Bioethics Controversy Paper Proposal

A controversy paper proposal for the 2012-2013 CEDA season

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I. Executive Summary

By: Jarrod Atchison and Sarah Godwin

We propose that the 2012-2013 Cross Examination Debate Association topic focus on federal government regulation of patents for genetic materials, reprogenetics, pharmaceuticals, genetic enhancement technologies, and stem cell research. The controversy develops out of the tension between the advocates for federal government regulation and the advocates for unrestricted innovation within this unique intersection of science and medicine. We believe that this tension has the potential to sustain an intercollegiate debate season while providing participants a unique opportunity to engage some of the most difficult questions that policymakers, intellectuals, religious leaders, and activists are facing today.

For the purposes of this controversy paper, we have selected "regulation" as the proposed mechanism, but we understand that the topic committee needs flexibility to create the best slate of resolutions. There are two examples of past resolutions that utilized regulation as the mechanism of the resolution. The 1979-1980 resolution was: "RESOLVED: That the federal government should significantly strengthen the regulation of mass media communication in the United States." Additionally, the 1996-1997 resolution was: "RESOLVED: That the United States Federal Government should increase regulations requiring industries to substantially decrease the domestic emission and/or production of environmental pollutants." We believe that these resolutions demonstrate that it is possible to craft a resolution built on a regulation mechanism. Additionally, we believe that this controversy topic fits well with the upcoming CEDA vote on topic rotation because the bioethics controversy can easily be adapted to a domestic or legal focused resolution.

II. Reasons the Debate Community Should Debate Bioethics

1. Timely….but not too timely

The upcoming Supreme Court decision over the constitutionality of the Patient Protection and Affordable Care Act demonstrates that the status of national healthcare in the United States is too tenuous to sustain a resolution. This bioethics controversy, however, uniquely intersects the contemporary healthcare debate without being too dependent upon the upcoming decision. Although many of the questions in this controversy have been with us for as long as we have been able to argue, the speed of innovation has thrust these questions back into the national spotlight while simultaneously challenging our traditional perspectives on these complex issues.

2. Great solvency advocates

Each author was responsible for finding solvency evidence that supported an increase in federal government regulation. We believe that the interdisciplinary nature of the controversy provides a unique opportunity to find solvency advocates from a variety of perspectives ranging from communication, law, economics, political science, religion, philosophy, think tanks, and a wide variety of non-governmental organizations.

3. The controversy is important

What does it mean to be human? Should we strive for human perfection? Should science be regulated by the federal government? A resolution centering on bioethics would focus a season worth of debates on questions that often lie at the periphery of our competitions, but at the forefront of our political discussions. In the same way that the Nuclear Weapons topic helped debaters develop a more nuanced understanding of a terminal impact, we believe that the bioethics controversy has the potential to advance

our debates over utilitarianism, the value to life, the role of empiricism, and the potential of science through philosophies like transhumanism.

III. Regulating Patent Law and Genetic Materials

By: Joel Diamond

An Introduction to Genetic Patent Law

The discussion over whether or not genetic material is patentable subject matter represents a critical question for the United States federal government to confront within the legal and regulatory system. Patenting of genetic material began in 1980 by the U.S. Patent and Trademark Office (USPTO), which approved a patent for genetically engineered bacteria that was used to clean oil spills. The Supreme Court upheld the patent in *Diamond v. Chakrabarty* by ruling that the compound was distinguished by a unique name, characteristics, and use as a result of human ingenuity.[1] This decision stood in contrast to the standing interpretation of the 1952 Patent Act, which excluded patents on living organisms found in nature, but delegated the interpretation of patentable subjects to the USPTO. Since the Court's ruling, the USPTO has overseen the implementation of patent applications and expanded this interpretation to include products of genetic material altered from their state in the natural environment. As a result, the 3000-5000 patents on human genetic sequences have been approved, and around 50,000 that include some form of human genetic material.[2] Attention from the media has devoted a large amount of attention to various criticisms and positions on this issue from various political, medical, economic, and moral perspectives on bioethics.

While the USPTO plays an essential role in patent law by determining a large portion of the application and review process as a result of the America Invents Act of 2011,

[1] Saladino, "PATENT LAW: A. NOTE: Seeing the Forest Through the Trees: Gene Patents & the Reality of the Commons", *Berkeley Technology Law Journal* 301 (2011): 301
[2] IBID.

other executive agencies and the court system play large roles as well.[3] The America Invents act is important as it shifted away from a *first-to-invent* towards a *first-to-file* system, designed to spur innovation and reduce incentives for legal manipulation. While this bill made significant progress, it has been deemed a compromise that deferred to the Courts on the question of the patentability of genetic material;[4] risking "greater uneasiness about US patents, which for the biotech industry can translate into lowered investment".[5] Other organizations that have substantial authority over patent policies include the International Trade Commission (ITC) and the Federal Trade Commission (FTC). Both have the ability to make decisions regarding the enforcement of regulations against infringement and implement anti-trust investigations to resolve disputes between private organizations.[6]

Nonetheless, the court system has had the largest influence in determining the future of bioethics within U.S. intellectual property law, given a recent trend of deference by congress to avoid the crux of the controversy. The Federal Circuit Court and the Supreme Court have relied heavily on the context of different cases to make decisions, and have not set a universal precedent. Recent cases highlight the extent of disagreement that currently exists between lower courts and the Supreme Court on the core question of whether or not altering genetic material produces a product distinct from its original form in nature. The two Supreme Court cases of *In Re Kubin* of 2009 and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* this past March best

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[3] Rai, "PATENT VALIDITY ACROSS THE EXECUTIVE BRANCH: EX ANTE FOUNDATIONS FOR POLICY DEVELOPMENT", *Duke Law Journal* 1237 (2012):
[4] Kathlyn Stone, "The Patent Reform Act of 2011 and the Pharmaceutical Industry" (2011), http://pharma.about.com/od/Government_IP/a/The-Patent-Reform-Act-Of-2011-And-The-Pharmaceutical-Industry.htm
[5] Jeffrey L. Fox, "America Invents Act receives cautious welcome", *Nature Biotechnology* 29 (2011): 953–954
[6] IBID.

represent this trend. In both cases, the Court ruled against the patenting of DNA in opposition with several decisions by the Federal Court of Appeals. Such disagreement has only helped to bring different ethical and religious concerns to the forefront of the controversy, both as part of court decisions and in larger media outlets.[7] The decision of *In Re Kubin* was explicitly limited to the specificity of the case and lacked evidence of the "obviousness" of human ingenuity to distinguish the genetic material from nature[8] and the decision in *Prometheus* was merely against the use of a particular method for administering genetic drug therapies.[9] In contrast, the Federal Circuit Court decision in *the United States Patent and Trademark Office (PTO) v. Myriad Genetics* upheld the product as patentable, ruling that there was, indeed, an "obvious" distinction between the original genetic isotopes and the cDNA and cRNA isotopes altered by human innovation, which could not be found in nature.[10] Additionally, this case has been appealed and given a secondary review by the Federal Circuit Court at the request of the Supreme Court after the *Prometheus* ruling. Thus, the constitutionality of patenting genetic material remains uncertain; creating ambiguity regarding the authority of current policies by congress and federal agencies to regulate intellectual property laws. This confusion makes this part of the topic both particularly relevant to current events and provides ample literature for both sides of the debate.

Patentable subject categories include the four following groups:

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[7] Joshua Sarnoff, *Patents and Innovation After the Mayo Ruling*, JURIST - Forum, Mar. 26, 2012, http://jurist.org/forum/2012/03/joshua-sarnoff-patents-mayo.php.
[8] Stephen W. Chen, et al., "Patent Protection in Medicine and Biotechnology: An Overview", *Journal of Health & Life Sciences Law* 4 (2011): 106
[9] John Conley and Allison Dobson, "Prometheus Patents Struck Down, 9-0: Mayo Collaborative Services v. Prometheus Laboratories, Inc. Analysis", *Genomics Law Report* (2012), http://www.genomicslawreport.com/index.php/2012/03/21/prometheus-patents-struck-down-9-0-mayo-collaborative-services-v-prometheus-laboratories-inc-analysis/
[10] Abigail Lauer, "THE DISPARATE EFFECTS OF GENE PATENTS ON DIFFERENT CATEGORIES OF SCIENTIFIC RESEARCH", *Harvard Journal of Law & Technology* 179 (2011)

- Process – method that includes a series of steps to reach a particular result (isolating a protein or detecting sequences of a patient's DNA)[11]
- Machine – a physical apparatus with moving parts (image scanner or a pulse oximeter)[12]
- Composition of Matter – chemical compounds, biomolecules, purified substances, or mixtures of them (DNA gene vector or a drug molecule)[13]
- Manufacture – broad category of tangible human-made products (could be anything from a surgical knife to an intravenous fluid bag)[14]

Affirmative Advantage Ground

The sectors affected by breakthroughs in genetically engineered material are reasonably large in terms of both breadth and depth. At the forefront of the debates about the research and development of technologies from genetic material is the question of how the federal government should regulate the industry to best to innovate and incentivize markets. The following are a list of potential advantages:

Disease: all four categories (processes, machines, compositions, and manufactured products) independently have the potential to revolutionize medicine as a result of bioengineering. Advantages have the potential to target hyper specific internal links to vaccines, treatments, or detection equipment for disease scenarios like HIV-AIDs, malaria, bird flu, cancer, etc.[15]

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[11] Chen, et al. (2011)
[12] IBID.
[13] IBID.
[14] IBID.
[15] Samuel Packer, "BIOMEDICAL RESEARCH AND THE LAW - EMBRYONIC STEM CELLS, CLONES, ANDGENES: SCIENCE, LAW, POLITICS, AND VALUES: ARTICLE: EMBRYONIC STEM CELLS, INTELLECTUAL PROPERTY, AND PATENTS: ETHICAL CONCERNS", *Hofstra Law Review* 487 (2009)

Stem-cells: current research and development faces large hurdles in terms of patent regulations and intense lobbying by organizations against stem-cells. Increased innovation could generate breakthroughs in all areas of medicine including disease scenarios, trans-humanism, cloning, and public health.[16]

Pharmaceutical + Biologics Industry: Obama singed the Biologics Price Competition and Innovation Act of 2009 to create the first biologics market designed for pharmaceutical companies to spur biologics development. The market is expected to expand to around $ 800 billion by 2015 and by 2010 it was estimated that half of U.S. Food and Drug Administration's newly approved drugs would be biologics.[17] However, the costs of producing a new patentable and FDA approved product have skyrocketed to an estimated $800 million to $1 billion, dis-incentivizing innovation.[18] As a result, there has been a recently growing need for additional regulation on behalf of the government to discourage free-riding and incentivize innovation through patent regulations.[19] The impact scenarios for this could range from the U.S. economy, competitiveness, disease, healthcare, and others specific to future biologic products.

Biotechnology: classic bioengineering key to overall biotech development arguments could gain affirmatives access to all the back-file biotech impacts including hegemony, high-yield agriculture, warming, food prices, economy, and disease. As indicated with the above biologics example, these scenarios have the potential to get very specific at both the internal-link and impact level.

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[16] IBID.
[17] Katherine Addison, "THE IMPACT OF THE BIOSIMILARS PROVISION OF THE HEALTH CARE REFORM BILL ON INNOVATION INVESTMENTS", *The John Marshall Law School Review of Intellectual Property Law* 553 (2011)
[18] Wendy H. Schacht, "Patent Reform: Issues in the Biomedical and Software Industries", *Congressional Research Service* (2011)
http://www.ieeeusa.org/policy/eyeonwashington/2012/documents/biomedsoftwarepatent.pdf
[19] IBID.

Inter-branch and inter-agency conflicts: given the large amount of overlap between competing federal branches; and, more specifically the multiple relevant executive agencies competing for influence over public policy, there is large ground for streamlining or cooperation, between them to generate unique internal-links and advantages to federal government action. These could include budgetary, backlog, or signal based scenarios.

Trans-humanism: as of 2005 twenty percent of the human genome has been patented[20] and encouraging further advances could result in the impact scenarios described in the more detailed section earlier in this paper.

Bioethics: as a result of ethical reviews established by congress in recent legislation, affirmatives could access more critical advantage ground designed to take a particular philosophical or ethical position regarding particular forms of biotechnology. These could get very specific regarding discussions about the human genome project, cloning, stem-cells, or genetic engineering.

Potential Solvency Mechanisms

Given the complex institutional structure that divides the powers of the three branches of government over patent law, the potential mechanism ground for affirmatives to generate solvency is both diverse and substantive. As a result of the recent Supreme Court decision, the America Invents Act of 2011, and the Affordable Care Act of 2010, there has been a large expansion in the literature bases advocating for additional intellectual property reforms by all levels of government to meet the challenges of rapid advancements being made by medical research and developments.

[20] Saladino (2011)

- Exclusivity rights and patentable material: both congress and the executive branches retain the authority to adjust the exclusive nature of patentable or approved drug product materials. Expanding either the amount of patentable / approved drug material or the rights protections given to current materials would incentivize companies to develop biotechnologies in all four categories discussed above.
- Compulsory licensing: could either mandate or incentivize companies with patented materials to publically disclose their scientific discoveries to the market in order to prevent industry duplication and encourage additional R&D without having to wait on current patents to expire.
- Patent pools: could be established to collectively organize similar products and materials in order to efficiently encourage overall market development and innovation based on a shared knowledge of current scientific research. This would spur innovation because companies would be able to feed off of each other's' product ideas.
- Time limits: both congress and executive agencies retain authority to adjust time limit specifics regarding how long patents and FDA approved products can be protected by exclusivity rights. While the America Invents Act reformed these limits, increasing or adjusting the start and end time for them could potentially incentivize scientific discoveries and marketability.
- Courts: the courts have experienced significant deference, in terms of the constitutionality of patentable subject matter, and this has given them leeway in incrementally defining the limits to the scope of patents on genetic material.

Negative Ground

Finally, patent law increases negative ground options both internally, in terms of case offense, and externally through topic disadvantages. First, the case debates regarding how patents undermine innovation in bioengineering fields are very large and specifically written to clash with opposing affirmative authors.[21]The majority of these arguments stem from the argument that patents encourage corporations to invest in extensive legal teams instead of researchers to protect current investments over new ones, and monopolization arguments based on the ability to restrict scientific advancements from the public to discourage further developments.[22] Given the uncertainty regarding the question of uniqueness described in the introduction, these debates could generate unique case turns for the negative in many situations. Other case turns could include backlog disadvantages based on the affirmative overloading federal agencies, causing budget or focus tradeoffs that would turn solvency or particular advantages.[23] Of course, straight impact turns to these sectors, such as biotechnology, are also large and updated more recent and specific literature. Secondly, external disadvantage scenarios could include brain drain scenarios of both talent and capital from other countries in pharmaceutical or bioengineering sectors and piracy or black market disadvantages to both international and domestic markets. Thirdly, counterplan ground will be large because of the larger number of actors that play significant roles in shaping U.S. intellectual property law, the diverse processes or policy angles that have been proposed, and the proliferation of literature coming out recently to discuss public

[21] Timothy Caulfield, "SYMPOSIUM: WHO OWNS YOUR BODY?: ARTICLE AND REMARK: HUMAN GENE PATENTS: PROOF OF PROBLEMS?", *Chicago-Kent Law Review* 133 (2009)
[22] IBID.
[23] Katherine Addison, "THE IMPACT OF THE BIOSIMILARS PROVISION OF THE HEALTH CARE REFORM BILL ON INNOVATION INVESTMENTS", *The John Marshall Law School Review of Intellectual Property Law* 533 (2011)

policy solutions. Lastly, critical literature, of course, exists within both ethical criticisms of genetically altering humans (opponents of bioengineering, trans-humanism, and bioethics), using genetic material for research, critiques of the legal institutions (CLS, normativity, CRT, etc.), critiques of using technology (Heidegger), and economic critiques of commodifying bioproducts into markets (Neoliberalism and Capitalism critiques).

IV. Regulation of Reprogenetics

By: Alexis Shklar

An Introduction to Reproductive Health Technologies

Assisted reproductive health technologies (ART) have recently been garnering a great deal of attention within the field of bioethics. The Center for American Progress defines ART as "any fertility procedures in which both eggs and sperm are manipulated outside the body in a laboratory."[24] Despite the increased prevalence and development of ART, concrete policy action has not been taken and the regulation of ART expansion is currently dependent on market and consumer demands.[25] Within a 14-year period, there has been roughly a 68 percent increase of fertility clinics offering ART. According to the Center for Disease Control, in 1995 there were 263 fertility clinics that provided ART, and in the CDC's most recent report for 2009, there were 441 fertility clinics that provided the technologies.[26]

The lack of a public policy stance has resulted in all issues pertaining to embryo research to become stigmatized along pro-choice and anti-abortion ideological lines.[27] The consequences of this are twofold. First, it has resulted in policy paralysis. The mischaracterization and association of all embryo research with abortion causes policymakers to avoid the issue all together.[28] An effective policy discussion about the regulation of reprogenetics would encourage policymakers to act, thereby allowing for reproductive research laws to be streamlined. Second, the lack of public policy action

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[24] Jessica Arons, "Future Choices: Assisted Reproductive Technologies and the Law," The Center for American Progress (2007): 5, http://www.americanprogress.org/issues/2007/12/pdf/arons_art.pdf
[25] Erik Parens and Lori P. Knowles, "Reprogenetics and Public Policy," *Hastings Center Report* (2003): s6, http://www.thehastingscenter.org/pdf/reprogenetics_and_public_policy.pdf
[26] "Annual ART Success Rates Reports," Center for Disease Control, last modified March 7, 2012, http://www.chicagomanualofstyle.org/tools_citationguide.html
[27] Erik Parens and Lori P. Knowles, "Reprogenetics and Public Policy," s10.
[28] Ibid.

has caused reprogenetics to be pushed into the private sector.[29] The private sector is not an effective sphere for reprogenetics. It stifles innovation as researchers do not receive public funding and feel that they must keep their projects confidential due to limited protections. The private sector also conceals the "direction of science" because it hinders incentives to evaluate public opinion which is necessary for effective policies.[30] Addressing the insufficient patchwork system for reprogenetics regulation through public policy is a necessary approach to bring it out of the private sector.

Affirmative Case Areas

A. Health Insurance

Health care coverage is a significant area of the reproductive health ethics debate. There are both policy and legal perspectives pertaining to health insurance coverage of infertility treatments.[31] The coverage of such treatments is only offered in fifteen states, and other states have strict limitations or directly outlaw coverage all together.[32] Restrictions also exclude single persons and non-heterosexual couples. As a result, there is legal debate surrounding health insurance and reprogenetics due to allegations of discrimination based on sex, pregnancy, and disability.[33]

Amidst such allegations, "judges have tried to answer whether infertility is a disability, whether lack of coverage for infertility treatments that only women use constitutes sex discrimination, and whether discrimination against the infertile is

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[29] Ibid.
[30] Ibid.
[31] Jessica Arons, "Future Choices: Assisted Reproductive Technologies and the Law," 8.
[32] Michelle Andrews, "Health Insurance Rules May Decide Whether Infertility Treatment is Essential," The Washington Post (2011): http://www.washingtonpost.com/wp-dyn/content/article/2011/01/24/AR2011012405363.html
[33] Jessica Arons, "Future Choices: Assisted Reproductive Technologies and the Law," 11.

pregnancy discrimination."[34] These types of evaluations are necessary in order to determine if contested reproductive health care cases meet the Americans with Disabilities Act, Title VII and/or the Pregnancy Discrimination Act.[35] The Americans with Disabilities Act (ADA) was passed in 1990 and serves to protect individuals with disabilities from employment discrimination. Employment privileges such as health insurance are also categorized under the ADA. One of the relevant qualifications is that the individual must have a physical impairment that "substantially limits a major life activity."[36] There have been Supreme Court cases considering whether infertility qualifies as a disability under the ADA. In *Bragdon v. Abbott* (1998), the Supreme Court ruled that infertility was a disability on the basis that it "affects the major life activity of reproduction."[37] Title VII and the Pregnancy Discrimination Act also pertain to employment discrimination policies. Title VII prohibits employment discrimination "because of sex," and the Pregnancy Discrimination Act (PDA) specifically includes discrimination "on the basis of pregnancy, childbirth, or related medical conditions."[38] The most notable court cases ruling on the basis of Title VII and the PDA include *Kravel v. IMMC*, *Saks v. Franklin Covey Co.*, and *Erickson v. Bartell Drug Co.* Contrary to the cases involving the ADA, most of these cases did not rule in favor of female reproductive protection.[39]

Ultimately, the emergence of infertility treatments raises many legal questions that the courts will need to address in order to adjust employee health insurance plans and antidiscrimination laws. These questions are not limited to whether current insurance

[34] Jessica Arons, "Future Choices: Assisted Reproductive Technologies and the Law," 8.
[35] Jessica Arons, "Future Choices: Assisted Reproductive Technologies and the Law," 12.
[36] Ibid.
[37] Ibid.
[38] Ibid.
[39] Ibid.

policies are discriminatory against infertile employees and females, and the classification of infertility as a disability.[40]

From a policy perspective, policymakers must evaluate whether financial resources should be allocated toward health insurance for infertility treatments in the first place:

> [There is the] question of whether health insurance coverage for infertility treatments should be a priority for policymakers in the first place. Not to minimize the suffering of people who face infertility, but with 47 million people in the United States lacking health insurance for basic health care, it may be hard to justify investing substantial resources in what is a relatively new and still somewhat experimental medical field. Moreover, our resources may be better spent investigating and addressing the upstream causes of infertility, such as untreated sexually transmitted infections and exposure to environmental toxins.[41]

Regardless of the aforementioned concerns, a survey conducted by Mercer Health and Benefits LLC with support from The National Infertility Association, found that 91 percent of employers that offered infertility coverage did not face a significant rise in costs.[42]

B. Embryo Screening

Another approach to the reproductive health ethics debate is the assessment of embryo screening. Embryo screening, also called preimplantation genetic diagnosis (PGD), is a process used to test fetal tissue of reprogenetic fetuses for disease genes. PGD can also be used to predict the sex or miscarriage of an embryo.[43] The use of the technology has been increasing in recent years, and as of 2006, 75 percent of fertility clinics offered PGD.[44] Of those clinics, 42 percent offered sex selection.[45]

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[40] Ibid.
[41] Jessica Arons, "Future Choices: Assisted Reproductive Technologies and the Law," 11.
[42] Michelle Andrews, "Health Insurance Rules May Decide Whether Infertility Treatment is Essential"
[43] Leslie A. Pray, "Embryo Screening and the Ethics of Human Genetic Engineering," *Nature Education* (2008): http://www.nature.com/scitable/topicpage/embryo-screening-and-the-ethics-of-60561
[44] Rick Weiss, "Increasingly, Couples Use Embryo Screening." The Washington Post (2006): http://www.washingtonpost.com/wp-dyn/content/article/2006/09/20/AR2006092001652.html

The process is controversial because there is dispute over whether a child with a disability or disease could still have a fulfilling life.[46] There are also concerns about sex selection resulting in gender discrimination or "transforming childbirth from a natural process full of surprise and wonder into just another commodity."[47] These arguments tie into the critical debate on capitalism. Michael Sandel, a political philosopher at Harvard University argues that embryo selection "runs the risk of turning procreation and parenting into an extension of the consumer society."[48]

C. Embryo Design

An offshoot of PGD's capabilities is embryo design. Researchers are discovering methods to use reprogenetics "not for health reasons, but for the sake of *improvement*."[49] There are already tests available for "eye color, handedness, addictive behavior, "nutritional" background, and athleticism."[50] The possibility of human genetic engineering is both a legal and ethical issue, and guidelines and policies need to be developed.[51]

Aside from a policy discussion about implementing regulations for genetic engineering, there is a significant amount of literature about the ethics of embryo design. Richard Hayes, executive director of the Center for Genetics and Society, warns:

> If misapplied, [these technologies] would exacerbate existing inequalities and reinforce existing modes of discrimination . . . the development and commercial marketing of human genetic modification would likely spark a

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[45] Ibid.
[46] David Quinn, "Embryo Screening Raises Too Many Ethical Questions," Irish Independent (2012): http://www.independent.ie/opinion/analysis/david-quinn-embryo-screening-raises-too-many-ethical-questions-2995025.html
[47] Rob Stein, "A Boy for You, a Girl for Me: Technology Allows Choice Embryo Screening Stirs Ethics Debate," Washington Post (2004): A01.
[48] Ibid.
[49] Leslie A. Pray, "Embryo Screening and the Ethics of Human Genetic Engineering"
[50] Danielle Simons, "Genetic Inequality: Human Genetic Engineering," *Nature Education* (2008): http://www.nature.com/scitable/topicpage/genetic-inequality-human-genetic-engineering-768
[51] Ibid.

