryo "has the full complement of human genes"[144] and is therefore equally deserving of human dignity. The statement goes on to further express the Church's stance: "If fundamental rights such as the right to life are based on abilities or qualities that can appear or disappear, grow or diminish, and be greater or lesser in different human beings, then there are no inherent human rights, no true human equality, only

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[143] All bible verses taken from: The New International Version (Compact Award Bible). Seoul: Word of Life Press, (2004).

[144] United States Conference of Catholic Bishops. *On Embryonic Stem Cell Research: a Statement of the United States Conference of Catholic Bishops.* (Washington, D.C.: USCCB Pub. 2008): 3.

privileges for the strong."[145] However, the Bishops' statement assumes that an embryo is in every way a human person equivalent to a born individual, a statement that is seemingly substantiated by the observation that embryos possess full human genomes. Conspicuously absent from the statement is any discussion of ensoulment, (perhaps mistakenly) implying the Church itself subscribes to biological reductionism, a stance that is inconsistent with the Church's views on the human spirit or soul. Also important is the 1995 Encyclical *Evangelium Vitae* where Pope John Paul II asserts that life begins at conception. "…The number of embryos produced [by Artificial Reproductive Technologies] is often greater than that needed for implantation in the woman's womb, and these so-called 'spare embryos' are then destroyed or used for research which, under the pretext of scientific or medical progress, in fact reduces human life to the level of simple 'biological material' to be freely disposed of."[146] He writes, more passionately: "How can anyone think that even a single moment of this marvelous process of the unfolding of life could be separated from the wise and loving work of the Creator, and left prey to human caprice?"[147] The Pope questions, "how could a human individual not be a human person?" He thereby intertwines personhood and genetics.[148] However, Pope John Paul II himself was forced to admit, "there are no direct and explicit calls to protect human life at its very beginning, specifically life not yet born." He is, Larry Arnhart criticizes "forced to draw indirect references from the texts that do not directly state a conclusion on this issue."[149] The final (relevant) teaching is when, in 1701, the Church sanctified the feast of the Immaculate

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[145] Ibid, 4.
[146] His Holiness Pope John Paul II. *Encyclical Letter: Evangelium Vitae*. (Washington, D.C.: United States Catholic Conference, 1995): 13-14.
[147] Ibid, 44.
[148] Ibid, 60.
[149] Arnhart, Larry. "The Bible and Biotechnology." *Biotechnology: Our Future as Human Beings and Citizens.*(Albany: State University of New York Press, 2009): 133.

Conception—Mary's conception without sin. If the Blessed Mother received saving Grace at the moment of her conception, the Church argues, then her soul must have been present to receive Grace at the time of conception. With the understanding that embryos are persons, the Church argues that it would be immoral to sacrifice the life of one person for the life/lives of others.

Further, many early Catholic leaders rejected the notion that conception marks the beginning of personhood in favor of a theory of gradual ensoulment. This approach supposes that as the embryo develops into a fetus, its soul also develops. It finally possesses a complete, developed, human soul at the point of "formation" or in some cases "quickening" (around the 22nd-24th week of pregnancy). The Church's position, having changed over time, illustrates that perhaps even the Church is unsure how to interpret certain passages of the Holy Text. More, it indicates that the exact moment of ensoulment is not written in Holy Scripture but is the political interpretation of those texts by mortal men.

Catholics do not have a monopoly on non-secular approaches to stem cell research however. Outspoken Jewish former-chair of the President's Council on Bioethics Leon Kass warns, "For anyone who cares about preserving our humanity, the time has come to pay attention.[150]" Balking at the speed with which biotechnology is developing and the seeming blind faith with which society accepts it, Kass led the Presidents Council to a cautionary review of recent biotechnologies and biomaterials, among them stem cell research. However, Hava Tirosh-Samuelson argues, Kass does not represent the views of the Jewish people. "Reform, Conservative, and Orthodox rabbis tend to be strongly in favor of 'more life, longer life, new