> techno-eugenic rat-race. Even parents opposed to manipulating their children's genes would feel compelled to participate in this race, lest their offspring be left behind.[52]

Supporters of the expansion of genetic engineering argue the opposite. Ronald M. Green, a Dartmouth College ethics professor, "sees PGD as a tool for reducing the class divide by "genetically vaccinating" individuals against potential hardships like obesity and dyslexia."[53]

D. Embryo Freezing

Embryo freezing involves removing a female's ovarian tissues and then re-grafting it into a body at a later time to produce offspring.[54] Although embryo freezing is relatively new and uncertain technology, the controversy is focused on the ownership and disposal of unused embryos rather than the procedure itself. In 2007, there were roughly half a million frozen embryos stored in U.S. fertility clinics.[55] Although patients are offered options for storing and disposing their unused embryos, most are abandoned. If the patient does not pay storage fees or does not select an option, clinics take ownership of the embryos.[56] Once the embryos become property of the clinic, they can be destroyed or used for research without the owner's consent. Since the processes of embryo freezing and storage are recent developments, "there is little statutory or case law to provide clinics and patients with guidance."[57]

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[52] Leslie A. Pray, "Embryo Screening and the Ethics of Human Genetic Engineering"
[53] Ibid.
[54] Bryony Gordon, "Women Should Not Trick the Biological Clock," The Telegraph (2012): http://www.telegraph.co.uk/health/women_shealth/9206948/Women-should-not-trick-the-biological-clock.html
[55] Jessica Arons, "Future Choices: Assisted Reproductive Technologies and the Law," 14.
[56] Ibid.
[57] Ibid.

Aside from public policy questions relating to embryo freezing, there are constitutional issues that need to be addressed.[58] A Center for American Progress report argues that the ambiguity of embryo ownership "potentially violates [patients'] right not to procreate, and it denies them their right to determine the disposition and use of their own genetic material."[59] The courts have previously ruled on disputes regarding the disposal of unused embryos between couples in *Davis v. Davis*, *Kass v. Kass*, *Litowitz v. Litowitz*, and *Roman v. Roman*.[60] Despite these cases, numerous legal and constitutional questions over embryo ownership remain:

- Should donors have the opportunity to indicate what they would like to happen to the embryos or to place limits on what may happen?
- Should the embryos be treated as the property of the intended parents, with them having exclusive control over disposition?
- Should an intended parent who used a donor have as much say as an intended parent who contributed sperm or eggs?
- When the right to procreate clashes with the right not to procreate, which one should prevail?[61]

[58] Jessica Arons, "Future Choices: Assisted Reproductive Technologies and the Law," 16.
[59] Ibid.
[60] Ibid.
[61] Jessica Arons, "Future Choices: Assisted Reproductive Technologies and the Law," 18-19.

V. Regulation of Pharmaceuticals

By: Amanda Pham

An Introduction to Pharmaceuticals

Debates over health benefits and the following successes of the Obamacare legislation have brought previously peripheral issues that had been glossed over, into the spotlight. A quintessential facet of the biomedical ethics debate manifests itself in discussions over the seeming infinitude of possibilities offered by pharmaceuticals. Despite the long life of variants of the healthcare debate, the myriad of groups affected by seemingly trivial changes in any aspect of the pharmaceutical industry are evidence of an even an exponentially diverse array of interests. The broad spectrum includes skepticism regarding leniency in pediatric care, outsourcing non-approved clinical trials, and extending into pricing and patent procedures.

A unifying investigation in pharmaceutical discussions is to identify and promote comparative methods for evaluation responsible for the paramount concern of consumers' health juxtaposed with the pharmaceutical corporation's tunnel vision on profit. Immersion in the research produced by authors throughout all arenas of academia reveal the obvious necessity for an increased dedication to be placed on the direction of the pharmaceutical industry and its impacts in the social, legal, economic, and political standing of the United States.

Patents

Patents are the mechanism used to establish adequate regulation between drug producing companies and their counterparts to preserve a productively competitive economic environment. In practice, this often takes form in government rulings over the rights of brand versus generic pharmaceuticals. Without protection for drug producers,

top biochemists and other essential professionals responsible for medical breakthroughs are not able to pay for their education. The disparity in education costs to income return makes financially pragmatic incentives for going into the pharmaceutical industry obsolete. A less attractive thus leading to dependence on foreign nations for expertise in the biomedical field which risks decreasing US leadership and threatening present alliances.

Pharmaceutical Detailing

A practice that has recently gained friction in the public and legal eye is that of pharmaceutical detailing. Pharmaceutical detailing is loosely described as the practice of pharmaceutical lobbyists informing medical practitioners about new medications. That description however would be considered misleading neutral in the current medical field. According to recent studies there is a great deal of controversy surrounding the ethics of pharmaceutical detailing. Medical professionals have objected to the use of pharmaceutical detailing indicating that it incentivizes doctors to use newly released medications which favor the industry more than the patients. [62] In 2006 the American Medical Association (AMA) joined forces with the Association of American Medical Colleges (AAMC) in order to launch an in depth investigation on the ethical and practical implications of the pharmaceutical detailing.[63] As a result private medical schools and institutions across the nation have banned the practice of pharmaceutical detailing and regardless of its legality it certainly sparks controversy when it arises in conversation.

> the academic case against detailing has depended upon studies examining bias in industry advertising and its effects on physicians. As summarized by Wazana in a widely quoted meta-analysis (Wazana 2000), this literature suggests that detailing induces physicians to prescribe new drugs too rapidly, to request the addition to formularies of drugs that offer no advantage over existing drugs, and

[62] Thomas Huddle, "The Pitfalls of Deducing Ethics From Behavioral Economics: Why the Association of American Medical Colleges Is Wrong About Pharmaceutical Detaling,"*American Journal of Bioethics*, 10, no. 1 (2010): 1, http://ehis.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=4&hid=1&sid=579e21e1-3ea0-4c1e-b70a-a7d59cba1139@sessionmgr11 (accessed April 18, 2012).
[63] IBID.

> to prescribe *fewer* generic drugs. Such conclusiosn have a good deal of face validity for many physicians, who, whether or not they participate in detailing, agree that information from drug representatives is inevitably biased (Manchanda and Honka 2005; Prosser and Walley 2003).

The literature not only investigates the negative impacts of pharmaceutical detailing but looks to aspects of behavioral economics to provide an argument on behalf of pharmaceutical detailing. Another term associated with the biases existent in the privatization of the pharmaceutical industry is that of "gift-giving". This practice, similar to pharmaceutical detailing has been linked to biasing medical professionals towards prescribing medications that are more profitable to companies. [64]

> A substantial body of research gives evidence that physician's prescribing is influenced by gifts. To illustrate, one study looked at the *effects* of free trips to luxury destinations to attend drug company symposia focusing on their new drugs (Orlowski and Wateska 1992). These gifts were followed by substantial increases in the physicans' prescribing of the new drugs, and these increases were too great to be accounted for by the fact that physicans generally were increasing their prescribing of these drugs. Even small gifts can have an effect; in another study, changes in prescribing practices based on a discussion with a pharmaceutical representative were shown to be independently associated with receiving free meals from the representative (Lurie et al. 1990).[65]

Clinical Trials

Clinical Trials are another avenue that has recently gained traction as a paramount method seen in the pharmaceutical industry. These trials enter a different realm of ethical contention specifically when facing corporations that intentionally outsource to developing nations in order to circumvent more stringent FDA regulations. Although this characterization casts pharmaceutical corporations in a malicious light, these industries are corporations that are only able to produce crucial medications through their ability to make ends meet. [66]

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[64] Carson Strong, "Why Academic Medical Centers Should Ban Drug Company Gifts to Individuals ,"*American Journal of Bioethics*, 10, no. 1 (2010): 13, http://ehis.ebscohost.com/ehost/detail?sid=579e21e1-3ea0-4c1e-b70a-a7d59cba1139@sessionmgr11&vid=7&hid=1&bdata=JnNpdGU9ZWhvc3QtbGl2ZQ==

[65] IBID.

[66] Emma Cohen, Jennifer O'Neill, Michel Joffres, Ross Upshur, and Edward Mills, "Reporting of Informed Consent, Standard of Care and Post-Trial Obligations in Global Randomized Intervention Trials: A Systematic Survey of Registered Trials," *Developing*

Agents

The United States Food and Drug Administration (FDA) is part of the U.S. Department of Health and Human Services budget and is the authority on enforcing regulations applicable to the pharmaceutical industry. The FDA specifically has a Pharmaceutical Science and Clinical Pharmacology Advisory committee devoted to ensuring the safety and effectiveness of drugs permitted for use in the United States. Furthermore the FDA is also responsible for cultivating policies that increase long term innovation in the medical field.

Other key Domestic and International Organizations Include:

- European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
- Drug Information Association (DIA)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- European Pharmaceutical Market Research Association (EphMRA)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- Japan Pharmaceutical Manufacturers Association (JPMA)
- New York Health Products Council (NYHPC)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Irish Pharmaceutical Healthcare Association (IPHA)

Regulatory authorities

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- European Medicines Agency (EMEA)

World Bioethics, 9, no. 2 (2009): 74-80, http://ehis.ebscohost.com/ehost/detail?sid=579e21e1-3ea0-4c1e-b70a-a7d59cba1139@sessionmgr11&vid=9&hid=1&bdata=JnNpdGU9ZWhvc3QtbGl2ZQ==

- Therapeutic Goods Administration (Australia) (TGA)
- U.S. Food and Drug Administration (FDA)
- Ministry of Health, Labour and Welfare (Japan)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Central Drugs Standards Control Organisation (India) (CDSCO)
- Ukrainian Drug Registration Agency

VI. Regulation of Genetic Enhancement Technologies

By: Richard Min

An Introduction to Transhumanism

The bioethical issues surrounding human enhancement are hotly debated and many revolve around the philosophy of transhumanism. Advances in biotechnology play a critical role in advancing humanity, but central questions involve "What does it mean to be human" and "how could these technologies be used ethically for a better society?" Winner of the Eugene R. Gannon Award, Nick Bostrom defines the end-goal of transhumanism: through the "responsible use of science, technology, and other rational means, we shall eventually manage to become post-human, beings with vastly greater capacities than present human beings have." [67]

Many intellectuals representing transhumanism diverge at certain points, opening up the space for nuanced debates surrounding the broader philosophy itself. A central issue for debate amongst transhumanists is how much role the government should play in advancing the pillars of transhumanism, especially with biotechnology. Currently the government has been struggling to keep up the pace of its regulations relative compared to scientific advances. The government could specifically limit its biotechnology regulations to stem cells, reproductive biotechnology, cloning, and gene therapy.

Solvency Mechanisms

Transhumanism will inevitably represent a significant portion of the bioethics debate in the near future and to represent that trend, authors have begun writing about public policies that could advance the transhumanism agenda. Washington began granting

[67] Bostrom, Nick. "Human Genetic Enhancements: A Transhumanist Perspective." *Journal of Value Inquiry*, 2003: 493-506.

research funds to develop guidelines on advancing health care that will lay out the groundwork for the core issues. The affirmative and negative will both be able to use rising research in think tanks and executive commissions to detail out specific policies.

The President's Commission for the Study of Bioethical Issues recently published a report that listed out its findings in the biotechnology field. They concluded that the risks and implications of developing biotechnology were uncertain, and advocated several policies that could both regulate and incentivize development. This will play a core part of the debate:

> The Commission endorses neither a moratorium on synthetic biology until all risks are identified and mitigated, nor unfettered freedom for scientific exploration. Instead, the Commission believes that the field of synthetic biology can proceed responsibly by embracing a middle ground—an ongoing process of prudent vigilance that carefully monitors, identifies, and mitigates potential and realized harms over time. Responsible stewardship requires clarity, coordination, and accountability across the government. While new agencies, offices, or authorities are not necessary at this time, the Executive Office of the President should lead an interagency process to identify and clarify, if needed, existing oversight authorities and ensure that the government is informed on an ongoing basis about developments, risks, and opportunities as this field grows. This process must be undertaken by an office with sufficient authority to bring together all parts of the government with a stake in synthetic biology and be sufficiently authoritative to effectively engage or oversee engagement with foreign governments. [68]

Pharmaceutical industries in the US play major roles in these fields and with the right incentives they could help society approach the next level in health care options.

The regulation debate becomes important for both the affirmative and negative. As mentioned previously, regulatory oversight on biotechnology is developing slowly. Markets are expanding on their own into the patent area, which will force the United

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[68] Presidential Commission for the Study of Bioethical Issues. "New Directions: The Ethics of Synthetic Biology and Emerging Technologies." 2010.

States to make a decision on whether to regulate biotechnology. Patents will be the next arena for government-market interactions on biotechnology, and there are numerous debates being held on how to protect intellectual property rights to incentivize biotechnology innovations. [69]

Affirmative Ground

Affirmatives that defend a transhumanist philosophy will be able to garner unique advantages both on the critical and policy angle that can take on multiple negative arguments. First, by advancing humanity to a "post-human" state, the affirmative can neutralize many of the negative's critical positions. The theses of many critical arguments could be characterized as being part of the "Old Order" which does not assume for the new radicalism provided through transhumanism. [70] Second, transhumanism allows the affirmative to access a variety of critical advantages: reinvigorating civic engagement and social justice (reproductive rights, LGBT rights, closing the gap between rich and poor) represent a few debates that the transhumanism debate will spark. [71]

If the new angles against the criticism aren't exciting enough for policy affirmatives, they will have a variety of policy advantages to choose from. Because affirmatives can defend a position that many policy arguments will not assume for, they can garner

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[69] Resnik, David B. "A Biotechnology Patent Pool: An Idea Whose Time Has Come?" *Journal of Philosophy, Science & Law*, 2003.

[70] FM-2030. *Optimism One*. 1970.

[71] Munkittrick, Kyle. *When Will We Be Transhuman? Seven Conditions for Attaining Transhumanism*. June 16, 2011. http://blogs.discovermagazine.com/sciencenotfiction/2011/07/16/when-will-we-be-transhuman-seven-conditions-for-attaining-transhumanism/ (accessed April 5, 2012).

unique advantage ground. Even though many teams have debated climate change and the numerous internal links to solve climate change, not many have argued that transhumanism could solve climate change. In fact, human modification opens the door for affirmatives to access large environmental impacts, especially climate change. [72] The transhumanist movement requires advancing technology safely, and combined with the bioethics debate the affirmative can access a variety of scenarios involving biotechnology. These industries have been growing exponentially in the last few years and will play significant and timely roles in boosting the economic competitiveness of the United States while also ensuring national security against threats such as bioterrorism. [73] Other countries, notably Russia and China, have been boosting their investments towards advances in biotechnology could also raise national security threats against American leadership.

Negative Ground

With new philosophies also come many disadvantages and criticisms. While the negative may lose many of their old arsenal of arguments (de-development is a possible example), the transhumanism debate will open the door towards new, innovative arguments for the negative.

At first sight, many criticisms might lose headway against an affirmative that defends a "post-human" world; however, negative teams will not have to fear that they

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[72] Andersen, Ross. *How Engineering the Human Body Could Combat Climate Change.* March 12, 2012. http://www.theatlantic.com/technology/archive/2012/03/how-engineering-the-human-body-could-combat-climate-change/253981/ (accessed April 17, 2012).

[73] Extropy Institute. *Transhumanist FAQ.* February 6, 2006. http://www.extropy.org/faq.htm (accessed April 15, 2012).

will lose all of their critical arguments. The transhumanist philosophy relies on several assumptions that are criticized heavily by a variety of authors. Affirmatives that defend transhumanism will claim to use technology to evolve humans from their imperfect, less-evolved state, which begs several questions about the value and meaning of what it means to be "human". The assumption that humans need to develop and use technology to find liberation could also be criticized.

A large negative literature base exists to debate the regulation mechanism. Many advocate for a free-market approach to biotechnology innovations, arguing that market forces are critical to shape these technologies and their social impact. [74] The coercion disadvantage becomes unique in this topic – government regulation over biotechnology gives it the power to regulate critical health issues in society, which could green-light government-sponsored eugenics. [75]

Policy debaters should find that the transhumanism debate will require innovations to traditional disadvantages. Negatives debating against a transhumanism affirmative will need to spend some time answering the immortality, singularity, and/or other large magnitude impacts of the affirmative so that the negative doesn't lose to the "try or die" framework. The technology debate will also be one of the easiest methods for the negative to access existential impacts, i.e. the biotechnology field has vast amounts of literature debating the risks and consequences of their development.

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[74] Genetics and Society. *About a "Post-Human" Future & Human Biotechnology*. n.d. http://www.geneticsandsociety.org/section.php?id=50 (accessed April 18, 2012).

[75] Horn, Thomas R. *The Hybrid Age*. 2012. http://www.khouse.org/articles/2012/1039/print/ (accessed April 17, 2012).

VII. Regulation of Stem Cell Research

By: Francisco Bencosme

An Introduction to Stem Cell Law

Stem cell controversy holds a prominent area of research that promises a full year of rich debates. Due its relevance and interplay in domestic politics, international relations and ethics it embodies the strength of any bioethics paper. Important to any discussion is to understand the current legal controversy under current U.S. policy on stem cell research that exists within all three legal branches. Stem cell policy in the US has never created an official ban on development only restrictions on funding and use under Congressional power.

These restrictions were put in place by the Clinton Administration under the Dickey-Wicker Amendment.[76] Attached as a rider to an omnibus amendment the Dickey-Wicker Amendment prohibits federal funds that are for the purpose of creating "human embryo" for research purposes or for research "in which a human embryo or embryos" are destroyed.[77] Full reauthorization has taken place every year following its passage thus it plays a very important role in current stem cell debates. Subsequent interpretations of the Dickey-Wicker amendment followed by the Department of Health and Human Services were established that the law did not prohibit federal funding of research using stem cell lines that were derived from blastocysts that had been previously destroyed using private funding.[78]

In February 2001, the Bush administration reviewed the National Institute of Health guidelines and implemented a policy that limited the number of embryonic stem cell

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[76] Dunn, Kyla. "The Politics of Stem Cells." *Nova Science Now*. http://www.pbs.org/wgbh/nova/sciencenow/dispatches/050413.html (Accessed 4 April 2009

[77] O. Carter Snead, "Science, Public Bioethics, and the Problem of Integration," 43 U.C. DAVIS L. REV. 1529, 1532 (2010)

[78] Id

lines used for research.[79] Reauthorizing the Clinton administrations' interpretation of the Dickey-Wicker amendment the Bush administration granted federal funds to support embryonic stem cell research for the first time.[80] These limitations created stipulated that the *only* embryonic stem cell lines that already existed on August 9, 2001 the date on which Bush's policy was announced would be eligible.[81] The rationale was to prevent further destruction of embryos attempting to make a distinction between allowing scientific research while avoiding much of the religious controversy. Although Bush claimed 78 lines of embryonic stem cells would be able to be used only 19 were actually were feasible due to both the time it was use and the restrictions of Dickey-Wicker amendment.[82] This prevented much needed research in embryonic stem cells.

In 2006 during Bush's second term he used his first veto on the Stem Cell Research Enhancement Act. This was an attempt to create federal legislation that amended the Public Health Service Act to provide human embryonic stem cell research but instead just failed under the veto pen.[83] Later that year the Stem Cell Therapeutic and Research Act of 2005 was eventually signed into law President Bush which increased and loosened federal restrictions on stem cells by providing 265$ million for adult stem cell therapy, umbilical cord blood and bone marrow treatment while also authorizing 79$ million for the collection of cord blood stem cells.[84]

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[79] President George W. Bush, Announcement to Allow Federal Funding for Research on Existing Stem Cell Lines (Aug. 9, 2001) (transcript available at http://www.speakout.com/activism/apstories/10048-1.html)
[80] Snead, "Science, Public Bioethics, and the Problem of Integration," (2010)
[81] Id
[82] John Ydstie and Joe Palca, "Embryonic Stem Cells Made Without Embryos," *NPR*, November 21, 2007, found at NPR website story of 11-21-09
[83] Lucas J. Mlsna, *Stem Cell Based Treatments and Novel Considerations for Conscience Clause Legislation*, 8 Ind. Health L. Rev. 471. (2010)
[84] OLPA Office of Legislative Policy Analysis, H.R. 2520—The Stem Cell Therapeutic and Research Act of 2005 (December 2006) http://olpa.od.nih.gov/tracking/109/house_bills/session1/hr-2520.asp

Early in his first term in office President Barack Obama removed certain restrictions on federal funding for research involving new lines of human embryonic stem cells.[85] Federal funding was only limited to non-embryonic stem cell research and embryonic stem cell research based on its existence prior to August 9, 2001. Subsequently the National Institute of Health issued new guidelines that allowed federal funds for embryonic stem cell research so long as the blastocyst had been originally created for reproductive purposes and were donated with informed consent.[86] These were very explicit in not allowing for research in therapeutic cloning yet had the effect of reauthorizing the interpretation of the Dickey-Wicker amendment.

In 2011 a United States District Court dismissed a lawsuit that challenged the use of federal funds for embryonic stem cell research. The lawsuit was brought forth by Drs. James Sherley and Theresa Deisher, scientists who use only adult stem cells in their research and say there is a direct funding competition trade-off that is necessary to complete their research. Last year Judge Lamberth blocked the use of federal funds for embryos causing a strong backlash. Then later though the decision was reversed by a three judge panel of the Court of Appeals for the District of Columbia. It was ruled in favor of the Obama administration due to that no federal funds were destroyed and that it was only conducted under strict ethical guidelines on derived stem cells. An important distinction was made that while federal law bans federal funding for the destructive act

[85] See President Barack Obama, Remarks Prepared for Delivery Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum (March 9, 2009) (transcript available at http://www.whitehouse.gov /the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/).
[86] Snead, supra note 1, at 1552-53.

of deriving cells from an embryo it does not ban funding a research project in which human embryonic cells would be used.[87]

Funding for stem cell research is provided in various forms either the National Institute of Health, state governments or through private actors. This different funding mechanism has been a result not due to any particular plan but instead due to a locked stalemate between the political branches on the issue.[88]

Currently the United States favors searching for alternative methods of stem cell research than they do funding federal research for stem cells if one looks at funding levels alone. Between 2007 and 2010 the NIH budget has never used nor been earmarked more than 11% of the annual research budget for stem cell research to hESC research.[89] Instead state funding and private funding are exceedingly outpacing any federal funding towards stem cells. By the end of 2009, $1.25 billion in grants were used by states to support types of stem cell research based off of 6 states.[90] While there is no national data based on the amount of private dollars that has been spent on stem cell research or that distinguishes between the different cells there is a continuing belief that the private sector will play an increasing role in stem cell research due to uncertainty in government funding.[91] An emphasis on private sector funding of stem cell research

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[87] ABC News, "Stem Cell: Fed judge throws out human embryo challenge,"(2011) http://abcnews.go.com/blogs/politics/2011/07/stem-cell-fed-judge-throws-out-human-embryo-challenge/

[88] Edward A. Fallone, "*Funding Stem Cell Research: The Convergence of Science, Religion & Politics in the Formation of Public Health Policy*," http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1199&context=facpub

[89] Nat'l Insts. Health Research Portfolio Online Reporting Tools, Estimates of Funding for Various Research, Condition, and Disease Categories, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Feb. 14, 2011), http://report.nih.gov/rcdc/categories/.

[90] These states are California, Connecticut, Illinois, Maryland, New Jersey, and New York. Ruchir N. Karmali et al., Tracking and Assessing the Rise of State-Funded Stem Cell Research, 28 NATURE BIOTECHNOLOGY 1246, 1247 tbl.1 (Dec. 2010).

[91] Jessica Reaves, Stem Cell Research Skirts Hurdles, but Raises Ethics Issues, Too, N.Y. TIMES, Oct. 22, 2010, at A23.

raises concerns on reliance on corporate funding and that financial concerns will dictate policy rather than science or medical needs.[92]

[92] Fallone, "*Funding Stem Cell Research: The Convergence of Science, Religion & Politics in the Formation of Public Health Policy*," Vol 12 (2011)

Glossary

Adult stem cell: An undifferentiated cell found in a differentiated tissue that can renew itself and (with certain limitations) differentiate to yield all the specialized cell types of the tissue from which it originated. (Source, President's Council on Bioethics, www.bioethics.gov). Can be found throughout the body, including in umbilical cord blood where it has been found to be able to differentiate beyond to create more diverse cells to treat diseases such as leukemia and aplastic anemia.[93]

blastocyst- the term for a fertilized egg which, after approximately five days, has developed into a hollow, fluid-filled sphere of around 150 cells. It contains an inner cell mass of pluripotent cells. Embryonic stem cells used for research are cultured from these pluripotent cells.[94]

embryonic stem cell- a non-specialized cell that can divide indefinitely and eventually give rise to all the cell types in the body.[95] Note hESC in this paper is abbreviated for Human Embryonic Stem Cells

Induced pluripotent stem cells, commonly abbreviated as **iPS cells** or **iPSCs** are a type of pluripotent stem cell artificially derived from a non-pluripotent cell - typically an adult somatic cell - by inducing a "forced" expression of specific genes.[96]

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[93] Valerie, Schmalz, *Cloning and Stem Cells: Definitions of Key Terms*, July 16, 2005, http://www.ignatiusinsight.com/features2005/vs_definitions_july2005.asp
[94] Science Society, *Stem Cells: Key Terms,* http://scienceinsociety.northwestern.edu/content/key-terms-stem-cells (2010)
[95] Id
[96] Baker, Monya (2007-12-06). "Adult cells reprogrammed to pluripotency, without tumors". *Nature Reports Stem Cells*. doi:10.1038/stemcells.2007.124

Potential Affs-

Increase Uniform State Regulations- Current state funding creates a patchwork of different regulatory systems that allows increases litigation to drag down the research plus a litany of reasons why this would be a good aff to read throughout the year while also having a good answer to the states cp.[97] This debate would ensure that it gets at the heart of the current stem cell problem which is a lack of uniformity in funding due to different systems of funding.

Increase Private sector Regulations- Much like the states the federal government leaves a lot of it up to the private sector which undermines private sector investment and prevents uniform guidelines. Instead these affs would increase private sector regulations.[98]

Cloning- Stem Cells could be used to induce human cloning. Human cloning is an area of science that has been denounced throughout the entire world. The US needs to create ethical standards and regulations that prevents stem cells from being used for human cloning[99]

Embryonic Stem Cell Research oversight (ESCRO) board- Experts advocate creating a board within the National Institutes of Health to review controversial research and recommend policy for the agency. While current oversight of research was left to universities and research institutes and private industries this would reinvigorate the NIH to play a strong leadership role in creating research policy.

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[97] Fallone, *Funding Stem Cell Research,* (2011)
[98] Jody Schechter, "Promoting Human Embryonic Stem Cell Research: A Comparison of Policies in the United States and United Kingdom and Factors Encouraging Advancement," Texas International Law Journal, 45, 603-629.(2010) http://www.tilj.org/content/journal/45/num3/Schechter603.pdf
[99] Kristen Matthews, "Wanted: Federal stem cell research oversight" (2009), Chronicles, http://www.chron.com/opinion/outlook/article/Wanted-Federal-stem-cell-research-oversight-1540593.php#page-2

Increase Regulations over Unethical Practices- Current federal regulations that apply to hESC research are not tailored with hESC in mind. Relevant regulations on human subjects, genetic material, medical privacy protections, lab standards for research resulting in Food and Drug Administration approval, animal care regulations, and biological material and data from other nations are all piecemeal regulations not designed for hESC allowing gaps in regulatory oversight.[100] These restrictions also only apply to federal dollars with federally funded institutions which can lead to bad practices. Affs could allow increased regulation over the private sector and states under these specific parts.

Negative Ground

Many of the core negative strategies will depend based on the specific aff but there will be core generics that bind the stem cell part of the debates. There will be important states and private sector debates that would prove to be important topic CPs. As state governments and private sector are the ones that currently are taking the lead and ways to cp out of their inefficiencies could remedy the problem.[101] Especially since the current system is decentralized a more federal oversight might unhinge a leg of the current federal structure the U.S. has. A very important agency debate exists in the literature as the Court is currently deciding the future of the stem cell research, while Obama used executive authority yet Congress appears to have the final say. [102] Another important aspect of debates could be the different stem cell pics where a team could pic out of adult stem cells or specialized stem cells and debate the controversial aspects and the

[100] Jody Schechter, "*Promoting Human Embryonic Stem Cell Research: A Comparison of Policies in the United States and United Kingdom and Factors Encouraging Advancement," Texas International Law Journal, 45, 603-629.(2010)* http://www.tilj.org/content/journal/45/num3/Schechter603.pdf
[101] Jonathan Moreno, Sam Berger, and alix Rogers, "DiviDeD we fail The Need for National Stem Cell Funding," Center for American Progress, (2007) http://www.americanprogress.org/issues/2007/04/pdf/stem_cell_report.pdf)
[102] Fallone, *Funding Stem Cell Research:,* (2010)

necessity for them to solving the benefits of stem cells. Increased research for NIH would allow funding to go to those sectors and trade-off from other important research that the NIH could be doing creating viable trade-off disads.[103] There are brain drain disads as more scientists are going to the EU and the plan could reverse the EU's scientific edge.[104] Politics will of course be an important generic as stem cell research creates strong partisan divisions and brings forth very conservative views of over religion, ethics, the free market and science. There exist a large array of critical literature in the question of stem cell research as federal oversight over reproduction and medicine technology is debated often raising important ethical considerations.

[103] *Christine Vestal,* Stem Cell Research at the Crossroads of Religion and Politics, Pew Research Center, (2008) http://www.pewforum.org/Science-and-Bioethics/Stem-Cell-Research-at-the-Crossroads-of-Religion-and-Politics.aspx

[104] Nicholas Watts, "US faces science brain drain after Europe backs stem cell funding," Guardian, (2006) http://www.guardian.co.uk/world/2006/jul/25/eu.genetics

VIII. Potential Resolutions

By: Jarrod Atchison and Sarah Godwin

Potential Resolution:

Below is an example of a potential resolution for this controversy. We have not investigated the wording of this resolution with the rigor that is required to frame the exact debate topic. Instead, we wish to provide the community with a starting point for discussing the 2012-2013 CEDA resolution.

RESOLVED: The United States federal government should substantially increase regulation of one or more of the following: patents for genetic materials, reprogenetics, pharmaceuticals, genetic enhancement technologies, and stem cell research.

One of the advantages of this controversy is that the topic committee *could* create broader and narrower resolutions by choosing different labels for the above areas. For instance, the committee could suggest a narrower version of the above resolution by changing "reprogenetics" to "Assisted Reproductive Health Technologies." We hope that this flexibility would allow the committee to create a slate of resolutions that would allow the community to choose just how expansive the resolution should be.

IX. Regulations Solvency Mechanism Evidence

A. Patent Law Solvency Mechanism Evidence

Congress should increase regulation over patent law by creating an exclusive category for genetic material as patentable subject matter to incentivize R&D innovation

Rose 12 (Simone, Wake Forest University Professor of Law, "ARTICLE: Semiconductor Chips, Genes, and Stem Cells: New Wine for New Bottles?", *American Journal of Law & Medicine,* 38 Am. J. L. and Med. 113, Lexis)

[*115] I. INTRODUCTION [I]nventions in most, if not all, instances rely upon "building blocks" long since uncovered . . . . n1 Congress can be trusted to consider issues arising from technological development and to craft appropriate solutions conferring statutory protection on the creative product of new technologies. n2 The Intellectual Property Clause of the U.S. Constitution ("IP Clause") empowers Congress to provide exclusive rights for a limited time to authors and inventors to promote the Progress of Science (i.e., creative expression) and the useful Arts (i.e., inventions). n3 The Supreme Court has interpreted "progress" to include promoting the economy as well as enhancing the overall knowledge base for the benefit of society as a whole. n4 Thus, any type of federal intellectual property protection must balance the competing interests of promoting innovation against public access and enriching the public domain. n5 [*116] The Federal Copyright Act carries out this charge by protecting original expressions fixed in a tangible medium for the "limited" term of life of the author plus seventy years. n6 The exclusive rights granted include the right to reproduce, distribute, create derivative works, and, where applicable, publicly perform and display the protected work. n7 The originality and fixation requirements of the Copyright Act create a social bargain providing a relatively long term of exclusive rights, which is offset by a host of limitations. n8 Limitations such as fair use ensure some degree of public access during this exceptionally long term of protection. n9 Unlike the Copyright Act, the Federal Patent Act has virtually no limitations and provides the more comprehensive right to exclude others from making, using, and selling the claimed invention. n10 The patent's much shorter term of twenty years from the filing date of the invention, however, offsets this broader range of rights. n11 Section 101 of the Patent Act provides that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." n12 Because society must retain access to certain "basic knowledge," section 101 excludes products and laws of nature, physical phenomena, and abstract ideas from qualifying as patentable subject matter. n13 To earn a patent, an inventor must establish that her invention is useful, novel, and non-obvious to one of ordinary skill in the particular area of technology. In addition, the patent specification and claims must be written in a way to enable one of ordinary skill in the art to duplicate the invention upon the expiration of the patent term. n14 The threshold requirements of patent law create a social bargain that ensures [*117] that at the end of the patent term, the public will gain an invention that enriches and adds something new to the public domain. n15 The question then becomes: how do we handle inventions that do not quite meet the threshold for patentability, but nonetheless are products of significant research and development capital? Included in this category are "building block" biological materials, such as isolated human genes and stem cells. These "upstream," or early research, materials are the building blocks for developing a host of "downstream" marketable products with specific utility. Upstream research products are viewed as "inchoate technology" because their downstream uses remain undeveloped without additional research by a broad range of scientists. n16 As upstream technology, isolated bioproducts fall into the unique position of requiring a property scheme that incentivizes innovation while simultaneously providing immediate access to this material for continued research and downstream product development. n17 The BRCA1 and BRCA2 n18 genes currently occupy center stage in a battle to gain public access to patented isolated genes and genetic sequence data. Scientists at the University of Utah first cloned these genes after it was discovered that mutations found on the BRCA1 or BRCA2 genes were linked to various types of breast and ovarian cancer. Since breast cancer is the second leading cause of death among women in the United States, accessing the BRCA diagnostic tests is crucial for women with strong family histories of breast cancer. n19 Unfortunately, Myriad Genetics ("Myriad"), the exclusive licensee of the BRCA family of patents, charges [*118] as much as $ 4000 for the basic BRCA diagnostic test n20 and refuses to grant any licenses for second-opinion testing. n21 Also, Myriad's research licenses typically prevent research scientists from disclosing BRCA mutation test results to their test subjects. Myriad's monopolistic pricing and exclusionary licensing practices raise serious social and political concerns. n22 As a result of restrictive licensing and the high cost of Myriad's BRCA diagnostic tests, n23 several scientific societies, non-profit women's organizations, research scientists, and individuals challenged the validity of the BRCA 1/2 isolated gene patents in federal court. In Association for Molecular Pathology v. U.S. Patent and Trademark Office, n24 (commonly referred to as the "Myriad Case"), n25 the United States District Court for the Southern District of New York evaluated the patentability of the BRCA1/2 isolated genes and sequences. The court held that patents for the isolated DNA containing the gene sequences BRCA 1/2 for detecting breast and ovarian cancer susceptibility were biologically the same as the naturally occurring DNA and thus constituted patent-ineligible "products of nature" under section 101 of the Patent Act and the Supreme Court case, Diamond v. Chakrabarty. n26 Although the United States Court of Appeals for the Federal Circuit [*119] recently reversed the district court's findings regarding most of these claims, the original plaintiffs have appealed to the Supreme Court. n27 Both parties initially requested a rehearing by the original three-judge panel but were subsequently denied. n28 Meanwhile, human genes are not the only isolated bioproducts for which the need for greater access has driven the public to challenge the validity of issued patents. Consumer groups seeking greater public

access to embryonic stem cell lines recently persuaded the U.S. Patent and Trademark Office (PTO) to reexamine and invalidate a series of claims relating to isolated embryonic stem cells and the methods for isolating these cells as obvious in light of the prior art. n29 The Wisconsin Alumni Research Foundation (WARF), assignee of this family of patents, responded by filing a request for a new prosecution (i.e., evaluation by the PTO) of the set of claims it amended during the reexamination process. As upstream research products, stem cells are valuable due to their capability for self-renewal and differentiation into a variety of cell types. This regenerative capability of stem cells is also useful for downstream development concerning how to repair and/or replace defective tissue and organs associated with a host of diseases. n30 No one can predict the outcome of the appeal of the Association for Molecular Pathology case or the new embryonic stem cell prosecution before the PTO. Nevertheless, the disputes over isolated gene patentability and invalidation of the WARF embryonic stem cell patents provide motivation to evaluate whether isolated bioproducts are properly placed within the patent intellectual property regime. In addition to current subject matter and non-obviousness problems, scholars have raised antitrust, utility, morality, n31 and the need for greater access as grounds for excluding isolated bioproducts and other upstream bioproducts from the Patent Act. n32 Removing these products from the patent regime, however, may prove disastrous to society. The biotechnology n33 industry relies on bioresearch patent [*120] portfolios to attract venture capital, generate licensing revenue, and cover the cost of continued isolated bioproduct research and development. n34 Arguably, a lack of corporate funding will stall this research because federal funding is insufficient to bridge any resulting gap. n35 This, in turn, will stall economic growth and future development of much needed downstream bioproducts with specific utility. n36 So, if isolated bioproducts are not patentable, is this one of the rare occasions for Congress to step in and offer some type of sui generis intellectual property protection for isolated genes, stem cells, and related bioproducts? Is it time for legislation that would strike the appropriate balance between innovation and access, despite isolated bioproducts' failure to meet the patent social bargain that requires novelty, utility, and non-obviousness? n37 Are we no longer one-size-fits-all and in need of another paradigm to meet the constitutional mandate to promote the "Progress of Science and the useful Arts?" n38 In other words, are isolated genes and stem cells a new and valuable type of intellectual property "wine" that needs a new and different type of intellectual property "bottle" for adequate protection? n39 If so, what factors should Congress consider when evaluating whether to go beyond the patent social bargain and add an additional set of exclusive rights to promote the progress of the "useful Arts?" In the past, Congress has taken a dim view of any type of sui generis, or stand-alone, intellectual property protection [*121] beyond patent and copyright and refused to create sui generis statutes for computer programs and databases. n40 Indeed, there are only two instances of Congress providing sui generis intellectual property protection in the past 100 years. n41 This Article makes a case for sui generis intellectual property protection for isolated genes, stem cells, and related bioproducts by analogizing how early semiconductor technology similarly warranted sui generis protection to appropriately balance access and innovation. n42 I use the term "isolated bioproducts" to describe bioproducts that have been isolated from the human body without any additional biological manipulation. Thus, isolated bioproducts that have undergone sufficient human engineering to be clearly distinguishable from their in vivo counterparts, such as complementary DNA (cDNA), are excluded from the scope of this Article. n43 In Part II, I establish that because isolated bioproducts, such as genes or embryonic stem cells, are one step away from falling outside the scope of patent protection as either obvious in light of prior art or patent-ineligible products of nature, we must look to alternative intellectual property legislation to preserve the incentive to innovate and increase our knowledge base. As part of this discussion, I criticize the Federal Circuit's recent decision in the Myriad case. I argue that in finding isolated genes patentable subject matter under section 101, the court focused too heavily on promoting innovation and the twenty-year industry reliance on the PTO guidelines rather than on the constitutionally mandated balancing of access and innovation to promote "Progress." I conclude Part II by noting that the questionable patentability of isolated genes and stem cells provides the motivation to explore how a sui generis intellectual property statute for basic isolated bioproducts could serve as an alternate property paradigm to fill any potential "progress gap." To provide a working analogy, Part III steps back to the 1980s and reviews how the semiconductor industry was able to persuade Congress to create sui generis intellectual property protection for semiconductor chips. The Semiconductor Chip Protection Act of 1984 (SCPA) contained a reasonable range of exclusive rights and a host of limitations which allowed greater access to semiconductors for research and development. In Part III, I outline how early semiconductor chips were a "misfit" for both the patent and copyright bargains, yet needed alternative intellectual property protection to fill the progress gap. n44 [*122] Next, I analyze the test promulgated by Congressman Robert Kastenmeier and attorney Michael Remington ("K-R test") to substantiate why sui generis protection is the only viable mechanism to achieve the constitutional mandate of incentivizing innovation while promoting progress through increased access. n45 The four-part K-R test requires Congress to evaluate the following: (1) whether the change (new legislation) fits within the current intellectual property framework without violating existing principles or concepts; (2) whether the new interest clearly defines the scope of property rights provided; (3) whether the benefits of propertization outweigh the costs; and (4) whether the new interest enriches the public domain. I conclude Part III by analyzing how successful the SCPA was in deterring piracy and contributing to the overall growth of the semiconductor industry. After illustrating the positive impact that the SCPA has had on the semiconductor industry, Part IV applies the sui generis analysis to isolated bioproducts. I apply the four-part K-R test to substantiate that enacting sui generis legislation for isolated bioproducts meets the exceptional standards for Congress to deviate from patent law and provide sui generis protection for this upstream technology. In Part IV, I also detail the lessons learned from the SCPA. Applying these lessons, I then outline which exclusive rights and limitations a model isolated bioproduct statute should contain to provide the "wings," or stimulus effect, of enhancing research and downstream development while enriching the public domain. Since patent protection is a prerequisite for venture capitalists seeking

to invest in genomics and regenerative medicine, I advocate adopting isolated bioproduct legislation that is more patent-like in scope than the SCPA. Yet, like the SCPA, the proposed Parapatent Act would provide a more limited term of exclusive rights. The legislation would also mirror the SCPA and include some type of limitation, such as a well-defined experimental use and/or compulsory licensing provision, which facilitates access to this technology for parallel upstream research and downstream product development.

Exclusivity rights regulations would incentivize biologics R&D by changing waiting periods through licenses designed to bypass current delays

Addison 11 (Katherine, intellectual property and patent attorney with Fulwider Patton LLP of Los Angeles, CA specializing in patent prosecution for clients of all sizes in the medical device and clean technology industries but welcomes clients with all varieties of intellectual property needs, "ARTICLE: THE IMPACT OF THE BIOSIMILARS PROVISION OF THE HEALTH CARE REFORM BILL ON INNOVATION INVESTMENTS", *The John Marshall Law School Review of Intellectual Property Law,* 10 J. Marshall Rev. Intell. Prop. L. 553, Spring, 2011, Lexis)

B. Is Patent Protection Still Needed? There has been some debate in late 2010 and early 2011 on the interpretation of the twelve year exclusivity period set out in the BPCIA. n175 More specifically, whether the twelve year period is for data exclusivity or market exclusivity is at issue. As mentioned, many initially believed the twelve year exclusivity period afforded by the BPCIA was for data exclusivity. n176 Data exclusivity would mean that no biosimilar producer could rely on the data already submitted in the reference product sponsor's application for twelve years, measured from "the date on which the reference product was first licensed." n177 A limitation of data exclusivity is that it does not prevent biosimilar producers from collecting their own data to cover their proposed biosimilar products. n178 A second comer can collect and submit its own independent data to support an independently filed biologics license application ("BLA") and, in the absence of patent protection, if the FDA approves there is nothing the pioneer manufacturer can do to preclude the second comer from competing in the marketplace. n179 Many generic manufacturers are considering this option of collecting their own data and filing a traditional BLA as a way to circumvent any new procedure implemented based on the BPCIA if such new procedures become unduly restrictive, burdensome, or risky. Despite their classification as "generic" manufacturers, many second comer companies have some trade secrets and intellectual property of their own that they would not want to disclose to innovators as required by the BPCIA to the extent that manufacturing processes are critical for evaluation of the characteristics of the biologic product and for evaluation of patent infringement. n180 If the FDA provided market exclusivity instead of data exclusivity for pioneer biologics this would solve the problem of innovators without patent protection being unable to stop biosimilar producers from generating their own data or replicating data to get their own products to market sooner.

Sui generis protection would promote market development for bioproducts by creating exclusive rights for new technologies – such regulation would incorporate changes within existing intellectual property law and address the current "progress gap"

Rose 12 (Simone, Wake Forest University Professor of Law, "ARTICLE: Semiconductor Chips, Genes, and Stem Cells: New Wine for New Bottles?", *American Journal of Law & Medicine,* 38 Am. J. L. and Med. 113, Lexis)

IV. IT IS BOTH TIMELY AND NECESSARY TO EXPLORE SUI GENERIS INTELLECTUAL PROPERTY PROTECTION FOR BASIC ISOLATED BIOPRODUCTS A. BACKGROUND As illustrated with the passing of the SCPA in the 1980s, Congress must explore sui generis intellectual property protection whenever a "progress gap" is created by attempting to protect new technology with existing intellectual property laws. The sui generis legislation will then bridge this gap and provide a set of exclusive rights for the new technology that creates an incentive to innovate while simultaneously enriching the public domain. One could question whether this evaluation is premature for isolated bioproducts since the PTO may allow the amended Thompson stem cell patent claims, and the Supreme Court may uphold the validity of the Myriad gene patents. This would eliminate, arguably, the need for sui generis legislation because isolated bioproducts would clearly fall within the scope of patent protection. Even if isolated bioproducts are patentable, however, the argument remains that they should be excluded from the Patent Act since patenting these upstream research tools creates an "anticommons" of knowledge, which impedes rather than promotes progress. Therefore, it is both timely and essential to explore an alternative propertization scheme for this material. Professors Rebecca Eisenberg and Mark Heller, in their seminal article exploring how patenting basic research potentially deters innovation, assert that upstream biological research tools, such as isolated genes and stem cells, are misfits for patent law. They argue that they are misfits because the cognitive bias of patentees n219 and potential licensees causes each to value upstream research tools differently. This inability to reach an effective

"meeting of the minds" creates market failures for both basic licensing and "reach through" n220 licensing agreements. n221 Market failures and the multiple layers of patents obtained at the [*147] various stages of research ("patent stacking") create intellectual property clearance problems, which delay the development of marketable downstream technology. Rather than having a "commons" of information created by effective licensing, we now have an "anticommons" where accessing knowledge becomes a Herculean task. n222 Eisenberg and others posit that we must ensure that the privatization of these rights results in stimulating economic development and "the public goals of biomedical research." n223 Suggestions for improving access to upstream bioresearch include: (1) making subject matter eligibility a constitutional requirement where the person having ordinary skill in the art (PHOSITA) is used as a baseline to determine if the property scheme promotes or impedes progress; (2) adding compulsory licensing or fair use provisions to the Patent Act for basic research; (3) forming biotechnology patent pools; or (4) having petit patents for biotechnology inventions. n224 In addition, a 2010 [*148] report issued by the Department of Health and Human Services recommends amending the Patent Act to include exemptions from liability if gene patents are used for research or patient care purposes. n225 I applaud the ongoing scholarly debate about how to provide greater access to upstream bioresearch and other "inchoate technologies" within the patent paradigm. n226 The analysis, however, should be taken one step further by using the K-R test to explore the procedural viability of protecting isolated bioproducts under an alternative sui generis property scheme. B. A SUI GENERIS "PARAPATENT" RIGHT FOR ISOLATED BIOPRODUCTS MEETS THE FIRST PRONG OF THE K-R TEST BECAUSE IT FITS WITHIN THE EXISTING INTELLECTUAL PROPERTY FRAMEWORK AND WOULD NOT DEGRADE EXISTING PATENT LAW n227 Regardless of the outcome of the Myriad and WARF patent disputes, Congress has the power to legislate a new "constitutional" framework to protect isolated genes [*149] and stem cells. Congress would likely gather industry, academic, and public-interest stakeholders together to craft a sui generis isolated bioproducts statute that would promote innovation as well as provide reasonable access to these basic upstream research tools. n228 It would not be difficult to draft a "Parapatent" Act, containing both patent and copyright-like provisions, that fits within the existing intellectual property framework without degrading existing patent and copyright law. Congress could increase bioproduct protection by adding a new section to the Patent Act for isolated bioproducts: parapatents. This sui generis legislation is properly placed in the Patent Act because the majority of its provisions are more aligned with patent law, rather than copyright. Similarly, the SCPA was properly placed in the Copyright Act since its key provisions were more aligned with copyright law. To remain consistent with the existing intellectual property statutory framework, the proposed sui generis parapatent statute should not degrade existing patent or copyright laws. Like the drafters of the SCPA, Congress could accomplish this by establishing a hybrid propertization scheme that is patent-like in scope, but copyright-like in its lower threshold for protection and limitations for public access.