[150] Kass, Leon. Life, Liberty, and the Defense of Dignity: The Challenges for Bioethics. (San Francisco: Encounter Books, 2003): 10. via *Biotechnology: Our Future as Human Beings and Citizens*, 82

life.'"[151] The Orthodox, Reform and Conservative Jewish communities all officially profess that prior to 40 days of gestation the fetus is "like water" and a greater responsibility is owed to the old and the sick, whose lives scientists might improve through stem cell research. Further, the Jewish Talmud (together with rabbinic teachings) contends that humans are co-creators with God, a position that carries with it a responsibility to "improve the world and do good" through the use of science and technology (among other means).[152] Muslim scholars are divided on the issue, asserting that personhood occurs prior to birth, but they are unsure when exactly. While several medieval Islamic philosophers determined the point of ensoulment to be 120 days, the Islamic Code of Medical Ethics stated in 1981 that personhood occurs at conception.[153]

In conclusion, refer back to our earlier discussion of the moral concerns regarding iPS cells. If a scientist creates an embryo, either through IVF or (when possible) reverse differentiation, is that embryo ensouled? The answer must be yes because otherwise the Church would have to argue that all IVF or ART conceived children are soulless. What is it about the recombination of DNA that causes the product of two unholy gametes to produce a holy, sacred entity? The Catholic Church argues the presence of a complete human genomic sequence makes an embryo a human person. Talmudic teachings conversely argue, "humans cannot accomplish procreation alone and must receive divine involvement."[154] If the Church subscribes to the idea that a genome alone defines a person, will that embryo continue to maintain its sacred nature as scientists unravel the mysteries of reproduction and recombination? What about when scientists learn to control it?

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[151] *Ibid,* 258. via *Biotechnology: Our Future as Human Beings and Citizens*, 82.
[152] *Ibid,* 259. via *Biotechnology: Our Future as Human Beings and Citizens*, 83.
[153] Islamic Organization for Medical Sciences. *Islamic Code of Medical Ethics*. (Kuwait: 1981).
[154] Kass, Leon. Life, Liberty, and the Defense of Dignity: The Challenges for Bioethics. (San Francisco: Encounter Books, 2003): 259. via *Biotechnology: Our Future as Human Beings and Citizens*, 83.

Harvesting hES cells requires terminating the life of an embryo. But what exactly is it that makes an embryo special? Or more precisely what makes killing an embryo worse than killing a skin, liver, or brain cell? McGee and Caplan argue there is only one redeeming unique quality to the stem cell: recombined DNA. "While the cytoplasm, egg wall, and mitochondria of the embryo are destroyed, we just noted that none of these cellular components identifies the embryo at the one hundred-cell stage."[155] They go on to argue that pro-life individuals should rejoice that embryos are being used to create stem lines. Rather than the DNA of the embryo being destroyed "the DNA in the cell lines has a much greater chance of continuing to exist through many years than does the DNA of a frozen embryo."[156] I see McGee and Caplan as being far too reductionist in their thinking by ignoring the concept of emergence. When a cell works with other cells of the same type they form an organ, which possesses the ability to perform functions that individual cells cannot. Similarly, merely preserving the DNA of an embryo would not preserve the emergent properties the embryo might have. It is undeniable that the embryo dies, while its genetic root may remain intact (if the cell line successfully takes root). However, McGee and Caplan are right to question what it is biologically that make embryos special.

At the root of a logical secular anti-stem cell research argument is the concern that stem cells are just that: the point from which all of us spring. They are the very beginning of human development. Their position in the linear timeline of development, argues conservative theologian Gilbert Meilaender, is critical to how we, as a society view the trajectory of life. To

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[155] McGee, Glenn, and Arthur Caplan. "The Ethics and Politics of Small Sacrifices in Stem Cell Research." *Kennedy Institute of Ethics Journal 9* 2 (1999): 151-58. Reprinted in *The Stem Cell Controversy: Debating the Issues*. Ed. Michael Ruse and Christopher Pynes. 2nd ed. (Amherst, NY: Prometheus, 2006): 161-68.