Compulsory Licensing and Patent Pools

Comprehensive patent regulations are essential to incentivize research and development of bioproducts – 3 key reforms include implementing a “fair use” doctrine that exempts scientists from infringement if they use patented genes for research, compulsory licensing, and patent pools to increase communication between patent holders and scientists

Lauer 11 (Abigail, Harvard Law School, Candidate for J.D., 2012; B.S., Biology, College of William & Mary, 2009, “THE DISPARATE EFFECTS OF GENE PATENTS ON DIFFERENT CATEGORIES OF SCIENTIFIC RESEARCH”, *Harvard Journal of Law & Technology*, 25 Harv. J. Law & Tec 179, Lexis)

B. Potential Solutions Gene patents impose significant costs on society and the progress of science, but removing genes from the scope of patentable subject matter might not be the best solution to the problem. Using the patentable subject matter doctrine of patent law to ban gene patents, as the district court did in Myriad I, does not necessarily serve the patent system's goals of incentivizing the development and commercialization of new technologies and encouraging follow-on innovation. There are several options for continuing to allow gene patents while still facilitating technological and

scientific advancement. Unfortunately, there is no perfect solution that serves both goals of the patent system with regard to all three scientific arenas (i.e., therapeutic proteins, diagnostic methods, and research tools). One possible solution is to adopt some form of experimental use exemption, n119 perhaps as a "fair use" doctrine that exempts scientists from patent infringement if they use patented genes for basic research or diagnostic test development. The biggest strength of this solution is that it would facilitate follow-on innovation by generally increasing the quantity of legal, non-commercial, scientific research. One of the biggest weaknesses of an experimental use exemption is that it would be incredibly hard to implement in this Bayh-Dole era, in which almost all basic research is undertaken with some commercial purpose. n120 Additionally, creating a research exemption doctrine in patent law would significantly weaken the market exclusivity associated with gene patents: manufacturers of commercial products such as drugs or diagnostics would be threatened by the possibility that "fair use" research might lead to a better drug or diagnostic for a particular genetic disease. Thus, an experimental use exemption might erode the incentives that the patent system currently provides to encourage the development and commercialization of therapeutic proteins and diagnostic methods. Another possible solution is for the government to institute a compulsory licensing scheme that would require gene patent holders [*197] to offer reasonable licenses to public sector scientists engaged in noncommercial research. In the United Kingdom, for example, the government is permitted to compel a company to license a patent if the invention has not been commercialized "to the fullest extent that is reasonably practical" after three years. n121 The U.S. has taken the position that there should be no general provision for compulsory patent licensing, n122 but the government could design a compulsory licensing scheme that limits licensees to specifically-defined uses of gene patents. As with the previous solution, compulsory licensing would undoubtedly serve the patent system's goal of facilitating follow-on innovation by increasing access to patented genes. Unfortunately, like a "fair use" exemption, compulsory licensing would probably weaken gene patent rights so that such rights would no longer offer a robust incentive for firms to invest in developing and commercializing certain technologies. The slight advantage this solution has over the experimental use exemption is that gene patent holders would at least be rewarded with licensing fees for discovering and patenting important genes. A final solution is to use institutional mechanisms to increase communication between patent holders and scientists interested in conducting genetic research. Historically, innovators engaged in mutually dependent relationships have created institutions to reduce the transaction costs of licensing patented technology. n123 A good example of this behavior is the establishment of cooperative cross-licensing agreements between members of the computer industry. n124 There are three institutional mechanisms that might alleviate some of the problems associated with gene patents: guidelines or best practices issued by industry leaders, patent pools, and clearinghouses. n125 All of these mechanisms attempt to reconcile the interests of patent holders, researchers, and patients. n126 Encouraging widespread and reasonable licensing would generally facilitate follow-on innovation with regard to therapeutic proteins, diagnostic methods, and research tools. The advantage of institutional mechanisms over an experimental use exemption or a compulsory licensing scheme is that such mechanisms have a less severe impact on incentives to develop and commercialize new technologies. More opportunities for licensing revenue may in fact increase incentives for scientists to discover and patent genes with important implications for human development or health. Pharmaceutical and diagnostic companies, however, may be leery of licensing [*198] their patented genes to others who could use them to invent a new and better commercial product. n127 One of the biggest challenges to establishing meaningful best practices, patent pools, or clearinghouses, therefore, is gene patent holders' resistance to participate. n128 Finding a solution to the gene patent problem requires balancing two important goals of the patent system: encouraging meaningful follow-on research while maintaining patent rights that offer a robust incentive to develop and commercialize new technology. Of the three proposed solutions, implementing institutional mechanisms seems to be the most promising, but there are significant hurdles to establishing patent pools and clearinghouses and encouraging gene patent holders to participate. n129 Whatever solution is ultimately chosen by legislators and judges, it should not be to apply the patentable subject matter doctrine to ban all gene patents or to allow all gene patents, as the courts did in Myriad I and Myriad II, respectively. The ultimate goal should be to narrowly tailor the law in order to counteract the disparate effects that gene patents have on different types of scientific research.

Specific regulations such as compulsory licensing, time limits, K-R tests, and offer royalty fees to incentive stimulate a new market for genetic products

Rose 12 (Simone, Wake Forest University Professor of Law, “ARTICLE: Semiconductor Chips, Genes, and Stem Cells: New Wine for New Bottles?”, *American Journal of Law & Medicine,* 38 Am. J. L. and Med. 113, Lexis)

To address access issues, the parapatent right could include a fair, or experimental, use limitation. Such a limitation would allow access to protected isolated bioproducts for developing

new upstream products (e.g., creating new isolated bioproducts). A separate compulsory licensing provision would allow reasonably priced access for downstream product development (e.g., therapeutic devices using isolated bioproduct technology), thereby avoiding the "reach through" and "patent stacking" licensing problems. n231 In reality, the compulsory licensing provisions would likely motivate parties to negotiate reasonable licenses in order to avoid the Parapatent Act's compulsory licensing provisions. n232 Under either scenario, this limitation would then provide an incentive to continue innovation and immediate public access to these essential basic research tools. Second, university researchers will not conduct significant upstream bioproduct research without a patent-like incentive. The Bayh-Dole provisions allow university researchers to receive federal funding for research and own the patent rights to the resulting inventions. n233 As a result, university researchers are far more likely to spend their time on projects where they ultimately share patent royalties with their university and/or corporate partners. n234 University researchers have little motivation [*151] to continue discovering additional genetic mutations linked to specific diseases or to isolate new genes and stem cell products for future therapeutic and diagnostic use without some type of exclusive right. Without patent-like rights, university and industry scientists would likely focus on using existing upstream isolated bioproducts to develop patentable downstream therapeutic products. This would leave a gaping hole in genomic and regenerative medicine research. A parapatent for isolated bioproducts would motivate scientists to continue research and development of these much-needed upstream bioproducts. Lastly, given the current depressed state of the U.S. economy, the government likely lacks the financial resources necessary to replace the level of industry funding that is currently devoted to upstream bioproduct research. n235 It is therefore crucial to continue incentivizing industry and academic scientists by providing sui generis parapatent protection that ensures reasonable public access to this basic knowledge. C. To MEET THE SECOND PRONG OF THE K-R TEST, THE ISOLATED BIOPRODUCTS PARAPATENT STATUTE MUST INCLUDE REASONABLY CLEAR AND SATISFACTORY DEFINITIONS OF THE SCOPE OF PROTECTION FOR ALL STAKEHOLDERS To meet the second prong of the K-R test, Congress must ensure that its Parapatent Act clearly defines the eligible subject matter, range of exclusive rights, and access limitations for all stakeholders. Isolated bioproducts like cDNA, that undergo additional human engineering to alter their chemical structure and biological functions, are currently patentable if novel, useful, and non-obvious. n236 Congress should limit any proposed parapatent protection to isolated bioproducts that are currently patent-ineligible products of nature. Consistent with the Patent Act, Congress should define the parapatent right as "the right to exclude others from making, using and selling the claimed invention" n237 during the term of the parapatent. Any requirements for parapatentability should be consistent with the impending changes to patent law contained in the recently passed Leahy-Smith America Invents Act. n238 Consistent with the new America Invents Act, a parapatent would be awarded to the first inventor to file an enabling application with the PTO, rather than the "first to invent" as currently provided for in section 102 of the Patent Act. n239 Like [*152] the new Patent Act, we should also have provisions that allow some limited use by the true first inventor who loses the race to the PTO. n240 The Parapatent Act should include enablement and written disclosure requirements. Stakeholders will likely agree to include these requirements, which mirror the current Patent Act, because they ensure that the invention is documented in a manner that allows a PHOSITA to learn from the invention during the parapatent term and duplicate it when the term expires. Like the new Patent Act, the sui generis statute should not have a "best mode" n241 requirement because inventors rarely know the "best mode" at the time of application. To be sure that each invention possesses a level of utility worthy of intellectual property protection, the Act should be limited to "useful" isolated bioproducts and define utility. In defining utility, Congress could use the current language in the PTO guidelines for biotechnological inventions, requiring that a "well-established utility" is "specific, substantial and credible" and "readily apparent to one skilled in the art." n242 Congress will face the most industry opposition in drafting the access limitation provisions. Fair use and compulsory licensing are foreign concepts to industry stakeholders who currently own significant patent portfolios. As patentees, they will be reluctant to part with their current unequivocal right to exclude others from making, using, and selling their claimed inventions. Congress could achieve a "meeting of the minds" by having separate fair use and compulsory licensing limitations in the Parapatent Act that address the concerns of both industry and public interest groups. For instance, the fair use defense could be limited to the following: (1) using protected isolated gene material to identify and isolate additional genetic information; or (2) identifying and isolating new upstream bioproducts, such as genes, gene sequences, or methods of cloning or isolating stem cells. A separate compulsory licensing provision could set a reasonable royalty rate for using isolated bioproduct material for second-opinion diagnostic testing and downstream product development. Taking into account the public interest arguments made for access to BRCA diagnostic testing in the Myriad case, n243 the compulsory licensing provisions could offer a royalty free or reduced-rate license for second-opinion testing. This would greatly benefit for-profit and non-profit laboratories as they could then serve a greater range of patients that need access to these tests. n244 In sum, parapatent legislation for isolated bioproducts that is drafted to limit the term of

exclusive rights, while also requiring novelty, specific utility, and an enabling well-written disclosure, signals that Congress is providing intellectual property protection that is both well-defined and bridges the progress gap. This [*153] legislation will mirror traditional patent protection, but take into account the unique "basic research" nature of isolated bioproducts. Also, limitations such as fair use and compulsory licensing will specifically address the need for greater access to these basic research tools during the parapatent's term.

Congress should establish patent pools to reduce market transaction costs and incentivize R&D on biodproducts

Zard 9 (Eric D, JD Candidate, 2009, University of St. Thomas School of Law; BS in Biology from the University of Minnesota, "Patentability of Human Genetic Information: Exploring Ethical Dilemmas Within the Patent Office and Biotechnology's Clash with the Public Good", *University of St. Thomas Law Journal;* Volume 6, Issue 2, Lexis)

2. Patent Pools In an attempt to overcome the concern that human gene patents limit access to researchers and other third parties, many commentators recommend that Congress require the use of "patent pools" for human gene patents. 258 While not yet mandated, this approach has been well received because the resources required "to develop any significant fraction of genetic information present in an organism" can result in a large expenditure of resources that no single company can afford. 259 Further, if this information is not shared freely or licensed in an affordable manner, researchers would be precluded from developing new diagnostic testing. 260 In the case of patents on human genetic information, a congressionally mandated patent pool would essentially allow for researchers "to contribute their patented genes to the pool and agree on reasonable licensing and royalty fees." 261 For non-member researchers wanting to make use of a patent already associated with an established pool, it has been suggested that "independent organizations" could be founded to "negotiate licensing" and reduce concern over defining reasonability standards. 262 Patent pools relieve concern that an individual patent holder could refuse to allow use of their patent as a means to extract exorbitant licensing fees. 263 By removing transaction costs associated with acquiring multiple licenses, it is likely that gene function could be identified more easily and diagnostic tests could be more efficiently developed, and thus result in lower costs for consumers. 264 Additionally, it removes the trepidation that genetic diagnostic testing would only be available at a few laboratories which were authorized by the original patent holder and, as a result, have overly inflated rates. 265 Finally, pooling offers members financial security by allocating the risk of research and development to all those affiliated with the pool. 266 While pools can be structured according to members' preferences, it is typical that "each member of the pool receives a certain percentage of the total royalties collected by the group." 267 Thus, to many commentators, the increased access to make use of another researcher's labor and the increased likelihood of recovering research and development costs makes this solution attractive. 268

Time Limits

Changing USPTO patent terms regulations from 20 years of the date an application is filed to the date an application is approved stimulates biologics innovation and development

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2. Independence of Patent Term and Development Time Another issue with the current U.S. patent system is that the patent term of the exclusivity period is uniform for all inventions and thus independent of the time and cost to develop different types of inventions. n259 The patent term is also independent of the commercial life of a product covered by the patent. n260 Some inventions are quick to develop and gain approval, and are on the market quickly to earn enough revenue to cover the investment costs (and financially justify their development) within the first few months on the market. n261 Other products take decades to develop, more years to get approved, and take decades or more of sales to become profitable. n262 Given these variations from one invention to another makes it reasonable to conclude that although the

current system for determining patent term is relatively easy to administer (at least without taking excessive adjustments into account) it may not be the most economically efficient system. n263 A more variable [*581] invention-dependent system would better reward innovation and investment without excessively tying up of the competitive marketplace with patent landmines. a. Patent Term is Uniform for All Patents, Measured from Filing Date Currently a patent term for a U.S. utility patent is twenty years from the date the application is filed with adjustments as necessary to account for PTO and regulatory delays. n264 b. Some Products Are Ready to Market when the Patent Is Granted, Other Products Require Additional Steps For some inventions a product is ready to be marketed commercially as soon as the patent is granted. For other inventions, several regulatory prerequisites must be met before the product can be marketed and the patent can be exploited. n265 Thus, a portion of a patent term is essentially wasted for some patents because the products that are covered by them cannot be marketed during the entire patent term. It would make more sense from an investment perspective to have the patent term measured from the earliest date at which both the patent was granted and the product covered by the patent was approved to market in the country where the patent was granted. Another factor that could be factored into patent term determination for economic efficiency would be the amount of investment required to arrive at the patentable product or a related metric, the amount of time required on the market to recoup investment (which would depend on amount of investment and market price).

Comprehensive Executive Reform

Executive reforms to the USPTO and other agencies should implement patent regulations to protect patents on genetic materials to resolve inter-agency conflicts

Rai 12 (Arti K., Latty Professor of Law, Duke University School of Law and Duke Institute for Genome Sciences and Policy. From 2009 to 2010, I served as the administrator of the U.S. Patent and Trademark Office's (PTO's) Office of External Affairs (now titled the Office of Policy and External Affairs, "PATENT VALIDITY ACROSS THE EXECUTIVE BRANCH: EX ANTE FOUNDATIONS FOR POLICY DEVELOPMENT", March 2012, *Duke Law Journal*, 61 Duke L.J. 1237, Lexis)

As a real-world matter, how might policymakers engineer more frequent consultation ex ante between the PTO and "competition-oriented" executive-branch agencies such as the DOJ Antitrust Division? In general, pressure to engage in interagency consultation is often provided by powerful White House offices and components such as the Office of Management and Budget or the National Economic Council. Prominent think tanks have recently emphasized the pressing need for individuals within these offices to focus on interagency innovation and long-term competition strategy. n159 The official job descriptions for members of these offices should include facilitating, or even mandating, consultation between agencies with diverse perspectives on innovation. IV. Rulemaking Authority over Questions of Patentability? To those with an administrative-law bent, the preceding discussion of guidelines and ex ante decisionmaking might seem a half-measure. Why not simply confer upon the PTO rulemaking authority over questions of patent validity? Under standard administrative-law doctrine, courts would then have to give such rules the strong form of deference enunciated in Chevron and its progeny. [*1278] Additionally, as contrasted with guidelines, which are likely to be prospective in nature only because they are likely to address issues presented in more recent applications, administrative-law doctrine affirmatively requires that, absent specific congressional authorization, rules address issues prospectively. n160 Rules enacted pursuant to congressionally delegated authority also would not have to wait for court approval to have the imprimatur of law. Indeed, unless challenged, they would be law. Rulemaking could therefore produce controlling authority even more quickly than guidelines. Yet most scholarly discussions of an administrative model for the patent system, including my own, have generally stopped short of advocating a congressional grant of rulemaking authority on core questions of patentability - that is, authority over such questions as what constitutes patentable subject matter, what represents nonobviousness, and what type of disclosure is necessary to satisfy Section 112 of the Patent Act. n161 In prior work, I argue that conferring such authority would be premature because the PTO lacks the large cadre of economists and policy-oriented thinkers possessed by other agencies - such as the Federal Communications Commission and the FTC - that work on questions of technological innovation and that have at least some rulemaking authority. n162 Since that work was published, however, the PTO has created and staffed an Office of the Chief Economist. Early versions of the 2007 patent-reform bill n163 included language conferring on the PTO rulemaking authority not only over questions of patentability but also [*1279] over all aspects of the Patent Act. n164 Perhaps in reaction to this expression of congressional interest, several scholarly articles advance the conventional suite of administrative-law arguments that favor conferring significant rulemaking authority on agencies that tackle technologically and economically complex questions. n165 These commentators argue that Congress should grant the PTO rulemaking authority over all issues of patent validity or, at the very least, over specific questions such as what constitutes patentable subject matter. n166 As these scholars emphasize, concerns about certain pathologies of the administrative state - including concerns about capture or about decisionmaking that is unduly responsive to changes in presidential administration - are hardly limited to the patent context. To the contrary, as discussed in Part II, the issue of PTO capture is more complex than most scholars acknowledge. Given the existence of competing well-heeled interest groups with diverse views, one-sided capture is unlikely. Notably, in the context of a grant of rulemaking authority to the PTO, Congress could explicitly require the PTO to consult with specific agencies before making a rule. Congress has already embedded such consultation requirements within a variety of statutes. n167 At least one empirical study involving the Federal Energy Regulatory Commission (FERC) found that appropriately designed consultation requirements can force an agency to consider concerns [*1280] that it would otherwise ignore. n168 Specifically, congressional passage of strict consultation requirements in the Electric Consumers Protection Act of 1986 n169 "forced FERC to pay attention to the environmental concerns it had long ignored." n170 The swift elimination of the expanded rulemaking-authority provision from the 2007 predecessor to the AIA suggests that a move in this direction might not be politically feasible, at least not in the political climate and setting in which the AIA was passed. No prominent interest group is advocating for such authority, and many interest groups view the regulation of patents as being inconsistent with the principle that patents are property rights. As the example of the EPA, among many others, illustrates, the view that agencies never regulate property rights is incorrect. Nonetheless, that view continues to hold sway among many powerful groups. Until that view is abandoned, an intermediate approach is needed. An approach based on ex ante PTO guidelines backed by the full weight of the executive branch has already shown some promise. Especially to the extent that courts properly give significant deference under Skidmore to considered executive-branch decisions, a guidelines-based approach should be made a much more integral part of patent policymaking. In fact, the executive branch could also use the postgrant-review authority conferred upon the PTO by the AIA to go one step further. As a doctrinal matter, under current Supreme Court precedent interpreting the contexts in which Chevron applies, the government could ask for Chevron deference

toward decisions made in postgrant review proceedings. n171 As a normative matter, in cases in which the PTO is applying guidelines formulated after widespread consultation with relevant stakeholders, courts should be inclined to give those guidelines strong deference. To be sure, administrative-law scholars generally disfavor large-scale policymaking through agency adjudication. As they rightly note, for purposes of policymaking, agency adjudication suffers from some of the same defects as [*1281] adjudication in the courts. n172 Rulemaking, not adjudication, is the innovation of the administrative state. But in this case, adjudication would have been preceded by an activity much like rulemaking: guideline formation through widespread consultation with relevant stakeholders. Conclusion Among patent scholars who address institutional questions, a significant number tend to favor the judiciary over the PTO as the policymaker of choice. Even though courts have familiar limitations with respect to policymaking, scholars often argue that the PTO is more likely to be captured. On closer examination, however, this capture story is less obviously true than it might seem. Further, at least in DNA-patenting cases, in which PTO decisionmaking has been heavily influenced by other executive-branch decisionmakers, the conclusions reached by the executive branch have been defensible vis-a-vis charges of capture. Executive-branch firepower should be deployed to a greater extent ex ante. The ex post development of patent law by the courts poses many familiar problems. Less recognized, but important, it often yields a one-way ratchet toward the expansion of patent protection. When courts expand patent rights, they generally do not have to worry much about retroactive effects. By contrast, as the Myriad case illustrates, courts face legitimate concerns about retroactive effect when they are called upon to curtail such rights. More frequent ex ante intervention would avoid these problems without precluding ex post development and adaptation. Moreover, whereas the existing system forces courts to act with only limited guidance from technologically and economically sophisticated executive-branch agencies, this Essay's call for ex ante intervention would help lay a sound foundation for further ex post development. Ultimately, as the DNA-patenting cases demonstrate, early and robust executive-branch discussion of patent policy should be welcomed by all those interested in improving the patent system.

Supreme Court

Because the Supreme Court deferred their opinion on *Myriad* to the Federal Circuit Court, a universal Court ruling to uphold and clarify the patentability of genetic material would incentivize further research and development

Rose 12 (Simone, Wake Forest University Professor of Law, “ARTICLE: Semiconductor Chips, Genes, and Stem Cells: New Wine for New Bottles?”, *American Journal of Law & Medicine,* 38 Am. J. L. and Med. 113, Lexis)

One question, however, immediately comes to mind after reading the court's holding that basic isolated gene and gene sequences that are biologically identical to native DNA are "markedly different" and patent-eligible: how can chemical differences supersede biological equivalence when the specific utility of the claimed invention depends on [*132] biological identity? In other words, the basic isolated BRCA1/2 genes and gene sequences must have the same nucleotide sequence as the naturally occurring or "native" genes for the lab to correctly evaluate whether the particular BRCA sequence contains the mutations associated with a particular type of breast or ovarian cancer. n109 The dominant focus for whether isolated genes and sequences are "markedly different" from their native counterparts should be on the biological identity of the genetic code as information, rather than the chemical differences resulting from purification and isolation. n110 As aptly put by Judge William Bryson in the dissenting portion of his mixed concurrence/dissent in Myriad: "What is claimed in the BRCA genes is the genetic coding material, and that material is the same, structurally and functionally, in both the native gene and the isolated form of the gene." n111 In contrast, Judge Lourie opines that the smaller and chemically-altered isolated gene is what allows for the "new utility" of detecting mutations; so, this "new chemical identity" can serve as the basis for establishing the marked difference between isolated genes and their naturally occurring counterparts. n112 I find puzzling the majority's creation of a "new utility" of detecting mutations for a product possessing the identical DNA information as its native counterpart. Establishing this "new utility" is an artificial distinction to force isolated genes into the box of patentable subject matter under section 101. n113 Indeed Judge Lourie concedes that biologists may view his argument differently, but the court must give [*133] great weight to the PTO's long-standing position since 2001--that isolated DNA molecules are patent-eligible. n114 According to PTO guidelines, isolated genes are patentable as "chemical compounds" if they meet the other statutory criteria for patentability. n115 Judge Moore, in her concurring opinion, agrees with Judge Lourie and supports keeping the PTO guidelines intact. n116 She notes that biotechnology companies have relied on these guidelines to develop significant genomic patent portfolios. n117 She reasons that patent protection for genomic material is crucial for continued innovation and economic growth of the biotechnology industry. n118 While promoting innovation is a laudable goal, the Federal Circuit misses the bigger "constitutional" target. The constitutional mandate to promote Progress in the useful Arts includes

more than simply focusing on whether protecting isolated bioproducts promotes innovation. Instead, we must also evaluate whether patent protection for these products allows for reasonable access to basic knowledge. n119 This balancing of access and innovation is the basis for excluding products of nature and abstract ideas from patentable subject matter under section 101 of the Patent Act. Access to this basic knowledge is crucial to our progress as a society. n120 Furthermore, the courts and not the PTO must have the final word on statutory interpretation. n121 The courts must utilize the plain language of the statute, legislative history, and case-law to interpret the boundaries of section 101 of the Patent Act. Most importantly, any interpretation must be vetted to ensure that it comports with the IP Clause's mandate to "promote the Progress of the useful Arts." n122 No matter how long they have been in place, PTO guidelines cannot supersede constitutional limitations on any section of the Patent Act, including section 101 's subject matter [*134] limitations. n123 The majority and concurring opinions in the Myriad case arguably gave too much weight to an administrative agency's view that failed to adapt to a changing technological landscape and lacked the level of legal analysis necessary to earn the court's deference. n124 In a continued effort to gain greater access to the isolated BRCA gene material for the public, the plaintiffs in Myriad have filed a request for certiorari by the Supreme Court. n125 I posit that the outcome of any appeal will turn on whether the reviewing court views isolated genes as biological "information" or purified "chemical compounds." n126 Which perspective the Court chooses will likely turn on how broadly or narrowly it views its role in statutory interpretation and how much weight it gives the PTO guidelines. Since at least one member of the three-judge panel of the Federal Circuit followed the biological information approach, it is plausible that the Supreme Court might agree with Judge Bryson and find isolated genes and gene sequences patent-ineligible products of nature. n127 The uncertainty surrounding the patentability of the isolated BRCA genes places basic isolated genes and gene sequences in the same precarious position as isolated stem cells--one step away from falling outside the scope of patent law and into the "progress gap" of intellectual property protection. As such, to stimulate a dialogue between industry, academic, and public interest stakeholders, n128 I will explore how a sui generis intellectual property statute for basic isolated stem cells and genes could pass the four-part K-R test and serve as an alternative property paradigm to fill any potential "progress gap." Before doing so, however, it is helpful to draw an analogy between the current dilemma and how Congress handled the "progress gap" that resulted from the failure of early semiconductors to qualify for either copyright or patent protection in the 1980s.

Court ruling on *Myriad* would have massive spillover effects on the biotechnology industry

Brougher 11 (Joanna T, JD, MPH, is senior counsel at Vaccinex Inc. and adjunct lecturer on health policy and management at the Harvard School of Public Health, **“**Gene Patent Reform: Still in Doubt. The patent-eligibility doctrine remains in limbo as the battle over gene patents cuts a tortuous path through the court system”, *Biotechnol Healthc*, Winter; 8(4): 28–29)

Myriad has now appealed the case to the Supreme Court. If the Supreme Court grants review of the case, the court’s holding could have far-reaching implications for the biotechnology industry, particularly molecular diagnostics, and for patients and healthcare providers. If Myriad’s patents are upheld, then Myriad would continue to control research into the BRCA1 and BRCA2 genes and the BRACAnalysis test would remain the only diagnostic test for those genes, at least until the patents expired. If the Supreme Court sides with the District Court and invalidates Myriad’s gene patents, then companies that focus solely on the discovery of genes and diagnostic methods based on such biomarkers may find themselves unable to obtain patent protection, which, as some have argued, could discourage innovation — those companies would still be able to commercialize and sell their products, but they could not prevent other researchers from doing the same. Moreover, faced with fewer intellectual property obstacles, researchers would be able to conduct experiments involving previously patented genes, gaining not only valuable insight into their biology but also insight into genetic research. This newly gathered information could then serve as the basis for developing new therapeutics and advancing personalized medicine, which is based on shared genetic characteristics. Consumers would benefit by having access to, perhaps, more accurate and less costly diagnostic products. Even if the Supreme Court upholds the patentability of isolated gene sequences, there is the possibility that researchers may soon have unlimited access to gene sequences anyway. Since most of the human genome is now either patented or publicly available, fewer opportunities remain to discover and patent new DNA sequences. With the patenting of new gene sequences subsiding, researchers and makers of molecular diagnostics need only wait until current patents expire when the genes will become available to them for research. Conclusion If the Supreme Court chooses to hear the Myriad Genetics appeal, its decision could signal a significant change in patent-eligible

subject matter, affecting — at least in the short term — the biotechnology industry and personalized medicine. Although the focus of the case is limited, the Supreme Court will nevertheless have an opportunity to clarify the patentability of genes.

Executive FDA Reforms

FDA applications are both superior and complimentary to USPTO patents – reforms such as public disclosure requirements would encourage greater research and development on top of exclusive rights protections to incentivize innovation

Addison 11 (Katherine, intellectual property and patent attorney with Fulwider Patton LLP of Los Angeles, CA specializing in patent prosecution for clients of all sizes in the medical device and clean technology industries but welcomes clients with all varieties of intellectual property needs, "ARTICLE: THE IMPACT OF THE BIOSIMILARS PROVISION OF THE HEALTH CARE REFORM BILL ON INNOVATION INVESTMENTS", *The John Marshall Law School Review of Intellectual Property Law,* 10 J. Marshall Rev. Intell. Prop. L. 553, Spring, 2011, Lexis)

1. Disadvantages of FDA Exclusivity Without Patent Protection Without patent protection it is doubtful that enough information will be publicly available for academics and skilled scientists, researchers and engineers to utilize. n184 This lack of publicly available information will hinder progress and result in economic waste as multiple parties spend money pursuing the same aims and efforts. n185 Without the possibility of an economically valuable patent and the chance for a limited term monopoly, inventors and their employers have no incentive to disclose the intimate details of their technologies and it will be economically advantageous and logical to instead keep this information confidential as trade secrets. n186 Applications for FDA approval do not require of applicants the same burden as applications for a patent. Applications for a patent require a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to [*573] enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. n187 FDA applications are concerned with the safety and effectiveness of a finished product on humans as opposed to how a product is made, why it works, and which method or version is most preferable (unless the process of creating the product affects safety and effectiveness). n188 Another point of distinction is that patent applications are published after eighteen months from the earliest priority date claimed regardless of whether the patent is granted and often before a patent is granted (given the long wait time for responses from the PTO). n189 For published applications that never result in a corresponding patent the material disclosed is forever donated to the public domain and free for all to access. n190 Today, most publications on cutting edge research are not free to the public but available only for purchase through a journal or online news and database service. n191 In addition, FDA applications are generally treated as confidential, unless the information has been previously disclosed, until the product is approved, licensed, or cleared. n192 The public does not currently benefit from the early disclosure of information in confidential FDA applications for products not yet approved. n193 If policies were changed, however, the public could benefit from early disclosure of information in confidential FDA applications, especially if there is not a corresponding published patent application to cover the product. Mandatory disclosure in published patent applications allows everyone to benefit, at least intellectually if not economically (until expiration of the patent term), from a research team's findings. n194 More specifically, in the biologics context, published patent applications allow other innovators and biosimilar producers to research what is known about a biologic (how it is made, manner of use, test data, etc. . . . as published in the patent application) to serve as an impetus and starting point for determining other mechanisms of treatment and/or other potential biologics for treatment or precursors for further research. n195 Pre-grant or pre-approval publication is especially important when there is a long wait time between the filing date of an application and patent grant or FDA approval. Otherwise, companies and their investors do not have any idea how many other teams are working on the same thing at the same time and they may be wasting time or duplicating research that [*574] has already been performed by someone else but is not yet publicly available. n196 Even with publication at eighteen months there is an eighteen month unknown waiting period or blackout during which patent applicant innovators do not know what other applications have been submitted to the PTO. n197 There is always the chance that an innovator may realize, the day after filing an expensive application, that a competitor filed an application seventeen months and twenty-nine days earlier disclosing the same or similar technology, which would render the innovator's patent application redundant.

B. Reproductive Health Solvency Mechanism Evidence

Increased regulation is key for reproductive health technologies – solves polarization, credibility, and accountability

Furger and Fukuyama 2007 (Franco Furger, PhD, executive director of the Human Biotechnology Governance Forum at the Foreign Policy Institute of the Paul H. Nitze School of Advanced International Studies at Johns Hopkins University ,and Francis Fukuyama, Senior Fellow at the Center on Democracy, Development, and the Rule of Law at Stanford and previous member of the President's Council on Bioethics. "A proposal for modernizing the regulation of human biotechnologies," The Hastings Center Report, July-August 2007, The Hastings Center, http://www.thehastingscenter.org/Publications/HCR/Detail.aspx?id=780)

What would a regulatory agency charged with implementing congressional intent be like? It should operate according to several basic principles. First, all affected constituencies should perceive it as independent: that is, it should be able to generate regulatory choices regarded by all affected parties as not unduly influenced by polarized interest groups. In the currently charged political environment, this requirement needs no further elaboration. A second basic requirement is accountability: regulators should not be able to make what in the legal jargon are known as "arbitrary and capricious" decisions. Third, the agency should be perceived by all interest groups and by the general public as authoritative: regulators should be not only technically competent but also morally credible. Scientific competence without moral authority would be just as inadequate as moral authority without scientific competence. At first, efforts to reconcile independence and accountability may appear contradictory. It would seem that independence can be achieved only at the expense of accountability, and vice versa. On closer examination, the contradiction disappears. An independent commission affords its members a measure of autonomy, especially with regard to the Office of the President. It is also well suited to perform what amounts to a quasi-judicial function: its members are selected by the president but confirmed by the Senate. Their appointment is stacked, and the president can remove them from office only in special circumstances. Finally, an independent commission operates in a deliberative, consensual manner. Ensuring accountability—making sure that organized interest groups do not exercise undue influence (what is generally known as regulatory capture)—requires some ingenuity. According to the Administrative Procedure Act, regulatory agencies must publish a proposed new rule in the Federal Register and solicit comments from all interested parties before finalizing a new rule. This provision, known as "notice-and-comment," was intended to ensure a measure of accountability: agencies are required to respond to every substantive comment and to take it into consideration. The courts have repeatedly underlined the need for regulatory agencies to provide extensive and detailed justifications for their regulatory interventions.

Regulation and public consultation are key – solves deadlock and spillsover to more effective regulation in other federal agencies

Furger and Fukuyama 2007 (Franco Furger, PhD, executive director of the Human Biotechnology Governance Forum at the Foreign Policy Institute of the Paul H. Nitze School of Advanced International Studies at Johns Hopkins University ,and Francis Fukuyama, Senior Fellow at the Center on Democracy, Development, and the Rule of Law at Stanford and previous member of the President's Council on Bioethics. "A proposal for modernizing the regulation of human biotechnologies," The Hastings Center Report, July-August 2007, The Hastings Center, http://www.thehastingscenter.org/Publications/HCR/Detail.aspx?id=780)

To prevent regulatory deadlock, we propose to complement notice-and-comment with a robust procedure of public consultation. One can envision different ways to implement a consultative process, but the following requirements should always be met: the consulted sample of the public should be representative of the population at large, the consultation should be deliberative—that is, based on two-way communication—and the outcome should reflect informed opinions. In addition, the

process should be designed so as to avoid polarization: it should promote reciprocal understanding among participants rather than reinforce the prejudices the participants held before the consultative process began. Public consultation is not meant to produce a consensus, but it is certainly intended to promote consensual views. The results of a consultative process are in no way binding. Regulators would be free to propose a new rule that departs significantly from the recommendations emerging in a public consultation. If they do, though, they would be required to provide a detailed rationale for ignoring informed public opinion. This gives regulators a strong incentive not to favor a special interest group over a clear consultative outcome. The agency would have to consider the possibility that the judiciary will review whatever rules it proposes—a possibility that, given the history of the regulatory state, seems quite real for any rule bearing on matters of reproduction. Furthermore, in particularly controversial cases a blatant abuse of administrative authority would likely attract wide public attention and eventually trigger intense congressional scrutiny. Most of the time, the combined risk of judicial review and public scrutiny should deter the agency from catering to special interests. In sum, a process of public consultation would ensure that a formally independent regulatory agency would be held accountable and that "arbitrary and capricious" decisions would be reduced. Failure to ensure that all societal perspectives are heard is a problem not limited to reproductive medicine or biomedical research; it is quite common across the regulatory state. Regulatory agencies from the Environmental Protection Agency to the Department of Energy and the Occupation, Safety and Health Administration have a long history of producing regulatory decisions driven by the most influential interest groups, to the detriment of the public at large. Commentators and practitioners have long ignored this phenomenon, however, for two main reasons. With the arrival of the theory of public choice in the 1960s, scholars of the administrative state largely abandoned the thought that regulatory and political action was based on the notion of public interest; they held instead that nothing more than the aggregation of self-interested motives explained what went on in government.

The United States federal government should increase federal regulation through a Reprogenetics Technologies Advisory Commission. The RTAC should make legislative recommendations, consult experts, and develop an oversight body
Parens and Knowles 2003 (Erik Parens, PhD Senior Research Scholar at The Hastings Center,and Lori P. Knowles, dependent consultant specializing in biotechnology law and ethics and Research Fellow at the Health Law Institute, University of Alberta Law School, "Reprogenetics and Public Policy Reflections and Recommendations," The Hasting Center Report, July-August 2003, The Hastings Center, http://www.thehastingscenter.org/pdf/reprogenetics_and_public_policy.pdf)

Second, to take action toward regulatory oversight in the United States, a commission must consolidate and translate the many documents that have already been written on this topic, solicit views from the diverse U.S. constituencies that are or should be engaged with this topic, and synthesize this material to make legislative recommendations about statutory authority for an oversight body. The work of the commission, referred to in this report as the Reprogenetics Technologies Advisory Commission (RTAC), would be similar in some respects to that of the Royal Commission in Canada, although the audience for this body would be Congress. The advisory commission would, in part, engage the public, stakeholder, and expert constituencies in consultation; articulate the ethical commitments that must guide such a regulatory effort; and draft the terms of reference for embryo research, including the limits, restrictions, and prohibitions to be written into legislation. That commission would then report its findings in the form of recommendations to Congress for a legislative initiative.

Reprogenetics is not regulated in the status quo – regulation is necessary to solve safety and prevent market takeover
Parens and Knowles 2003 (Erik Parens, PhD Senior Research Scholar at The Hastings Center,and Lori P. Knowles, dependent consultant specializing in biotechnology law and ethics and Research Fellow at the Health Law Institute, University of Alberta Law School, "Reprogenetics and Public Policy

Reflections and Recommendations," The Hasting Center Report, July-August 2003, The Hastings Center, http://www.thehastingscenter.org/pdf/reprogenetics_and_public_policy.pdf)
For a variety of reasons, research involving the use, creation, alteration, and storage of gametes and embryos is subject to little regulation in the United States. This situation is potentially dangerous. Unlike older in vitro fertilization (IVF) techniques, many new reprogenetic techniques make structural changes to cells, and with structural changes arise concerns about the safety of the children produced by the technology. Further, both older and newer techniques raise concerns about the safety of the women who donate the eggs and the women in whom the fertilized eggs are implanted—the egg donors and the gestating mothers. But concerns about reprogenetics are not only about safety. Just as important are concerns about the well-being of children produced by these techniques—and about the well-being of the families and society that will welcome those children. Are we in danger of allowing the market mentality to colonize childbearing, as it has already colonized so much of our lives? Could the proliferation of techniques that increasingly enable us not just to have children, but to choose characteristics unrelated to their health, exacerbate our tendency to think of children as the objects of our making? Could these techniques lead us to think of ourselves as mechanisms that are valued for our individual parts or traits rather than as individuals who are valued for being unique wholes? Could it aggravate some forms of unfairness, or complicity with unjust norms? 3 Put positively, what can we do to increase the chances that these techniques are used in ways that further the happiness of children, families—and ultimately the well-being of our society as a whole?

A federal Reprogenetics Technologies Board should be established for increased regulation. The Board should outline restrictions, conditions, and limits on the use of embryos. Solves status quo uncertainty and legal disputes
Parens and Knowles 2003 (Erik Parens, PhD Senior Research Scholar at The Hastings Center,and Lori P. Knowles, dependent consultant specializing in biotechnology law and ethics and Research Fellow at the Health Law Institute, University of Alberta Law School, "Reprogenetics and Public Policy Reflections and Recommendations," The Hasting Center Report, July-August 2003, The Hastings Center, http://www.thehastingscenter.org/pdf/reprogenetics_and_public_policy.pdf)
Third, in formulating its recommendations, the commission should carefully consider the possibility of creating a standing federal entity, a Reprogenetics Technologies Board (RTB), to facilitate reasoned and systematic public and policy deliberation about the purposes of reprogenetic research and practice. The board's authority would extend to the public and private sectors, and it would factor concerns about safety and well-being into policy-making and license-granting decisions. The board would, in important respects, resemble the United Kingdom's Human Fertilisation and Embryology Authority (HFEA). Drawing from the lessons learned in the United Kingdom and Canadian experience, it will be important, first, that the Reprogenetics Technologies Advisory Commission's recommendations for Congress be framed in general terms; it should only outline its suggested restrictions, conditions, and limits on the use, storage, and creation of embryos and gametes. Second, in defining the Reprogenetics Technologies Board's purview, the recommendations (and the eventual legislation) should articulate acceptable and unacceptable purposes of embryo research rather than specific techniques. Third, recognizing that it is impossible to keep pace with scientific and technological developments, the legislative initiative should incorporate a mechanism for adding to or adapting the enabling legislation in the face of new developments or information. Fourth, the RTB should be granted significant discretion, since its members will need to develop an expertise not likely shared by the members of Congress. Fifth, a detailed informed consent procedure should be considered to enable patients to contemplate what they want done with their embryos and gametes in unexpected circumstances like death and divorce; such procedures would be aimed both at preventing unnecessary litigation and respecting patient autonomy. And, finally, the RTB should be responsible for developing a code of practice as a means of educating researchers, clinicians, and patients.

The establishment of a federal regulatory board would change the fundamental structure of oversight over reprogenetics and connect the private and public sectors

Parens and Knowles 2003 (Erik Parens, PhD Senior Research Scholar at The Hastings Center,and Lori P. Knowles, dependent consultant specializing in biotechnology law and ethics and Research Fellow at the Health Law Institute, University of Alberta Law School, "Reprogenetics and Public Policy Reflections and Recommendations," The Hasting Center Report, July-August 2003, The Hastings Center, http://www.thehastingscenter.org/pdf/reprogenetics_and_public_policy.pdf)

The RTB's scope of authority would be articulated in the legislation that creates it, as called for by the advisory commission. The legislation should indicate that the RTB would grant licenses, monitor and inspect facilities, create a code of practice, consult with the public, and keep an information registry. The legislation would articulate those purposes, related to both treatment and research, involving the creation, use, manipulation, and storage of gametes and embryos for which licenses may be granted by the RTB. The RTB would be empowered to make licensing decisions in light of concerns about both safety and well-being. In addition, an important function of the legislation is to articulate those practices that are unacceptable and therefore may not be the subject of a license. Both the British and Canadian acts forbid, for example, reproductive cloning and use of an embryo past fourteen days of development. Which practices should be identified as unacceptable would be part of the deliberations of the advisory commission. The RTB's authority would extend to both the public and private sectors. At least with respect to safety concerns, a system of regulatory separation is arbitrary. It defies commonsense to protect participants in federally funded research from bodily harm, but not to protect those in privately funded research from the same. Respect for the safety and dignity of persons does not change with their location. In accordance with this line of reasoning, NBAC recently recommended the creation of a new federal-level body to oversee all human subjects research.

The regulatory body should create a Code of Practice, set standards, and engage in public consultation

Parens and Knowles 2003 (Erik Parens, PhD Senior Research Scholar at The Hastings Center,and Lori P. Knowles, dependent consultant specializing in biotechnology law and ethics and Research Fellow at the Health Law Institute, University of Alberta Law School, "Reprogenetics and Public Policy Reflections and Recommendations," The Hasting Center Report, July-August 2003, The Hastings Center, http://www.thehastingscenter.org/pdf/reprogenetics_and_public_policy.pdf)

A body such as the RTB can be thought of as fulfilling three intimately related functions. The first would be to make policy regarding the things people do with gametes and embryos, from basic embryo research to reprogenetics services, by applying and interpreting the purposes, principles, and strictures of the enabling legislation. This policymaking function would be accomplished by granting (or denying) licenses for laboratories and clinics to carry out the research and clinical activities described in the legislation. The enabling legislation will probably flatly prohibit some activities, but other activities will likely be left partly to the RTB's discretion. Thus the licensing might, for example, make it possible to sell pre-implantation genetic diagnosis to prospective parents seeking to test for disease-related traits but not to test for traits unrelated to disease (such as height, if testing for such traits became technically feasible). The licensing would be analogous to that performed by the HFEA in the United Kingdom. 123 Also like the HFEA, the RTB would monitor and inspect premises and activities carried out under a license and maintain a register of information about donors, treatments, and children born from those treatments. The second function of the RTB is to set standards for those activities by creating a Code of Practice. Such a code might detail informed consent procedures, for example, or delineate the proper handling of embryos that are to be transferred to a woman's uterus in the course of IVF. The code would necessarily change over time, of course, but at any given time it would establish a uniform standard for everyone offering reproductive services covered under the legislation. The code would also articulate the general guiding principles, which might build on the established U.S. principles of justice, beneficence, and autonomy. A third and fundamentally important function of the RTB would be to engage in public consultation and promote public conversation about emerging issues in embryo research generally and reprogenetics more particularly. This responsibility to promote public conversation—indeed to

create new constituencies committed to exploring this fascinating and important new arena of endeavor—is essential. In effect, we are calling not merely for the creation of a regulatory body, but for richer and more nuanced democratic deliberation about these vital issues. But one note of caution must be sounded here. Public consultation and transparency of political process are both important, and public consultation must not stand in the way of action. Public consultation should be immediate and ongoing, but so too must be the creation of policy.

A regulatory model should be adopted for reprogenetics

Caulfield et al. 2004 (T Caulfield, Faculty of Law, Faculty of Medicine and Dentistry, University of Alberta, L Knowles, Education and Outreach, The Hastings Center, and E M Meslin, Indiana University Center for Bioethics, Indiana University School of Medicine. "Law and Policy in the Era of Reproductive Genetics," Journal of Medical Ethics, August 2004, Volume 30, Issue 4, http://jme.bmj.com/content/30/4/414.full)

Though extensive details of such a scheme are beyond the scope of this paper, we believe that any future scheme should strive to incorporate the following characteristics. First, those responsible for creating a regulatory scheme must be knowledgeable and informed in the scientific, technological, and ethical issues. Second, recommendations for governance should be broadly and generally framed to allow the regulatory scheme to adapt to changes in science and social mores. That is, the enabling legislation should set the framework, articulate the relevant values and guiding principles, and set the standards for analysis; but the details of regulation, including the handling of the relevant definitions, should be left to a regulatory body.[26,34] Third, the regulatory body should facilitate and encourage an ongoing public and interdisciplinary discussion.[35,36] Fourth, any regulatory body created should have oversight powers with respect to reproductive genetics in both the public and private sectors. It makes little sense to carefully regulate only publicly funded research while leaving all the other activities to the whims of the marketplace. Finally, the enabling legislation should be framed to permit regulators to develop familiarity with the science and technology so that they can develop an expertise in reproductive genetics. Such expertise will permit foresight and a deep understanding of not only the science but also the social implications that a particular application of reproductive genetics brings to bear. It will be important—for example, for those involved in regulating reproductive genetics to identify when protocols or techniques involve modification of the human germline, or where issues of human dignity may be implicated.

Congress should establish a new regulatory agency for the promotion of ARTs based on moral principles

Furger and Fukuyama 2007 (Franco Furger, PhD, executive director of the Human Biotechnology Governance Forum at the Foreign Policy Institute of the Paul H. Nitze School of Advanced International Studies at Johns Hopkins University ,and Francis Fukuyama, Senior Fellow at the Center on Democracy, Development, and the Rule of Law at Stanford and previous member of the President's Council on Bioethics. "A proposal for modernizing the regulation of human biotechnologies," The Hastings Center Report, July-August 2007, The Hastings Center, http://www.thehastingscenter.org/Publications/HCR/Detail.aspx?id=780)

What we propose consists of a set of ethical guiding principles, a series of prohibited and regulated activities, and a new regulatory institution. In the enabling legislation, Congress would spell out the ethical principles it considers indispensable to inform the operation of the newly established regulatory agency, identify which activities should be taken off the table up front and which can be performed under suitable regulatory oversight, and establish in some detail the structure of the new regulatory institution. Finally, Congress would also adopt a number of procedures beyond the usual requirements of the Administrative Procedure Act that are designed to ensure agency independency and to prevent administrative drift. The ethical principles we have identified in our proposal touch upon several basic aspects of the human experience. They reflect what we believe are widely shared values, not only in the United States but also in many other

Western democracies: * Children's well-being and health should be protected. * Biomedical procedures on human embryos must respect their intermediate moral status. * Infertile couples' access to ARTs should be promoted. * Women's well-being and health should be protected. * Those making use of ARTs must give free and informed consent. * Therapeutic uses of biomedicine should be favored over enhancement uses. * Limits on the commercialization of eggs, sperm, and embryos should be imposed.

Negative Evidence

There is also extensive negative ground and literature. Here is evidence for a potential counterplan against an affirmative that increases regulation over reproductive health ethics:

Congress should lift the current ban on funding embryo research – prerequisite for ethical reprogenetics policies and preventing market takeover
Parens and Knowles 2003 (Erik Parens, PhD Senior Research Scholar at The Hastings Center,and Lori P. Knowles, dependent consultant specializing in biotechnology law and ethics and Research Fellow at the Health Law Institute, University of Alberta Law School, "Reprogenetics and Public Policy Reflections and Recommendations," The Hasting Center Report, July-August 2003, The Hastings Center, http://www.thehastingscenter.org/pdf/reprogenetics_and_public_policy.pdf)

First, to bring embryo research into the light of public deliberation, Congress should lift the current ban on federally funded embryo research. We cannot have responsible oversight of reprogenetics research and practice, nor of embryo research generally, if we do not first acknowledge that we already support those activities in a wide variety of ways. Our country has already embarked upon "one big embryo experiment." If we do not forthrightly accept that fact by allowing the federal government to oversee research and practice involving embryos, then the market will be the only mechanism that will distinguish between the acceptable and unacceptable purposes of those activities.

C. Pharmaceutical Solvency Mechanism Evidence

In light of Obamacare's success in congress, a complete restructuring of healthcare regulation has ensued

Daemmrich 11, Arthur. "U.S. Healthcare Reform and the Pharmaceutical Industry." Harvard Business School . http://www.hbs.edu/research/pdf/12-015.pdf.

Fiercely contested before, during, and since its passage, the 2010 Patient Protection and Affordable Care Act (ACA) will restructure the U.S. healthcare market if fully implemented in coming years. This article describes the institutional and political context in which the ACA was passed, and develops estimates of its likely impact on the biopharmaceutical industry. Universal insurance, either through a government-run system or by mandated purchase of private insurance, has been controversial in the United States since it was first proposed in the mid-1930s. Even in the absence of national health coverage, the United States became the world's largest prescription drug market and emerged as the global leader in new drug research and testing. With health benefits globally from the availability of new drugs, albeit for poorer populations only after patent terms expire, changes to the U.S. healthcare system are also of significance to patients and the pharmaceutical industry internationally. This article evaluates how the ACA will affect the size of the biopharmaceutical market and competitive dynamics within the industry. Estimates are developed for healthcare spending in 2015 and 2020, especially for expenditures on prescription drugs in nominal terms and as a percentage of overall health spending. The article concludes with a discussion of the political economy of insurance and the sustainability of largely free-pricing of pharmaceuticals in the United States.