[156] Ibid, 65.

disrupt that trajectory not only calls into question the idea of a natural order and progression, but also the inevitability of aging and death.[157] Moreover, using embryos as a form of biotechnology to be studied, honed, manipulated—instrumentalized—has severe implications for traditional notions of human embodiment. Paul Lauritzen raises the concern that today's research "understands the human body simply as something to be manipulated."[158] Lauritzen goes on to argue that it is not just embryonic stem cell research but all stem cell research that challenges traditional notions of embodiment and biomaterialism. He portrays a future in which stem cell therapies cross species and begin to blur the lines between the human and the non-human animal. This distinction, he argues, is at the very root of universal identification, sympathy, and morals.[159]

The first concern that needs to be addressed is Lauritzen's fear of instrumentalizing humanity, or rather using components of the body as biomaterials. This "phenomenon" is not new. Rather, it has arisen before with other revolutionary forms of medical and biotechnologies. It was a concern highlighted by the development of organ transplant technology, when natural organs became the technology by which doctors saved patients in organ failure. It reemerged in the form of genetic determinism, a school of thought created and cultivated by DNA testing, genetic sequencing, and IVF. It continues to be a real concern in fields like synthetic biology, where scientists are progressing in leaps and bounds, creating unique organisms and pinpointing causative genes. It appears, and Lauritzen agrees, that researchers have shifted their focus from mechanical tools to natural tools—and why wouldn't they? There is no more incredible

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[157] Meilaender, G. "Terra es animata: On Having a Life." *Hastings Center Report 23:*4. (1993): 25-32. via Lauritzen, Paul. "Stem Cells, Biotechnology, and Human Rights: Implications for a Posthuman Future." *Hastings Center Report 35:*2. Mar-April (2005): 27.

[158] Lauritzen, Paul. "Stem Cells, Biotechnology, and Human Rights: Implications for a Posthuman Future." *Hastings Center Report 35:*2. Mar-April (2005): 31.

[159] Ibid, 27.

mechanism than the cell of the human body, which is so efficient that scientists still have nothing that comes close to replicating its capabilities. You would not try to open a can with your teeth when you have a can opener, and likewise you would not invent a less efficient machine to do the work that our cells are naturally programmed to do. We are so frightened by the images of bionic beings that we balk at any attempt to portray the natural as a technology.

So to return to the fear at hand, I would reply to these secular logical thinkers: why shouldn't researchers use the embryo as a biomaterial? Holm argues that approval of stem cell research "justifies the (non-painful) killing and use of any prepersonal human entity from the fertilized egg to the prepersonal infant."[160] He goes on to argue that legalization of stem cell research justifies the killing of infants for their stem cells. "There is no principle difference between the two killings," he writes. In response I would challenge Holm to ask any person if they had to destroy one, would they choose to destroy an embryo or an infant? I guarantee all would choose the embryo. Logically, Holm makes the assumption that embryos, fetuses and infants all exist as ethical equivalents and perhaps at one point in history he would have been right. However, technology and science education have changed the way we view the human body, and our ethical definition must change as well. Today, we understand and can watch as development occurs: zygote to embryo, embryo to fetus, and fetus to infant. We can visualize and articulate the differences between the phases of development; the categorizations of which imply some kind of inherent difference or hierarchy. There *is* a difference between an embryo and an infant that people, through medical imaging technologies, can finally see and understand. But they also knew it before these technologies existed.

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[160] Holm, Soren. "The Ethical Case Against Stem Cell Research" *Cambridge Quarterly of Healthcare Ethics* 12 (2003): 372-383. via *The Stem Cell Controversy: Debating the Issues***,** 169-185.