Despite its origin in the 19th century, the resulting impact of mergers of pharmaceutical affiliates has created monoliths in the industry. Small businesses advocates in conjunction with public health activists are just two examples of members that are part of movement for increased regulation of the industry.

Daemmrich 11, Arthur. "U.S. Healthcare Reform and the Pharmaceutical Industry." Harvard Business School . http://www.hbs.edu/research/pdf/12-015.pdf.

As a sector, the pharmaceutical industry during its first century was characterized by low levels of concentration, heterogeneity in firm size and disease orientation, and relatively high barriers to entry stemming from patent strategy and government regulations that require testing new drugs for up to a decade prior to their marketing.[81] From its historical origins concentrated in a few geographic locations, the pharmaceutical industry evolved into one of the first global industries. Yet, even though drug firms expanded sales internationally already in the 1920s and 1930s, and located manufacturing in a variety of countries after the 1950s, many of the benefits – employment of skilled labor, development of new research technologies, and tax revenues – accrue primarily to the country where firms are headquartered.[82] Nations thus compete for pharmaceutical industry research laboratories and clinical testing sites in order to benefit from the economic growth they stimulate, the scientists and other skilled workers they employ, and to ensure access to the medicines they invent and manufacture. In some cases, notably in France, governments have sought to protect the pharmaceutical firms located within their borders when cross-national mergers were proposed, viewing them as national assets.[83]

Mergers and Acquisitions

Pharmaceutical "Mergers and Acquisitions" have proved to be a frequent and profitable method for companies looking to avoid the current disadvantages associated with present research and development practices that leave intellectual property vulnerable. These M&A practices have proven to be key to US economic growth however similar to the oil industry of the 20th century the industry has yet to be regulated allowing for the monopolization of the industry.

Paragon Report 12 [The Paragon Report: provides stock research on top pharmaceutical companies including paramount corporations Illumina and Amylin Pharmaceuticals: http://www.marketwatch.com/story/large-pharmaceuticals-look-to-acquire-smaller-biotech-companies-to-drive-growth-2012-04-20?reflink=MW_news_stmp]

Large Pharmaceuticals Look to Acquire Smaller Biotech Companies to Drive Growth
The Paragon Report Provides Stock Research on Illumina and Amylin Pharmaceuticals
NEW YORK, NY, Apr 20, 2012 (MARKETWIRE via COMTEX) -- Mergers and Acquisitions have been a hot topic in the Biotechnology Industry recently. According to a recent report by Dealogic, pharmaceutical deals totaled $18.5 billion globally this year, an increase of 5% from the same period last year. The Paragon Report examines investing opportunities in the Biotechnology Industry and provides equity research on Illumina, Inc. ILMN +0.68% and Amylin Pharmaceuticals, Inc. AMLN +0.66% . Access to full reports can be found at: www.ParagonReport.com/ILMN www.ParagonReport.com/AMLN As larger companies reduce spending on research and development they are looking at smaller biotech companies to diversify their product lines. M&A allows bigger companies to acquire products and technology that are already proven in the market place, avoiding the many risks associated with research and development.

Patents

Although scarce, the recent Supreme Court unanimous ruling in favor of drug producing companies as opposed to the pharmaceutical distributer proves that regulations are gaining attention in the field. This decision ruled that generic medication patents were for the use of the drug rather than the drug itself. This means that if a drug was later found to have multiple uses the pharmaceutical company which purchased the patent are not entitled to advertising those uses.
Noguchi 12 [Noguchi, Yuki. "Generic Drug Industry Wins Patent Court Case ." NPR. http://www.npr.org/2012/04/18/150854347/generic-drug-industry-wins-patent-court-case.]
LYNN NEARY, HOST:]

The Supreme Court yesterday handed a victory to the generic drug industry. In a unanimous decision, the high court said generic drug makers can challenge how the big pharmaceutical companies describe their patents to the Food and Drug Administration. It sounds like an obscure legal battle, but as NPR's Yuki Noguchi reports, it has potentially big implications for the industry. YUKI NOGUCHI, BYLINE: There's a diabetes drug approved for three uses. Novo Nordisk has a patent on one of the uses. But to the FDA, the company described its patent broadly, applying it to the other two uses. Generic drug maker Caraco wanted to challenge Novo Nordisk's description. But because the FDA doesn't issue such corrections, Caraco could not make generics for the other, unpatented uses of the drug. Jeff Kraws is CEO of Crystal Research, an independent research firm. He says this decision is big for a generic drug industry that's $225 billion in size and growing. JEFF KRAWS: So you've now got a very large market with a potential for smaller companies to go and challenge the 800-pound gorilla. NOGUCHI: He says companies like Caraco have a new tool for challenging their rivals. But Novo Nordisk General Counsel James Shehan denies this is a blow to big drug brands. He says disputes about patent descriptions are relatively rare. JAMES SHEHAN: It affects a relatively narrow area of commerce. NOGUCHI: In a related case, Caraco is disputing the validity of the Novo Nordisk patent. Yuki Noguchi, NPR News, Washington.

Clinical Trials

Ethical controversies in the pharmaceutical industry rarely are in the media's limelight due to the implementation of clinical trials. This means that those who undergo these trials are in an often legally confidential relationship with the company. The lack of transparency in this relationship has resulted in abuse on both the administrator as well as the patients rights. Only increasing government regulations solves.
Christine 8 [Grady, Christine. "Clinical Trials." The Hasting Center. http://www.thehastingscenter.org/Publications/BriefingBook/Detail.aspx?id=2164&terms=pharmaceutical+and+%23filename+*.html.]

Clinical trials are necessary to find out what is safe and what works so that health professionals know how to prevent and treat illness effectively. Nonetheless, there are ethical concerns about clinical trials because human research participants are a means to developing knowledge that

will benefit others. Although participants may be among the beneficiaries of research knowledge, they do not necessarily benefit directly from participation in research—and, more importantly, their benefit is not the goal. The ethical principle of respect for persons requires that individuals be treated with respect for their dignity and not used merely as means for others' ends. **Ethical codes and guidance help delimit when and how research should be conducted with human participants**. The Nuremberg Code, the Declaration of Helsinki, the *Belmont Report*, and the U.S. Code of Federal Regulations (45 CFR 46 and 21 CFR 50, 56, and others) provide guidance for researchers to respect and protect the rights and welfare of human research participants. Most of these codes and regulations were formulated in response to historical examples of abuse, such as experimentation by Nazi doctors, the Public Health Service Tuskegee syphilis study, and others. A synthesis of this guidance and the literature suggests that to be ethical, clinical research should satisfy several criteria (see box, "**Requirements of Ethical Clinical Research**"). According to U.S. federal regulations, clinical trials must be reviewed and approved by an institutional review board, or IRB, before they begin and then periodically throughout the study. An IRB is a committee of physician-investigators, statisticians, community advocates, and others that determines whether a clinical trial is ethically acceptable and whether the rights of participants are adequately protected. Federal regulations also require that the participants give their informed consent, except in particular cases allowed by the regulations and deemed acceptable by an IRB—for example, for certain kinds of minimal risk research (45 CFR 46.116(d)), and some cases of emergency research (21 CFR 50.24). Informed consent is a process that involves disclosing study information to the participant so that he or she has sufficient knowledge to make an informed and voluntary decision to participate or continue to participate in the research. Although widely accepted as an integral part of ethical clinical research, the goal of well-informed individuals making voluntary choices about research participation is often imperfectly realized (see box, "**Informed Consent**").

The pharmaceutical industry presents a unique set of conflicts since it exists at the intersection of free-market interests and public health this conflict historically relies on increased government regulations to alleviate tension.
Daemmrich 11, Arthur. "U.S. Healthcare Reform and the Pharmaceutical Industry." Harvard Business School . http://www.hbs.edu/research/pdf/12-015.pdf.

Pharmaceutical manufacturers have long operated on the boundary between free-market inventors and sellers of drugs and providers of a key component to public health and welfare.79 Since its origins in the late 19th century, the industry has played a leading role in globalization by developing, testing, and marketing new drugs worldwide. Leading firms originated with apothecaries that moved into wholesale production of drugs in the middle of the 19th century and chemical companies that established research labs and discovered medical applications for their products starting in the 1880s. A merging of these two types of firms into an identifiable pharmaceutical industry took place nearly simultaneously in Germany, Switzerland, France, the United Kingdom, and United States at the end of the 19th century. Companies coalesced around a vertically integrated organizational model under which they carried out nearly every aspect of drug discovery, testing, and commercialization. Pharmaceutical firms built networks of contacts with academic chemists and physicians, but operated largely independent of one another.80

Agents

The committee includes experts in a multitude of fields all of which show potential for specific affirmative advantages. Organizations responsible for overseeing and/or enforcing government regulations on pharmaceuticals specifically in the United States include the following.
FDA [http://www.fda.gov/AdvisoryCommittees/Calendar/ucm286681.htm]

Committee Membership The Committee shall consist of a core of 26 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of **pharmaceutical sciences** (pharmaceutical manufacturing, bioequivalence research, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, molecular biology, immunology, microbiology) and **clinical pharmacology** (dose-response, pharmacokinetics-pharmacodynamics, modeling and simulation, pharmacogenomics, clinical trial design, pediatrics and special populations and innovative methods in drug development), biostatistics and related biomedical and **pharmacological specialties, current good manufacturing practices, and quality systems implementation**. The core of voting members may include two technically qualified members, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include up to four non-voting members who are identified with industry interests.

Although foreign nations are not subject to FDA restrictions abroad, important partnerships and joint transnational research groups provide a litany of partnership potentials.
FDA
[http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/EuropeanUnion/EuropeanUnion/EuropeanCommission/ucm114339.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=pharmaceutical%20regulation&utm_content=1]

Transatlantic Cooperation in Pharmaceutical Regulation: Identifying Opportunities for Administrative Simplification December 4, 2007 The Food and Drug Administration co-chaired, with the European Commission, the Transatlantic Administrative Simplification Workshop in Brussels on November 28. The workshop was organized in collaboration with the European Medicines Agency (EMEA) and the heads of the EU National Medicines Agencies (HMA). The workshop was held under the auspices of the Transatlantic Economic Council and is an important step towards "promoting administrative simplification in the application of regulation of medicinal products," as is foreseen in the "Framework for Advancing Transatlantic Economic Integration between the European Union and the United States of America" signed by President Bush, President Barroso and Chancellor Merkel in April 2007. The overall project objectives were to identify opportunities for administrative simplification through transatlantic cooperation, and the workshop provided the transatlantic pharmaceutical regulatory partners a unique opportunity to hear the pharmaceutical and biotechnology industries' proposals. Proposals for administrative simplification include harmonization of administrative practices and guidelines and should not necessitate changes to legislation. Proposals for administrative simplification should maintain or increase the current levels of public health protection in the EU and U.S. By freeing up resources, administrative simplification through transatlantic cooperation will allow the industry to focus more of its resources on developing and supplying high quality medicines to meet the needs of patients. Transatlantic regulatory partnership allows the sharing of regulatory expertise and best regulatory practice. The workshop builds on existing successes, notably the EU / U.S. Confidentiality Arrangements on Medicinal Products and the International Conference on Harmonization which have proven to deliver on bilateral and international collaboration and harmonization. The European Commission, EMEA and FDA remain committed to both, and any work items that are agreed following the workshop will be delivered through these successful structures and processes. Industry presented a diverse range of excellent proposals for administrative simplification through transatlantic and international collaboration and harmonization. The proposals were presented in four panels on: quality and inspections, pharmacovigilance, scientific collaboration, guidelines, format harmonization and electronic submission. The next steps in the process will be careful public health, legal, practical consideration of the proposals by the EU and U.S. regulators with a view to making public, in the context of the bilateral collaboration, joint prioritized roadmaps for administrative simplification by June 2008.

FDA Globalization
FDA
[http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/default.htm]

Globalization is a fact of 21st century economic life. It has resulted in United States markets being composed of a myriad of imported goods that our consumers want and need. Based on the volume of imported products from specific areas, problems that have been associated with products over the years,

and value to be derived from leveraging the activities and resources of trusted foreign counterpart regulatory authorities, U.S. FDA has identified China, India, Europe, Latin America, and Middle East and North Africa as areas in which to establish a permanent in-country presence.

Price controls are an under researched yet essential component of the field. Although different methods of price control have taking place throughout Europe and the United States, the lack of comprehensive comparative.
Daemmrich 12 [Daemmrich, Arthur. "U.S. Healthcare Reform and the Pharmaceutical Industry." Harvard Business School . http://www.hbs.edu/research/pdf/12-015.pdf.] ap

Despite increasing regulatory requirements for pre-market testing and proof of drug safety and efficacy starting in the late 1930s, the industry historically faced few price controls. Ironically, one consequence of the post-WWII growth of state-financed and state-run healthcare systems in Europe, and greater availability of private health insurance in the United States, was that neither patients nor physicians paid close attention to drug prices. Governments became slowly aware of drug prices in the 1960s as overall prescription use shifted from short-duration antibiotics to treatment for long-term chronic diseases.84 Starting in the late 1980s, a variety of price regulation mechanisms were implemented, initially in northern Europe, but soon mimicked elsewhere. These varied among direct price controls, for example, in France; indirect controls through national pharmaceutical budgets accompanied by mandates for rebates from manufacturers, for example, in Germany; and profit controls accompanied by reimbursement decisions based on quality of life metrics, for example, in the United Kingdom. As these policy experiments proceeded, countries continually modified approaches, making it nearly impossible to undertake comparative analysis between price policy and either health outcomes or industry research investments. In many cases, polices promoted perverse outcomes, such as firms in France promoting new products with the knowledge that budget overruns were spread across the industry, or German patients having to seek out a physician who had not yet exceeded their annual prescription limit for a particular drug.85 In the 2000s, reference pricing – based on a median cost within a therapeutic class, or an average price across comparator countries – drew the attention of European policymakers. Germany, Europe's largest pharmaceutical market, began to implement a novel reference pricing approach in 2011 that also covered new drugs. Under the new legislation, after a oneyear period of industry-determined prices, negotiations will set prices based on calculations of a drug's costs and benefits compared with other pharmaceuticals in the same class, but in any case below a reference price based on median prices across other EU countries.86 Broadly, Germany's move is part of an international convergence in price regulation through reference pricing, albeit with the United States as an outlier with no national approach to drug price negotiations. Yet, as numerous critics have observed, treating pharmaceutical prices in a silo misses the fact that drugs are but one part of patient care, which often involves a variety of treatments and payments to physicians, hospitals, and other service providers in the course of generating "health" as an outcome.87

D. Transhumanism Solvency Mechanism Evidence

The research is growing for transhumanism research

Horn 12 – Dr. (Thomas R., "The Hybrid Age", http://www.khouse.org/articles/2012/1039/print/)

I have personally debated leading transhumanist, Dr. James Hughes, concerning this inevitable posthuman future on his weekly syndicated talk show, Changesurfer Radio. Hughes is executive director of the Institute for Ethics and Emerging Technologies and teaches at Trinity College in Hartford, Connecticut. He is the author of Citizen Cyborg: Why Democratic Societies Must Respond to the Redesigned Human of the Future, a sort of bible for transhumanist values. Dr. Hughes joins a growing body of academics, bioethicists, and sociologists who support: Large-scale genetic and neurological engineering of ourselves…[a] new chapter in evolution [as] the result of accelerating developments in the fields of genomics, stem-cell research, genetic enhancement, germ-line engineering, neuro-pharmacology, artificial intelligence, robotics, pattern recognition technologies, and nanotechnology…at the intersection of science and religion [which has begun to question] what it means to be human.1 Though the transformation of man to this posthuman condition is in its fledgling state, complete integration of the technology necessary to replace existing Homo sapiens as the dominant life-form on earth is approaching an exponential curve with many experts predicting the first substantive steps in Grins human-enhancement starting any time after the year 2012. National Geographic magazine concurred in 2007, speculating that within ten years, the first "human non-humans" would walk the earth, and retired San Diego State University professor and computer scientist Vernor Vinge (who delivered the now-famous lecture, "The Coming Technological Singularity," at Vision-21 Symposium sponsored by NASA Lewis Research Center and the Ohio Aerospace Institute in 1993), agreed recently that we are entering that period in history when questions like "What is the meaning of life?" will be nothing more than an engineering question. Most readers may be surprised to learn that in preparation of this posthuman revolution, the United States government, through the National Institute of Health, recently granted Case Law School in Cleveland $773,000 of taxpayers' money to begin developing the actual guidelines that will be used for setting government policy regarding the next step in human evolution—"genetic enhancement." Maxwell Mehlman, Arthur E. Petersilge Professor of Law, director of the Law-Medicine Center at the Case Western Reserve University School of Law and professor of bioethics in the Case School of Medicine, led the team of law professors, physicians, and bioethicists over the two-year project "to develop standards for tests on human subjects in research that involves the use of genetic technologies to enhance 'normal' individuals."2

Regulation over biotechnology can jump-start transhumanist technologies

Hughes 6 - Public Policy Studies, Ph.D. (James Hughes, "Democratic Transhumanism 2.0", January 26, http://www.changesurfer.com/Acad/DemocraticTranshumanism.htm)

First, state action is required to address catastrophic threats from transhumanist technologies. Most transhumanists acknowledge that nanotechnology, genetic engineering and artificial intelligence could cause catastrophes if used for terrorist or military purposes, or accidentally allowed to reproduce in the wild. Contemplation of these catastrophic scenarios has led prominent transhumanists, such as Max More the founder and president of the Extropy Institute, to move away from libertarianism and to endorse prophylactic government policies. Requiring nanotechnology firms to take out insurance against the accidental destruction of the biosphere just isn't very practical. What insurance policy covers accidental destruction of the biosphere? How could the externalities of bioterrorism be internalized into a cost accounting of a gene therapy firm? Only governments are in a position to create the necessary levels of prophylaxis, and most transhumanists can agree on this point. Second, only believable and effective state-based policies to prevent adverse consequences from new technologies will reassure skittish publics that they do not have to be banned. Because of the weakness of social democracy in the U.S., current technology policy is dominated by ignorant hysteria on one side and greed on the other, politicians feeding off of populist Luddite hysteria and corporate anti-regulatory lobbyists. Publics must be offered a choice other than that of unfettered free-market technology versus bans. If transhumanists do not acknowledge the legitimacy of regulation, and attempt to craft and support responsible legislation, they cede the field to the Luddites. These choices require strong social democratic governments, such as those of Europe,that can act independent of corporate interests and vocal extremists. We need a strong social democratic regulatory apparatus that does not block transhuman technologies for Luddite reasons, but that also will ensure that transhuman technologies are safe and effective. The case of cryonics shows how spectacular frauds or iatrogenic disasters can set back acceptance of transhuman technology altogether. Human enhancements must be proven safe before being used, but not held hostage to vague Luddite anxieties. Third, social policies must explicitly address public concerns

that biotechnology will exacerbate social inequality. Libertarian transhumanists have a forceful answer to the challenge that biotechnology will be used for totalitarian applications: in a liberal society, each individual will choose for themselves whether to adopt the technologies. But what is their answer to the threat of growing class polarization? Biotechnologies will make it possible for the wealthy to have healthier, stronger, more intelligent and longer-lived children. Overcoming popular resistance to technology will require not only assuring publics that they are safe and will not be forced on anyone, but also that there will be universal, equitable access to their benefits through public financing. In other words, genetic choice and enhancement technologies must be included in a national health insurance program.

Regulations on biotechnology could make them more available

Cave 5 (Stephen Cave and Friederike von Tiesenhausen Cave, May 27, "The most dangerous idea on earth?", http://www.ft.com/intl/cms/s/0/c7eb8502-cda3-11d9-9a8a-00000e2511c8.html#axzz1spZHBfZP)

In Citizen Cyborg, James Hughes maps what he sees as these emerging parties in bio-politics and their relationship to the ideologies and isms of the 20th century. A transhumanist, he nonetheless believes it is possible to find a middle way between the libertarians who advocate a technological free-for-all and the bio-conservatives who want the lot banned. He places himself within the traditions of both liberal and social democracy, arguing that "transhumanist technologies can radically improve our quality of life, and that we have a fundamental right to use them to control our bodies and minds. But to ensure these benefits we need to democratically regulate these technologies and make them equally available in free societies." Contrary to Fukuyama, Hughes does not believe that the biotech wonders of the transhumanist era will create new elites. He argues that they could even strengthen equality by empowering those who are currently downtrodden: "a lot of social inequality is built on a biological foundation and enhancement technology makes it possible to redress that." But despite his support for some regulation of transhumanist inventions, Hughes, like Naam, is unrelentingly technophile. At times this becomes a naive utopianism, such as when he claims that "technology is about to make possible the elimination of pain and lives filled with unimaginable pleasure and contentment." He rightly argues that in Our Posthuman Future, Fukuyama "treats every hypothetically negative consequence from the use of technology with great gravity, while dismissing as hype all the possible benefits". Unfortunately, he does not always recognise when he is mirroring that very mistake. The biotechnology revolution has caused Fukuyama to revise his contention that we have reached the end of history - history rolls on, but driven by scientists instead of kings. What all these writers have in common is the firm belief that the biotech era will shake up the old political allegiances and create new dividing lines. On one side will be those who believe such meddling unnatural and unwise. On the other, those who want to take the offerings of the biotech revolution and become something more than human. Won't you be tempted?

IPR is a possible solvency mechanism for regulating biotechnology

SS 12 (Sigma Scan, Funded by the British Department of Business Innovation & Skills, "R.I.P?: The future of Intellectual Property in a Knowledge Economy", January 31, http://www.sigmascan.org/Live/Issue/ViewIssue/508/4/r-i-p-the-future-of-intellectual-property-in-a-knowledge-economy/)

Intellectual Property Rights (IPR) protect the application of ideas and information that have commercial value. The four most common forms of IP are patents, copyrights, designs and trademarks. This paper will consider the first two. Patents are designed to protect useful ideas. Industries such as pharmaceuticals, biotechnology and high-tech rely heavily on patent protection to produce commercially viable products. Copyright is used to protect original expression and subsists in a wide range of creative or artistic forms or 'works'. A work under copyright cannot legally be reproduced, distributed, communicated to the public, lent, rented out or publicly performed without the consent of the owner. The comparative advantage of developed countries in a globalised economy may come from 'knowledge intensive goods and services.' [1] Nearly half the gross domestic product of the U.S, is based on intellectual property. [2] In 2004, creative industries in the UK contributed 7.3 per cent of UK Gross Value Added, and from 1997 to 2004 they grew significantly quicker than the average rate across the whole economy. [1] As a result, the ownership of these ideas, the rights to intellectual property are an important foundation of economic activity and prosperity. Wealth creation depends on the commercialisation of innovation, which requires effective protection of that innovation: if every invention could be stolen, or every new drug copied, the incentive to invest in innovation would be dramatically reduced. However, too much protection can limit "incremental innovation"— innovations that build, in some way, on others. [3] Publicly available resources perform a variety of important but difficult to quantify economic functions, contributing to a vibrant public culture, a free flow of information and an accessible educational system. [4] Lawrence Lessig, founder of the Creative Commons movement believes we must find a middle way between the 'Hollywood' model in which 'all rights are reserved', therefore innovation becomes almost impossible because ideas are so heavily protected, and the 'no rights reserved' model of near anarchy in which no one gets rewarded for their ideas so no one has any incentive to invent. It is unclear whether Intellectual Property

Rights are the right mechanism to strike this balance. There is no guarantee that the existing IP model will be able to cope with the kinds of challenges outlined by The Gowers Review of Intellectual Property, [1] an independent review commissioned by the UK government to look at the current IP regime: To quote directly: "First, the digitisation of information and the ability to store it electronically has made it far easier to copy, distribute and reverse engineer products. Second, the innovation process has become more networked and complex, with greater collaboration between firms, and with high-tech projects often requiring the combination of thousands of individual IP rights. Third, new technologies such as genetics, software and databases require IP protection but do not fit easily into existing categories." [1] Some suggest the death of IP is imminent with IPR, particularly copyright easily infringed. [5] Little evidence points in this direction however, as legislators have been prompted to reinforce existing laws and have become increasingly vigilant for infringement and piracy. The current trend is for strong protection or what James Boyle calls a 'maximalist rights culture'. [6] A counter trend to the emergence of stronger IPR has been 'open source' mechanisms. [7] Open Source approaches reject proprietorial approaches to knowledge, instead allowing open access to products, ideas and inventions, enabling information to be shared and developed freely, as seen in Linux operating systems. The question is how to make creativity pay without smothering the possibility of innovation in the first place. The answer may lie in production strategies that harness the public domain, ensuring connectivity and innovation for commercial ends. This "copyfight" between strong IP and a Commons model will define the character of the knowledge economy. [8], [9] The IPR regime could continue to develop a regime of stronger IP rights but it could evolve to recognise the importance of collective production and use of knowledge as, in principle, more efficient and more equitable than more proprietorial approaches. In the UK and Europe there have been signs that the strong IPR environment may be becoming more moderate; 'The Gowers Review' recommended that copyright should not be extended on the grounds that the economic benefits and incentive to innovate were negligible [1] and in Europe, legislation has not introduced patents for free software. [10] However, the climate in the US is more proprietorial, for example, Lessig argued unsuccessfully before the U.S. Supreme Court in 2002 against an extension of the term of existing copyrights. [11]

Several possible solvency mechanisms exist to regulate biotechnology patents

Resnik 3 – J.D., Professor of Medical Humanities, Brody School of Medicine, East Carolina University (David B. "A Biotechnology Patent Pool: An Idea Whose Time Has Come?", January, http://www6.miami.edu/ethics/jpsl/archives/papers/biotechPatent.html)

Option (c), developing policies to minimize the threats posed by biotechnology patents, would appear to be the most reasonable course of action to take. It would be proportional to the level of the threat posed by biotechnology patents because it would take some response to this threat beyond simply maintaining the status quo. It would also reflect a careful balancing of benefits and risks because the policies that are developed would be designed to maximize the scientific, technological, and social benefits of patenting and minimize the risk. So what are some policies that could be developed to minimize threats to discovery and innovation in biomedicine posed by biotechnology patents? Many different writers have suggested a wide variety of policies (some of which have been mentioned earlier) for minimizing the harmful effects of such patents. Some of these are as follows: 1. Raise the bar on the various conditions for awarding patents in biotechnology, such as novelty, non-obviousness, utility, or the enabling description.[43] [44] For example, in 1999, the USPTO raised the bar for proving the utility for a patent on DNA.[45] Raising the bar on patents in biotechnology may help prevent some of the problems related to licensing, since it may decrease the number of patents awarded. It may also increase the amount of work required to defend a patent application, which will increase the legal costs associated with patenting. However, raising the bar too high could have a negative effect in research and development in biotechnology by reducing the incentives for researchers and companies. Thus, while this solution could help alleviate some of the potential licensing problems in biotechnology, it is no panacea. 2. Restrict the scope of patents on materials and methods in biotechnology in order to allow competitors to develop "work-around" inventions, i.e. new inventions or improvements on existing inventions.[46] Patent attorneys usually attempt to state very broad claims in patent applications in order to give the patent holder maximum control over the invention. A patent examiner or a court may reduce the scope of patent claims that are excessively broad in order comply with legal requirements and protect public interests. However, if the scope of a patent is too narrow, the patent holder may not be able to obtain an adequate return for his investment. Thus, overly restrictive limits on the scope of patents can also reduce incentives and therefore deter discovery and innovation. In establishing the scope of a patent, patent agencies and the courts must strike the correct balance between private interests and public access.[47] Since there are some legal and practical limits to restricting the scope of patents, this proposed solution also does not adequately address potential licensing problems. 3. Reinforce, clarify, and legislate the research exemption for researchers in biotechnology and biomedicine.[48] In the U.S., the research exemption is a rarely used defense to patent infringement that allows academic researchers to use or make patented inventions without the permission of the patent holder.[49] The exemption is not part of the U.S. patent statute but is based on judicial interpretations of the statute. As it currently stands, the research exemption applies only to research undertaken for "philosophical" or "academic" purposes with no prospect of commercialization.[50] Since the line between commercial and non-commercial research is often very difficult to draw in biomedicine, any research exemption would need to be carefully worded and implemented, and researchers who want to take advantage of the exemption would have to adhere to stringent conditions. The research exemption, like the other proposed solutions, is probably not an adequate solution to address licensing problems because most research in biomedicine today has commercial implications. Unless the exemption is interpreted very narrowly, it could significantly erode patent protection in biotechnology and

also deter investment in research and development. 4. Use antitrust laws to respond to anti-competitive practices in biotechnology and biomedicine. Since a patent explicitly grants a patent holder a monopoly on an invention for a limited time period, one does not normally think that antitrust laws would have any bearing on patents. However, U.S. antitrust laws can apply to situations where patent holders refuse to deal with competitors and collude to fix prices.[51] For example, if a company attempted to corner the market on genetic tests and refused to license its tests to other companies or organizations, this might be a situation where antitrust laws might apply. Patent pools can also raise antitrust issues when members of the pool fix prices. Indeed, the courts have applied antitrust to several cases involving patent pools, and the justice department has issued guidelines for forming patent pools so that they do not raise antitrust issues.[52] However, most of the licensing problems in biotechnology, with the possible exception of "blocking" patents, raise no significant antitrust concerns. Thus, antitrust laws would also not be very effective at addressing the wide range of licensing problems in biotechnology. 5. Use compulsory licensing laws to prevent patent holders from engaging in problematic licensing practices. The U.S., unlike some European countries, has no compulsory licensing provision in its patent laws.[53] Under U.S. law, it is perfectly legal to patent an invention and then keep it on the shelf for the entire duration of the patent. In countries that have compulsory licensing, the inventor must make, use, or commercialize his invention or license others to do so.[54] Although compulsory licensing might be useful to deal with some situations, such as patents on upstream technologies that block downstream inventions, it is probably not a very effective solution to potential licensing problems. First, many corporations operating within the U.S. economy would oppose any changes in the current patent statute, including a change that would implement compulsory licensing. Second, even if the U.S. passed a compulsory licensing law, patent holders could still stifle downstream research by issuing "reach through" licenses.

E. Stem Cells Solvency Mechanism Evidence

Increasing regulatory environment for stem cell research is key to prevent state wasteful spending

Moreno 2007 (Jonathan Moreno, Sam Berger, and alix Rogers, Center for American Progress, April 2007, DiviDeD we fail The Need for National Stem Cell Funding, http://www.americanprogress.org/issues/2007/04/pdf/stem_cell_report.pdf)

States have made valiant attempts to advance stem cell research, but they cannot replace federal support. States lack the revenue, infrastructure, and incentives to properly promote basic research on their own, especially with federal policies that limit collabo-ration, impede their funding, and fail to provide **guidelines** for moving forward with research. The federal government needs to update its stem cell policy to fund the best science using ethically derived stem cell lines, **establish uniform regulations**, increase overall support for the field, and dedicate more funding to embryonic stem cell research. The federal government provides the lion's share of funding for stem cell research—79.4 percent through 2007—and will continue to do so for the foreseeable future. The federal government will even spend more specifically on embryonic stem cell research than the states, meaning that unless we update our stem cell policy, at least 55 percent of the fund-ing currently designated for embryonic stem cell research through 2018 will go to research on outdated stem cell lines. Our national stem cell policy also forces states to waste money building new laboratories and purchasing new equipment. So far, states have only spent a paltry 15 percent of their funding on actual research. And even though infrastructure costs decrease over time, states will still spend at least 29 percent of their money on infrastructure, equipment, and other non-research expenditures through 2018. Allowing states to drive stem cell research also means that each state will develop its own re-search standards, potentially leading to a **patchwork quilt of regulations that discourages col**-laboration and slows research. States also have less incentive to coordinate research support, which will cause research overlap and waste. And states will likely spend money on research expected to yield quick returns, not the basic research that is needed to advance the field. States are doing their part, and should continue aggressively funding embryonic stem cell re-search while striving to have uniform research standards and little research overlap in different states. But their efforts are not enough; funding for embryonic stem cell research by the fed-eral and state governments is only 20.6 percent of all the money spent on stem cell research. Our outdated stem cell policy remains a national problem requiring a national solution. By adopting uniform research standards and supporting research on any ethically derived stem cell lines, the federal government can provide the strong leadership needed to advance the science and fulfill the promise of stem cells

Lack of uniformity is hampering the industry- uniform funding scheme is key

Fallone 11 (Edward A. Fallone, Marquette University Law School, "Funding Stem Cell Research: The Convergence of Science, Religion & Politics in the Formation of Public Health Policy," http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1199&context=facpub)

While it is unfeasible to dismantle state funding schemes for stem cell research at this time, it is nonetheless worth examining the reasons why a unified federal funding scheme administered through the NIH is the preferred mechanism for funding medical research. First of all, unified funding through the NIH promotes an allocation of resources that directs research dollars to the most meritorious projects. This is because channeling grant requests through a single funder allows that funder to use uniform application guidelines and a rigorous peer review process in order to select the most promising projects. It is inefficient for individual states to replicate this administrative infrastructure, and, by splitting the application pool among multiple funding sources, it is also possible that worthy applications will fall through the cracks. Another advantage of federal funding of medical research is that it promotes collaboration among researchers nationwide. The NIH can impose uniform guidelines and ethical standards concerning the derivation, donation, and cultivation of stem cell lines. By creating a set of research data where all projects comply with the same standards, researchers can more easily share their data and compare results. In addition, collaboration is more easily fostered by a single nationwide funder, both because the NIH can give preference to joint projects and because state boundaries need not constrain where the funds are spent. The expected high demand among the public to participate in clinical trials for stem cell therapies provides another reason to prefer channeling research funding through the NIH. State funded clinical trials are likely give priority to state residents, given that state tax dollars were used to fund the underlying research. However, patients outside of the funding state might be superior candidates to participate in a clinical trial. A

federal funding scheme ensures that only medical criteria are used to determine access to clinical trials. In addition, the federal government is in the best position to ensure transparency, so that the public is fully informed about what researchers are doing. By accepting federal dollars, research institutions agree to comply with the NIH's ethical guidelines and to report on their activities. In contrast, state funded research operates outside of any federal oversight, and, while California researchers operate under extensive state guidelines, other states employ varying degrees of supervision over the use of state dollars.97 Meanwhile, privately funded research occurs without any government oversight at all. The use of federal funding serves an important function both as a means of imposing ethical limits on the research and also in ensuring a level of public oversight. Without federal funding, a greater percentage of this research will occur outside of the public eye. Finally, federal funding of research also helps to promote industry standards and practices that eventually will be adopted by for profit entities. An absence of federal funding is the equivalent of an absence of federal rules. Already, overseas stem cell clinics are marketing their services to residents of the United States. The growth of ‚stem cell tourism' is of great concern, especially given the wild claims and unproven therapies that are being touted by many foreign companies. At some point in the future, companies will team with scientists in order to offer stem cell based therapies to the public domestically. Without federal research grants and standards, practices in the field will be driven by market forces rather than government created guidelines. The infertility industry is an example of a medical specialty that has grown largely independent of federal funding and oversight throughout its history, leading bioethicist Arthur Caplan to refer to in vitro fertilization clinics as ‚the wild, wild west of medicine.'98 While the federal funding of medical research offers several advantages, a scheme that relies on multiple state funders presents several disadvantages. First, state funding sources typically impose legal restrictions that limit the use of state funds to research that is conducted within the state's borders. For example, money granted to researchers by the California Institute of Regenerative Medicine must be spent in California.99 These restrictions make it difficult for researchers in different states to collaborate with each other. Second, various forms of regulatory inconsistency are created where there are multiple funders of basic research, even beyond restrictions on the use of research dollars.100 Perhaps the most vexing inconsistencies involve intellectual property rights. For example, when universities and research institutions license patented technology that they have developed using private funds, these institutions will often assert the right to exercise control over any discoveries that result from the use of the patented technology.101 In patent law, this is called a ‚reach through,'102 and critics assert that the aggressive assertion of patent rights on basic scientific methods can chill future research that seeks to build on the prior discoveries.

This type of funding is necessary for stem cell research projects

Fallone 11 (Edward A. Fallone, Marquette University Law School, "Funding Stem Cell Research: The Convergence of Science, Religion & Politics in the Formation of Public Health Policy," http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1199&context=facpub)

Research projects involving embryonic stem cell lines require an uninterrupted stream of funding in order to succeed. While the uncertain and changeable nature of governmental funding policies can impact this stream, funding is also vulnerable to disruption by non-governmental sources. In two high profile instances, groups with religious objections to embryonic stem cell research have used litigation in an attempt to disrupt the financing of research.

The fed govt should increase uniform regulatory guidelines and standards for stem cell research

Moreno 2007 (Jonathan Moreno, Sam Berger, and alix Rogers, Center for American Progress, April 2007, DiviDeD we fail The Need for National Stem Cell Funding, http://www.americanprogress.org/issues/2007/04/pdf/stem_cell_report.pdf)

The current federal stem cell policy acts as a dead weight on the research, hurting the efforts of NIH, states, and individual scientists alike. Rather than constrain cutting-edge science with outdated policy, the federal government should update its regulations to support any stem cell research on ethically derived stem cell lines. Al-lowing legislation like the Stem Cell Research Enhancement Act of 2007 to pass into law would be a good start. The federal government should act quickly to create uniform regulatory guidelines and standards for stem cell research. Those guidelines should closely match those proposed in the National Academies Guidelines for Human Embryonic Stem Cell Research.

Inherency

Despite Obama's pivots on stem cells, there is still a large call for increasing more funding

Fallone 11 (Edward A. Fallone, Marquette University Law School, "Funding Stem Cell Research: The Convergence of Science, Religion & Politics in the Formation of Public Health Policy," http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1199&context=facpub)

There are also indications that the balkanized funding landscape itself has influenced the types of stem cell research that have received government funding. First of all, evidence shows that a substantial amount of hESC research currently being funded by the states would have qualified for federal funding even under the Bush administration's 2001 NIH guidelines.106 This fact suggests that **there is a greater demand for federal dollars to support embryonic stem cell research than the NIH has been able to satisfy**. It also suggests that the total amount of federal funding is insufficient even to support research using the original twenty-one hESC lines, much less to support research on all four types of stem cells.

The same article shows that there is potentially for different mechanism types to be explore from removing congressional restrictions, administrative rulemaking as well as potential CP ground (state-private funding partnerships)

Fallone 11 (Edward A. Fallone, Marquette University Law School, "Funding Stem Cell Research: The Convergence of Science, Religion & Politics in the Formation of Public Health Policy," http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1199&context=facpub)

It appears unlikely that the traditional paradigm of the National Institutes of Health serving as the single funding mechanism for basic medical research will ever be attained in the case of stem cell research. Despite the efforts of the Obama Administration to expand the types of stem cell lines that are eligible to receive federal funding, future congressional restrictions and future legal challenges to administrative rulemaking will almost certainly continue, and any hope of an uninterrupted stream of NIH funding is slim. In such an environment, it is doubtful that states will abandon their parallel funding schemes, while other alternatives to federal funding, such as state-private funding partnerships, will be explored.

Increased oversight of the private sector is key to stem cell research

Schechter 10 (Jody Schechter, "Promoting Human Embryonic Stem Cell Research: A Comparison of Policies in the United States and United Kingdom and Factors Encouraging Advancement," Texas International Law Journal, 45, 603-629.(2010) http://www.tilj.org/content/journal/45/num3/Schechter603.pdf)

The key issue in the United States regarding hESC research has generally not been what to allow and what to prohibit, but rather what to fund with federal dollars. 30 The decision to provide federal funding is seen as an endorsement of a particular pursuit as worthy of the nation's support and encouragement.31 The United States has always held medical progress as a high priority. 32 Federal funding, however, is generally peppered with restrictions, mainly due to moral concerns and limitations.33 In the debate over hESC research, the government has attempted to pursue a middle ground between those arguing that embryo "exploitation and destruction" is completely offensive and unjustifiable, based on the moral position that an embryo is deserving of life, and others arguing that embryo research is morally worthy or even socially obligatory because of the immense potential for good. 34An important note is that federal funding limitations do not restrict state or private funding or activities in this field.35 Indeed, hESCs were first isolated and cultured in the private sector.36 Research on embryos is not illegal in the United States, except in a few states.37 However, a lack of federal funding is accorded substantial weight for numerous reasons. First, the sheer amount of money available should not be underestimated—the U.S. federal government is by far the greatest sponsor of science in the world. 38 Second, the lack of federal funding for a particular project does constrain private investors in practice; institutions that receive federal funding are often provided incentives to abide by federal restrictions for any research conducted within them, not just those activities directly funded with public money. 39 At the very least, an institution receiving both federal and private funding must establish a clear separation—a daunting task.40 If a scientist researching with private funds so much as accidentally places an embryo in the wrong refrigerator, one maintained using federal funds, the whole facility could be threatened with a total loss of federal funding.41 Third, federal sponsorship of research encourages sharing of information among scientists, which greatly accelerates scientific progress.42 Conversely, when research is done privately, dissemination of knowledge is often delayed due to intellectual property issues.43 Next, the payoff for investment in stem cell research is likely to remain considerably far off in the future, and federal funding is crucial for research that is "too far upstream from marketable products to attract private investment."44 Many argue that restrictions on federal funding and the surrounding controversy also cause a "chilling effect" on the private investment market.45 Political uncertainty resulting from the instability of this field "not only turns off investors, but also turns off the other source of funding for biotech, which [is] pharmaceutical partners, who at this point in time are completely uninterested in this field."46 Uncertainty regarding standards for conduct and lack of oversight may also

discourage would-be researchers and investors.47 Perhaps most importantly, if the federal government declines to fund this research, it essentially delegates regulation to the private sector rather than retaining control to more effectively ensure against abuse.4

Various proposals are being recommended- from creating different regulatory boards in charge of stem cell funding-

Matthews 09 (Matthews is a fellow in science and technology policy at the *Baker Institute*. She is responsible for managing the activities of the Science and Technology Policy Program, including the institute's International Stem Cell Policy Program. Matthews has a B.A. in biochemistry from The *University of Texas at Austin* and a Ph.D. in molecular biology from The *University of Texas Health Science Center* at Houston. February 15, 2009, "*Wanted: Federal stem cell research oversight" http://www.chron.com/opinion/outlook/article/Wanted-Federal-stem-cell-research-oversight-1540593.php#page-2)*

In the absence of federal oversight and coordination, the National Academies stepped in with voluntary guidelines in 2005 — but there was no mechanism to ensure these practices are followed. Additionally, as the federal government has pulled back from stem cell research, the United States' leadership role in this area has diminished, with research here stagnating compared to the rest of the world. To rectify this, the Obama administration should create a comprehensive federal stem cell policy with the National Institutes of Health (NIH) taking the lead. This could be done by creating an Embryonic Stem Cell Research Oversight (ESCRO) board within the NIH to review controversial research and recommend policy for the agency, similar to the committee recommended by the National Academies, the most distinguished society of scientists and engineers in the country. The ESCRO board would contain representatives with expertise in ethical and legal issues and biology, as well as policy scholars and patient advocates. The role of the board should be to review grant applications and to develop policy options for all aspects of research involving human embryos. Moreover, NIH should work with states that have already implemented human stem cell programs to provide guidance on ethics and research, as well as to help with peer review. The government must also outlaw any effort to clone a human being, regardless of the source of funding. Human reproductive cloning has been denounced by scientists and policymakers around the world. Fourteen states and more than 40 countries have already banned the practice. This increased federal involvement reflects public sentiment. Public support for stem cell research has increased over the past seven years, with 56 percent of Americans supporting federal funding according to Research!America. And approximately two-thirds of Americans agree that there should be a uniform federal stem cell policy. There is also a historical precedent for an empowered NIH. In the past, NIH has played a strong leadership role in creating research policy for controversial areas of biomedical research. For example, the Recombinant DNA Advisory Committee (RAC) was created to review proposals involving the use of DNA in research and clinical therapies. Additionally, President Obama should continue the President's Council on Bioethics (PCB) and provide it with a mandate, along with the necessary financial support, to guide the president on bioethical questions as well as serve as a means for public outreach on these topics. These steps are critical if the United States is to resume its leadership role in scientific research and help establish global standards that reflect scientists' interests while respecting human dignity.

Specific stem cells

Experts advocate for more funding for IPCS as specific stem cell proposals

Prentice and Christensen 10 (Dr. David Prentice is senior fellow for the Center for Human Life and Bioethics at the Family Research Council. David Christensen is senior director of congressional affairs at the Family Research Council, "Stem Cell Ruling Could Focus Funding on Treatments," http://www.humanevents.com/article.php?id=38837)

But what does the ruling mean for patients if it remains and NIH must stop funding all hESC research? Since only adult stem cells are being used to treat patients, it clearly frees up millions more dollars for such adult stem cell treatments. These stem cells, including cord blood stem cells, are uncontroversial and currently treating thousands of patients. Other kinds of novel stem cells, such as the Induced Pluripotent Stem Cells (iPSCs) act just like embryonic stem cells but are generated by reprogramming the genes of body cells. No embryos are involved, and government funding is allowed. For examples of the many diseases treated by adult stem cells, visit Stem Cell Research Facts. In contrast, hESC have been used to treat no one, have controllability problems leading to tumors, and have the ethical baggage of coming from destroyed embryos. It is true that the federal government is funding adult stem cell research. But it could do much more. It may require legislation to push the government, still bent on funding embryonic stem cell research, to put

patient treatments first. The bipartisan legislation called the Patients First Act (H.R. 877), sponsored by Rep. Randy Forbes (R.-Va.) and Rep. Dan Lipinski (D.-Ill.), would do just that.

AT: Stem Cell PICs/ Examples of literature base

Fallone 11 (Edward A. Fallone, Marquette University Law School, "Funding Stem Cell Research: The Convergence of Science, Religion & Politics in the Formation of Public Health Policy," http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1199&context=facpub)
In summary, there is no scientific rationale that argues in favor of giving preferential treatment to one type of stem cell research over another. In light of the science's rapid progress upon multiple fronts, it is simply premature to declare that any one form of stem cell research is more likely to lead to therapies or cures than another, or that any particular type of stem cell research is unworthy of public funding. Arguments in favor of directing public funding towards one form of stem cell research and away from another are premised upon religious or political agendas.41

Either remove Dickey-Wicker amendment all-together or amend it to non-political definition of an embryo

Reed 10 (Don C. Reed, Sponsor, California's Roman Reed Spinal Cord Injury Research Act of 1999, Overturn Dickey-Wicker Abomination, or Forget Stem Cell Cures for a Generation, http://www.huffingtonpost.com/don-c-reed/overturn-dickeywicker-abo_b_693426.html)