One might argue that my earlier challenge was biased, as it appeals to the emotional sentiments of the questioned. People do not hold an embryo, count its toes, or hear it cry—it is not a person in the same sense that an infant is. The issue of defining, or perhaps redefining, what it means to have human personhood is *essential* to maintaining an ethical handle on research as it progresses. Research has moved far beyond Descartes and old ideas of life and humanity. To quote Lisa Cahill "few doubt that there exists from conception, some form of human life in the literal sense."[161] Cahill unwittingly articulates the problem in this debate: the interchangeable way in which the terms life and personhood are being used. No one would deny that an embryo has a full set of human genes. However many, myself included, would balk at the notion that personhood and by extension human rights, requires nothing more than genes. Perhaps personhood is how we connect to and identify with one another. In fact, Martha Nussbaum argues that universal personhood is our ability to feel sympathy and compassion for one another. "We have compassion insofar as we believe the suffering person shares vulnerabilities and possibilities with us."[162] Realistically, we are more likely to identify with, or attribute our own vulnerabilities and possibilities to, an infant than an embryo. Is our decision to destroy the embryo solely linked to its lack of resemblance to ourselves? Arguably, no. One must also consider the normal fate of the embryo; we do not attempt to save every embryo that is naturally or artificially created. Those that are naturally created and fail to attach to the uterine wall are shed. Those that form atopic pregnancies are removed. Those that implant in cancerous uteruses are killed when the wombs are removed. Doctors do not, in any of these cases, search for the embryo and attempt to save it. We accept that some embryos are not intended, depending

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[161] Cahill, Lisa Sowle. "Abortion" *The Westminster Dictionary of Christian Ethics* ed.James Childress and John Macquarrie. (Philadelphia: Westminster Press, 1986): 3. via *The Stem Cell Controversy: Debating the Issues,* 121.

[162] MC Nussbaum "Compassion and Terror" *Daedalus* 128:4 (2003): 10-26. via Lauritzen, 29.

on your belief system by God or biology, to become persons. In contrast, there is no circumstance under which a doctor would fail to do everything possible to save the life of an infant.[163]

The second concern, raised by Meilaender, is that using embryos for research purposes disrupts the natural progression of life. This fear is presented several different ways: tinkering with nature is unnatural, hES cell research cheapens conception and the subsequent course of life, we are playing God, etc. However, the response to all these objections is the same: nothing is more natural than cultivating and expanding human knowledge. Galileo wrote in his letter to the Grand Duchess Christina "I do not think one has to believe that the same God who has given us senses, reason, and intellect would want us to set aside the use of these."[164] That expansion of knowledge will certainly, as it continues, shift cultural and societal norms of thought, among which is the notion of developmental potential. Embryonic stem cell research challenges the assertion that all things have a singular inherent developmental potential. Instead, embryos have whatever developmental potential scientists and individuals assign them. The word potential is defined by Merriam-Webster as "existing in possibility: capable of development into actuality.[165]" By the very definition of the word potential, we can see how science and research could prevent an embryo from having the potential to form a human person. Take for example

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[163]At this point I am forced to wonder, if polled, if people would rather perform research on an adult primate or on a human embryo, given that the research would cause pain and the ultimate destruction of the primate. Myself, I would choose the human embryo as it is more likely to give useful, applicable scientific results, will feel no pain, will not be missed (i.e. has no community that cares what happens to it), and is not denied a future life because it never graduated to the point where it would be given such a life. In contrast, the animal is a living, breathing, sentient creature, which would be deprived of a life it is already living and the death of which would cause sadness within its own community.

[164] Finocchiaro, Maurice A. *The Galileo Affair: A Documentary History* (University of California Press. Berkley: 1989): 94.

[165] "Potential." Def. 1. *Merriam Webster Online Dictionary*. Encyclopedia Britannica. Web. 24 Mar. (2011).

two sources of embryos that scientists seek to use: 1) embryos from IVF clinics slated for destruction and 2) embryos created expressly for research purposes. I would argue that neither the IVF nor the constructed embryo has the potential to become human, because scientists will halt their development. There is no reasonable scenario in which those embryos could form persons. Extra IVF embryos are excess biological waste disposed of by the IVF clinic after the couples that created them no longer want them.[166] These embryos have, realistically, *only* the potential to become biological waste because they would need to be actively cultured, cultivated, and implanted to form a fetus. Likewise embryos created specifically for research purposes have no potential future beyond being harvested for stem cells. They have no potential because, so long as they remain in a Petri dish and not implanted, they cannot form a fetus. Suppose scientists created an embryo with a knock out gene in the genetic information that codes for extra embryonic membranes or with a suicide gene that would cause the embryo to self-terminate before entering the fetus stage. Neither of these embryos would be able to develop into a fetus. Would the embryos still be ethically suspect? We should not be so willing to allow personhood to be defined, solely, by our biological development.

Conclusions

All of the arguments above are reasons why hES cell research should not be prohibited. However I have yet to make the case for why stem cell research should be pursued. First and foremost is the potential that these cells have to cure illnesses. The ability to regenerate lost or damaged cells could help eliminate many of the degenerative diseases that plague humanity today. The hope is that stem cells could be directed to target those areas of the body where cell death or mutations have occurred. Stem cells could be used to form complete, functional organs;

[166] Query who if not the two donors of the genetic material that created the embryo in the first place, has the right to decide to discard them.

a process that would eliminate the need for donors and would help hundreds of thousands of patients who die of organ failure due to scarcity. More, stem cells could be used to cure diseases like sickle cell and leukemia by replacing the existing, malfunctioning stem cells with healthy, genetically sound ones.

Second, is that politicians and especially theologians should not determine alone the trajectory of scientific research in a secular nation such as our own. It is not for the Christian Right to impose upon this country its views of personhood and morality, just as it is not for a politician to impose his personal beliefs upon the people who elected him. Scientists and researchers have become thoroughly dependent upon money from the government, a fact that will not be changing anytime in the foreseeable future. However, the problem comes, not from scientists' dependence on government but from the politicization of research. Research is neither inherently evil nor inherently good, but politics and the media work to present research and technologies as either one or the other. Labeling research as good or bad, pro-life or pro-choice, black or white, ignores the reality that humans determine how these technologies are used. Humans make technologies good or bad. Scientific funding should not be slashed because of political upheavals. Cynics criticize the lack of progress scientists have made within the field of stem cell research. But how could progress be made when funding is dictated by the fickle whims of politics?

Third, as emphasized earlier, embryos are not human persons. While I certainly do not advocate the trivial use of stem cells in research, I would elect to use them where a pressing scientific need can be demonstrated. They could be used to test the effects of pharmaceuticals before beginning human trials, potentially saving lives. They could be induced to form complete human organs that do not run the risk of contamination or rejection. They could recreate the

neural pathways that disintegrate in diseases like Parkinson's and Alzheimer's. They have the potential to improve the quality of life in infirm and older persons, allowing a happier and healthier life. They have the potential to unlock the secrets of aging and more, currently unforeseeable, uses. No one can say how long these developments will take; a month, a year, ten years or perhaps researchers will never discover them. But we will certainly never know unless we are brave enough to choose that path. Moreover, we should not forego promising avenues of research in an effort to keep our definitions of humanity and personhood static.

Fourth and finally, I do not believe in discouraging scientific developments, technologies, and creativity solely because they are new. As with the Asilomar conference, it is sometimes necessary for society to pause and reevaluate the state of research. Such discussions and debates are not only admirable but also necessary. However, progress must not be dictated by the draconian attitudes of dogma. Think of this, if Galileo had failed to challenge the Church, we might still live with a geocentric view of the universe. If Weismann did not ignore social critics and publish his cell theory, preformationist ideas might still dominate scientific knowledge. If Darwin had followed the Church's lead we might still be taught Creationism. We live in a global network where technologies and information are being shared and developed every instant of every day— far faster than in the times of Weisman, Darwin or Galileo. Those Ludites who reject new technologies, which are becoming increasingly more biologically based, will be left for history to judge. Progress will happen regardless of dissent—if not by stem-cell researchers than by synthetic biologists or whatever may come next. It is better to set up effective ethical governing systems than to naively think we can prevent bioethical issues from arising by halting research. Further, it is necessary to realize that our definition of life cannot be static, because the

things scientists are achieving are revolutionary. With these cautionary tales in mind I look forward to the future with hope and excitement at the prospects of things to come.

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