By now you've heard about Judge Royce Lamberth's ruling to block federal funding of embryonic stem cell research. This Texas-reared conservative, appointed by Ronald Reagan and reportedly an opponent of stem cell research, has used an arcane restriction, the Dickey-Wicker Amendment, to strangle the research. Dickey-Wicker forbids federal funds for the endangerment of embryos--even when the microscopic dots of tissue are already going to be thrown away. Dickey-Wicker is not a law; it was never debated and passed. It is an amendment, attached to the budget bill every year--and everyone has been afraid to mess with it, so it goes through unchallenged. Ironically, it was not originally designed to affect stem cell research. Dickey-Wicker was first passed in 1996, before human embryonic stem cell research even existed. Yet this undebated prohibition may destroy the hopes of cure for a generation, or longer. Until now, Dickey-Wicker has been regarded by scientists as something like a badly-functioning streetlight. If your streetlight was stuck on red for ten years and nobody ever came to fix it, what would you do? Sit stopped at the crossing till you died of old age? Or would you find a way to deal with it, like maybe looking both ways and going ahead carefully. That was what has been done so far. The original Clinton stem cell policy was simple; Dickey-Wicker forbade funding for the endangerment of an embryo, so only the stem cells themselves could be worked with. There is precedent for this sort of age-related different treatment, of course. Think of soldiers in World War II, who were drafted and sent into combat--but only at a certain age. Babies were not sent to war, only youths 18 and over. Similarly, children are not allowed to drink alcohol, or to vote. A different portion of the arc of age brought different privileges, prohibitions--and the right to send a human being into battle where he or she might die. So, the idea of a stem cell being eligible for research funding, but not a blastocyst, was something that could at least be worked with: a reasonable compromise. But there is nothing reasonable about the denial of funds for an entire field. First, it must be clear what is at stake here.Federal funds are the main pie, not a piece of it. Example: a California law named after my paralyzed son, the Roman Reed Spinal Cord Injury Research Act, spent $14 million of the taxpayers money over 9 years--but it brought in $60 million, primarily federal matching grants--that is the level of funding which would be sacrificed by this litigious lunacy. After we just overturned the Bush prohibitions, now worse ones would be imposed? It would be the end of hope for embryonic stem cell cures in this generation. In the future, of course, seeds planted previously will bear fruit. Results will spring from the California efforts, Geron and the California Institute for Regenerative Medicine , and New Hampshire, Maryland, Illinois, New York, Ohio's Third Frontier, New Jersey--not many states, and all working with one hand tied behind their backs, if this denial of funding goes through. The Dickey-Wicker Amendment will eventually be seen as the anti-cures abomination it is. Future generations will look back upon us, and wonder how we could have been so stupid--to have the tools of cure in our hands, and put them aside. Where did Dickey-Wicker come from? The Dickey-Wicker Amendment is the work of retired Arkansas Congressman James (Jay) Dickey, famous for three things: one, his statement that there are no homosexuals in his district; two, that the invasion of the fictional country Fredonia (in the Marx brother's movie Duck Soup) was the fault of President Clinton--and for the Dickey Amendment. The other author is Roger Wicker of Mississippi, an ultra-conservative from an ultra-conservative state. These two men, with the boundless support of the Republican Party, may have doomed cure research. This is a devastating blow. Champion advocate Bernie Siegel likened the judge's ruling to the emotions he experienced after a hurricane: when he found his home in ruins. For me, the judge's ruling is an assault on my family. Not only is my son Roman paralyzed, but as I write this, my wife Gloria

may have breast cancer. She had three bad mammograms in a row, and today we are waiting for the lab results of a biopsy. If she does have cancer, I want the best medicine modern science can provide, which every family deserves. But if the judge's decision stands, research which might actually cure cancer would not be allowed to go forward with federal dollars. The people filing the lawsuit claim repeatedly that adult stem cell research is superior. This is unmitigated nonsense. Let both go forward; that the best science may prevail. My sister has cancer. The adult stem cell therapies proposed as an exchange for embryonic? She had them. They took my brother's blood from him, in an eleven hour ordeal: a tube in one arm sucked the blood out, passed it through a machine which removed adult stem cells, and then put the remainder of the blood back into his other arm. They took my sister to the edge of death with chemo, to shut down her body's immune system, so it would not reject the foreign adult stem cells. She went into a comatose condition, and could not respond to touch or sound. The adult cells were put in her, and she got better for a while--but not well. The chemo and radiation to shut down her immune system apparently gave her leukemia and several other medical conditions, including graft versus host, meaning the adult stem cells are being fought back against by her own body. She received the best adult stem cell treatments available, but it was not enough. Embryonic stem cell research may be able to do something completely different, making natural cancer killer cells, the cells which keep some people safe from cancer-- in a dish of salt water. Think of the difference between embryonic stem cells which build tissues of any part of the body, and adult stem cells which are a repair kit for minor injuries. If you cut yourself, adult stem cells will sew the flesh together, but slowly, and leaving a scar. That is the work of adult stem cells, and very useful it is, too. But a baby is born without a single scar, because he or she is built by the enormous power of embryonic stem cells. Common sense tells us which is stronger. Naturally the case will be appealed, as early as this week. Too much is at stake. One hundred million Americans with an incurable disease or disability? Even if we win, and the research funding is reinstated, the cost in delay will be measured in lives. The same sort of Religious Right people also sued to shut down the California stem cell program, and they succeeded in delaying the research for about two years. Research delayed is research denied. Putting off the cure means people keep the disease or disability longer, maybe die from it. How many people should have to die because of the decision of one Texas-raised judge (reportedly an opponent of the research in his private life) and the anti-science lawsuits brought by the Religious Right? Medical science policy should not be decided by an ideological fringe group, no matter how powerful. Some of the judge's decision is so ludicrous that is virtually certain to be thrown out--like the part where adult stem cell scientists are being unfairly hurt, because spending money on embryonic stem cell research means fewer dollars for them? This is like horse-and-buggy companies suing the auto industry--if people have cars, they won't buy as many horses, so we should stop funding automotive engineering! Not to mention adult stem cells have been massively over-funded compared to embryonic. The judge claims his ruling will only maintain the "status quo"--but his decision is so extreme it would apparently ban funding for the Bush stem cell lines as well. We, the American families with chronic illness, put up with a lot. We watch our loved ones suffer every day. We have tried to be non-political, because there are fine and decent people in the Party of Lincoln. But this is too much. With the official Republican party platform calling for a "ban on embryonic stem cell research, public and private", and the example set by one Republican-appointed judge, it is hard to have bi-partisan feelings now. The Republican-backed Dickey-Wicker Amendment must be removed. As long as it is allowed, the opposition will have a weapon to hit us with. For several years I have been writing about the threat of Dickey-Wicker, but more cautious souls feared "rocking the boat"--well, the boat is sinking. There are several ways to go: 1. My preference, kick out Dickey-Wicker altogether. A law which was never intended to affect stem cell research should not be used as an ideological club; 2. Require Dickey-Wicker to use the original non-political definition of embryo: "especially: the developing human individual from the time of implantation to the end of the eighth week after conception." (There is no implantation in stem cell research. No implantation, no womb, no mother, no child); 3. Pass a stem cell research protection law, as California did. Our law specifically allows embryonic stem cell research; no religious extremists can block our funding, ever again.

Decrease Dickley-Wicker Regulations-

Reed 09 (Don C. Reed, Sponsor, California's Roman Reed Spinal Cord Injury Research Act of 1999, Repeal Dickey-Wicker: Time to Stop Renewing the Anti-Research Law, http://www.huffingtonpost.com/don-c-reed/remove-dickeywicker-time-_b_780071.html)

A law exists which may prevent my paralyzed son from ever leaving his wheelchair, but that law has never been debated on the floor of Congress. Attached to must-pass legislation, the Dickey-Wicker Amendment was imposed on America. If Congress wanted the Health and Human Services Appropriations Act, they had to accept Section 509, which contained the Dickey-Wicker Amendment. That no-questions-asked technique has been used to renew it ever since. Prohibiting government funding of "endangerment" of embryos, the Dickey-Wicker Amendment sounds harmless at first, but it may have devastating, even unintended consequences. Human embryonic stem cells were first isolated by Dr. Jamie Thomson of Wisconsin in 1998. As Dickey-Wicker began three years before that, in 1995, it is difficult to say it was intended to block stem cell research, which came three years later -- but that may well be its effect. Reportedly, President Bill Clinton objected to the Amendment's inclusion; he was told that, if he did not accept it, the conservative-controlled legislature would block all funding for the entire National Institutes for Health. Thanks to the careful work of attorney Harriet Rabb, General Counsel for Health and Human Services at the time, a compromise was worked out so that research on embryonic stem cells (which of course are not embryos) could be funded. This approach was deemed acceptable by three Presidents and eight Congresses. Presently, however, that compromise is under threat. Dickey-Wicker is being used by a lawsuit (Sherley vs. Sebelius) to try to permanently block federal funding of embryonic stem cell research. Conservative judge Royce Lamberth is interpreting Dickey-Wicker as the "unambiguous intent of Congress" -- opposing federal money for that research. If Judge Lamberth holds to that opinion, he will very likely rule to prohibit federal dollars for the research which might one day allow my son to fulfill Christopher Reeve's great prediction to "stand up from our wheelchairs, and walk away from them forever." After Judge Lamberth waits a 3-judge appeals court, also conservative, with two Bush-appointed Republicans -- and then,

the Roberts Supreme Court, arguably the most conservative in modern history. The Dickey-Wicker Amendment must be stripped out from the bill in which it hides. Right now, the bill which contains Dickey-Wicker (L-HHS Appropriations Act) has not been voted on. The committee which had it last was the Senate Subcommittee on Labor, Health, Human Services, Education and Related Agencies. If the judge is right, and the Dickey-Wicker Amendment reflects the will of Congress that embryonic stem cell research should not be funded, that will show in their votes on that subject.

Remove the Dickey Amendment

Matthews and Lane, 08 (Kristin Matthews, Phd Fellow in Science and technology policy james a. baker III institute for public policy rice university, and neal lane phd senior fellow and Malcolm gillis university professor, rice university, "Human Embryonic Stem Cell Research: Recommendations for the Next Administration," 2008, http://www.bakerinstitute.org/publications/ST-pub-ObamaTransitionMatthewsLane-121908.pdf)

Recommendation 1.3: Remove the Dickey Amendment (which severely limits the National Institutes of Health funding of embryonic research) from the Department of Health and Human Services (DHHS) appropriation bills. Findings: • Starting in 1995, the Dickey Amendment, named after an appropriation rider introduced by Rep. Jay Dickey (R-AZ), has been attached to DHHS appropriation bills each year. • The amendment bans any federal funding for "the creation of a human embryo or embryos for research" and "research in which a human embryo is destroyed, discarded, or knowingly subjected to risk of injury or death." In the future, any federal restriction on the use of human embryos for research should be passed as a bill, signed into law, not as a rider on an annual appropriations bill. This approach would allow for appropriate discussion and informed debate on the subject. It will also stabilize the policy instead of leaving it in its current ambiguous state, where researchers are unsure if the amendment will continue to appear year to year. President Obama should veto any DHHS appropriation bill that contains the Dickey Amendment or similar rider.

Lack of federal regulations could lead to bad practices when it comes to stem cells

Schechter 10 (Jody Schechter, "Promoting Human Embryonic Stem Cell Research: A Comparison of Policies in the United States and United Kingdom and Factors Encouraging Advancement," Texas International Law Journal, 45, 603-629.(2010) http://www.tilj.org/content/journal/45/num3/Schechter603.pdf)

Certain federal regulations apply to hESC research, although not specifically created with hESC research in mind. 73 Relevant regulations include human subjects' protection for donors of genetic material, medical privacy protections, laboratory standards for research resulting in products requiring Food and Drug Administration approval, animal care regulations, and rules regarding transfer of biological material and data from other nations. 74 These piecemeal regulations, not specifically designed for hESC, leave definite gaps in regulatory oversight. 75 The restrictions only apply to research conducted with federal dollars at federally funded institutions, or research which will eventually be used to create products for which FDA approval will be sought.

The US should increase regulation on private sector stem cell funding

Schechter 10 (Jody Schechter, "Promoting Human Embryonic Stem Cell Research: A Comparison of Policies in the United States and United Kingdom and Factors Encouraging Advancement," Texas International Law Journal, 45, 603-629.(2010) http://www.tilj.org/content/journal/45/num3/Schechter603.pdf)

The task of executing federal funding of biomedical research is designated mainly to the NIH. These guidelines allow federal funding only on hESCs that are derived from human embryos created for reproductive purposes, no longer needed for that purpose, and donated for research. 79 Additionally, the guidelines impose rigorous eligibility standards requiring stringent informed consent mechanisms for embryo donors. 80 While this system is a significant improvement in that it would allow federally funded scientists to conduct research on stem cell lines created in the future, the strict eligibility standards may rule out research on stem cell lines approved even under the Bush administration.81 It is worth noting that policymakers in both countries have recognized a special moral status for the embryo between that of a fully formed human and a cluster of cells.229 Scientific and ethical inquiry committees and political representatives in both countries have recognized that the public's views vary between two extremes: that of utmost regard for the status of an embryo and that of a social obligation to utilize medical potential to do good.230 However, the United States and the United Kingdom differ greatly in their handling of this universal impasse and their consequent approaches toward political treatment.231 The United Kingdom has reacted to this inherent dilemma by side-stepping the moral debate and instead working toward a utilitarian approach that

binds all. After accepting that an embryo has a special moral status, deserving of some, but not absolute protection, 232 policymakers addressed concerns over moral issues by increasing centralized regulatory oversight.233 Scientists and researchers accepted that they must cede to this oversight in order to obtain funding and continue scientific advancement. In addition, the United Kingdom bestowed ultimate oversight and control on an independent body comprised of medical specialists to provide valuable insight, as well as significant lay representation to maintain the public's trust.234 The United States has instead responded to the ethical quandary by imposing restrictions on federal funding, generally leaving it up to states and private organizations to make their own determinations on otherwise unfunded activities and research.235 This is consistent with a general U.S. pattern of leaving regulation to individual states and industries to handle according to their divergent convictions. 236 Many hail the U.K.'s progressive approach toward stem cell research technology, claiming that its policies will allow it to "take the global lead in biomedical technology."237 Some advocate that the United States should adopt a similar system, or at least move in the direction of expanding government regulation and vesting control in one independent body.238 They argue that the lack of regulations puts the United States at a technological and economic disadvantage, 239leaves an undesirable patchwork of state regulation, 240 and permits abuse.241 Many however, maintain that due to the philosophical, political, legal, and healthcare climate differences between the two countries, the British system is simply not feasible in the United States.242 Still, if the United States wants to stay competitive in this field and benefit from hESC research, the federal government needs to actively support this science. VII. CONCLUSION As embryonic stem cell research continues to progress, nations must address challenging moral and logistical issues arising from new technologies. The United States employs a decentralized system with little **federal regulatory authority and broad discretion** left to states and private entities. In contrast, the United Kingdom utilizes a centralized, independent body, enabling it to act more quickly and predictably. The United Kingdom has become a world leader in stem cell research, with a progressive stance towards the development of revolutionary techniques. U.S. policy has progressed more slowly, with shifting and unpredictable policy decisions by the government. While the U.S. government has not directly hindered hESC research, it has not acted to significantly advance it. To some, it may seem counterintuitive that the United Kingdom, with its stringent regulatory and licensing standards, would be more effective at encouraging research than the United States and its relatively lax, unrestrictive approach. However, considering the state of the science in this field, the level of uncertainty created by the lack of uniformity and oversight, and the benefits of comprehensive regulation, the federal government needs to play an active role in this area if it wants to see real, competitive progress. Wholesale adoption of the U.K. regulatory model may be infeasible in the United States, given the inherent differences in the cultural, political, and medical climates of the two countries. Nevertheless, if the United States wishes to advance hESC research, both to improve medical treatment and to stay competitive internationally, it should take some cues from the history and policy of the United Kingdom. The United States must vest more control, or at least influence, in independent, accredited scientific bodies and take a more progressive stance that encourages hESC research.

Increase regulations for human cloning from stem cells

Matthews and Lane 08 (Kristin Matthews, Phd Fellow in Science and technology policy james a. baker III institute for public policy rice university, and neal lane phd senior fellow and Malcolm gillis university professor, rice university, "Human Embryonic Stem Cell Research: Recommendations for the Next Administration," 2008, http://www.bakerinstitute.org/publications/ST-pub-ObamaTransitionMatthewsLane-121908.pdf)

Recommendation 2.1: *Ban any effort to clone a human being, regardless of the source of funding.*

Findings: • Human reproductive cloning is the process of creating a human being that is the exact genetic copy of the donor. • In contrast, therapeutic cloning (also known as SCNT)—which should not be banned— refers to a process in which the cells are grown in vitro (outside the body, in a lab), not in utero (in a woman's uterus) to produce an infant. • Attempts at reproductive cloning for animals have been error-prone and inefficient, resulting in the failure of most clones to develop. Those that do survive have a marked shorter life expectancy. • Human reproductive cloning has been denounced by both scientists and policymakers around the world. Polling from Research!America found that between 77 percent and 83 percent of Americans oppose human reproductive cloning.6 • Fourteen states and over 40 countries have already banned human reproductive cloning. For these reasons, the United States should ban human reproductive cloning—both in the public and private sectors.

Create the ESCRO Board on Stem Cells

Matthews and Lane 08 (Kristin Matthews, Phd Fellow in Science and technology policy james a. baker III institute for public policy rice university, and neal lane phd senior fellow and Malcolm gillis university professor, rice university, "Human Embryonic Stem Cell Research: Recommendations for the Next Administration," 2008, http://www.bakerinstitute.org/publications/ST-pub-ObamaTransitionMatthewsLane-121908.pdf)

Recommendation 2.2: *Create an Embryonic Stem Cell Research Oversight (ESCRO) board within the National Institutes of Health to review controversial research and recommend policy for the agency.* Findings: • Oversight of hESC research during the George W. Bush administration was left to the universities and research institutes as well as private industry. • In the past, for previous controversial areas of biomedical research, NIH would play a strong leadership role in creating research policy. For example, the Recombinant DNA Advisory Committee (RAC) was created to review proposals involving the use of DNA in research and clinical therapies. • Since the majority of hESC research was performed without federal funding, NIH was not involved in the oversight. But, the public would support an increase in its role; Research!America polling showed that approximately two-thirds of Americans agree that there should be a uniform federal hESC policy.7 • Responding to the demand for guidance by the research community and the lack of a comprehensive research and oversight policy, the National Academies (National Academy of Science, National Academy of Engineering and the Institute of Medicine) filled the vacuum and assumed a leadership role. In 2005, they released the report "Guidelines to Human Embryonic Stem Cell Research" to help steer universities and research institutes on how to provide research oversight on this ethically contentious issue.8 • The National Academy guidelines were voluntary, and some state and private funding agencies already had organizations in place with their own oversight procedures. Moreover, there was no mechanism with which to oversee the fulfillment of the guidelines. The next administration should use the NIH and an ESCRO board within the agency to oversee stem cell research. The ESCRO board (similar to those recommended for universities by the National Academies) should contain representatives with expertise in developmental biology,

Remove guidelines that only allow hESC based on a certain date

Matthews and Lane 08 (Kristin Matthews, Phd Fellow in Science and technology policy james a. baker III institute for public policy rice university, and neal lane phd senior fellow and Malcolm gillis university professor, rice university, "Human Embryonic Stem Cell Research: Recommendations for the Next Administration," 2008, http://www.bakerinstitute.org/publications/ST-pub-ObamaTransitionMatthewsLane-121908.pdf)

Recommendation 1.2: Authorize federal funding for human embryonic stem cell research on lines derived according to strict ethical guidelines, regardless of the date the cell lines were derived or created. Findings: • When the Bush administration's policy was announced in 2001, the National Institutes of Health (NIH) declared that there were 60 to 75 lines that met the qualifications for federal funding. Since that announcement, only 21 lines were found to be available for distribution. • In using these lines, scientists have come across additional problems.| All 21 lines were created using mouse cells and reagents to help support growth, which means that the cells could be contaminated with mouse cells or proteins. This could potentially limit their use for medical purposes.| Several of the lines have proven difficult to grow.| Each line has a propensity to grow into specific cell types, which restricts research.| The cell lines lack genetic diversity, which could limit potential treatments for a broad number of patient communities.| None of the cell lines are disease-specific, thereby limiting research on genetic diseases.| Of the 21 lines, five are suspected to have been obtained without appropriate informed consent.3 • To counteract the limited funding situation, some universities, including Harvard and the University of Wisconsin–Madison, were able to obtain private funding for their research. Other researchers were able to convince state legislatures and governments such as California, Illinois, and Connecticut, to fund projects. But many researchers were left without readily available funding sources outside of NIH, the major funding source for biomedical research in the United States. • Over the past seven years, while research on adult stem cells has surged in the United States, hESC research has stagnated compared with other parts of the world.| From 2002 to 2004, the fraction of hESC research publications from American researchers decreased from one-third to approximately one-quarter.4| Recent research from Georgia Institute of Technology confirmed that the United States is underperforming in hESC research.5 The report found that American researchers produce fewer publications than would be predicted based on other areas of biomedical research. The next administration should permit NIH to provide funding for: (a) research on hESCs regardless of when they are derived and who derives them, (b) the derivation of new hESC lines, e.g., from discarded embryos from IVF clinics, and (c) SCNT derived stem cell lines. Using these lines, scientists will be able to study genetic diseases more quickly and efficiently, and hopefully even discover new therapeutic techniques that will, in the future, avoid the need for hESC lines.

Support research of all types of human stem cells

Matthews and Lane 08 (Kristin Matthews, Phd Fellow in Science and technology policy james a. baker III institute for public policy rice university, and neal lane phd senior fellow and Malcolm gillis university professor, rice university, "Human Embryonic Stem Cell Research: Recommendations for the Next Administration," 2008, http://www.bakerinstitute.org/publications/ST-pub-ObamaTransitionMatthewsLane-121908.pdf)

Recommendation 1.1: *Support research on all types of human stem cells, including embryonic, adult, nuclear transfer derived* *(also known as therapeutic cloning), and induced pluripotent derived.* Findings: • Stem cells can be located in the embryo during the early stages of development (around five or six days after fertilization), in the umbilical cord and placenta, and in several adult organs. • Embryonic-like stem cells can be created by stimulating normal cells to revert back to an earlier form—known as induced pluripotent stem cells or iPS cells—or by removing the genetic material from an egg and replacing it with the genetic material from a normal cell—known as somatic cell nuclear transfer (SCNT) or therapeutic cloning. • Induced pluripotent stem cells are not yet a feasible replacement for all hESCs. The process by which iPS cells are created might, in fact, alter the cells so they are not viable for therapeutic research. And without hESCs, we cannot determine if the iPS cells have undergone any potential undesirable changes. • Each type of stem cell is valuable in different areas of research. For instance hESCs can be an important tool for understanding early human developmental biology, perhaps elucidating issues involved in infertility and birth defects, while iPS or SCNT derived cells could further understanding of the development of specific diseases such as Parkinson's or Alzheimer's. • Current federal funding only supports umbilical cord, adult, very limited embryonic stem cell research, and research with iPS cells. SCNT derived cells and hESCs created after Aug. 9, 2001, cannot be used in federally funded research. • In fiscal year 2008, NIH spent $41 million on hESC and an additional $203 million on non-embryonic human stem cell research from its $29.5 billion budget, while California alone predicted it would spend $100 million during the same time. The United States needs a new progressive stem cell policy that will increase federal support of all human stem cell research. By encouraging research on all types of human stem cells, we will allow the best research to move forward regardless of the cell source. Research on all human stem cell types is also essential to develop future therapies and cures for debilitating diseases and injuries such as diabetes, spinal cord injuries or Parkinson's, which impact millions of Americans.

Congress vs Executive debates-

Guardian 10 (Government funding for stem cell research blocked by US court, August 23, 2010, http://www.guardian.co.uk/world/richard-adams-blog/2010/aug/24/stem-cells-research-us-funding-blocked)

The judge's decision is almost certain to be appealed by the administration but it does confirm fears at the time of President Obama's order that an executive ruling would provide weaker protection for funding than legislation passed by Congress.

X. Definitions

By: Sarah Godwin

****In alphabetical order***

Assisted reproductive technology (ART):

Assisted reproductive technology—medical definitions:
Dorland's Medical Dictionary for Health Consumers 07 (Sauders, an imprint of Elsevier, Inc.)

Technology /tech-nol-o-gy/ (-je) scientific knowledge; the sum of the study of a technique.
Assisted reproductive technology (ART) any procedure involving the manipulation of eggs or sperm to establish pregnancy in the treatment of infertility.

Mosby's Medical Dictionary 09 (8th Edition, Elsevier)

The manipulation of egg and sperm in treating infertility. The processes include the administration of drugs to induce ovulation, fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and cryopreservation of gametes. See also in vitro fertilization.

The International Committee for Monitoring Assisted Reproductive Technology and WHO define ART as the following:
Zegers-Hochschild et al. 2009 ("The International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) Revised Glossary on ART Terminology, 2009," *Human Reproduction*, vol.24, No.11 pp. 2683-2687, 2009, http://www.who.int/reproductivehealth/publications/infertility/art_terminology.pdf)

Assisted reproductive technology (ART): all treatments or procedures that include the in vitro handling of both human oocytes and sperm, or embryos, for the purpose of establishing a pregnancy. This includes, but is not limited to, in vitro fertilization and embryo transfer, gamete intrafallopian transfer, zygote intrafallopian transfer, tubal embryo transfer, gamete and embryo cryopreservation, oocyte and embryo donation, and gestational surrogacy. ART does not include assisted insemination (artificial insemination) using sperm from either a woman's partner or a sperm donor.

Assisted Reproductive Health Technologies include any fertility procedures in which both eggs and sperm are manipulated outside the body
Arons 2007 (Jessica Arons, Director of the Women's Health and Rights Program at American Progress, "Future Choices: Assisted Reproductive Technologies and the Law," The Center for American Progress, December 2008, http://www.americanprogress.org/issues/2007/12/pdf/arons_art.pdf, pg. 5)

Assisted Reproductive Technologies, or ART in medical parlance, are defined as any fertility procedures in which both eggs and sperm are manipulated outside the body in a laboratory. 8 Perhaps the most well-known type of ART today is In Vitro Fertilization. IVF involves the mixing of an egg and sperm in a laboratory dish. Once an embryo has developed from the fertilized egg, it can be implanted in a woman's uterus to be gestated and born. Variations on IVF include injecting sperm directly into an egg, combining sperm and egg in the lab but transferring them to the woman's body before fertilization, or transferring an embryo to the fallopian tubes instead of the uterus. 9 Once an embryo has been created, Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening can be used to screen embryos for genetic characteristics or chromosomal defects, respectively. Embryos with desired traits are then implanted; those with unwanted traits discarded. 10 Technically, fertility drugs that stimulate egg production in ovaries and Intrauterine

Insemination—or IUI, also known as Artificial Insemination—in which sperm is injected into the uterus, do not qualify as ART because the processes occur inside a woman's body and each process by itself only involves the manipulation of eggs or sperm, not both. 11 Nevertheless, we include them in our discussion because they are still fertility treatments, and very popular ones at that, and are implicated by the laws and cases described below.

Biotechnology:

Biotechnology has broad applicability to the bioethics topic
Medical Definition—Biotechnology
Stedman's Medical Dictionary 02 (The American Heritage by Houghton Mifflin Company, Published by Houghton Mifflin Company)
The use of microorganisms, such as bacteria or yeasts, or biological substances, such as enzymes, to perform specific industrial or manufacturing processes. Applications include production of certain drugs, synthetic hormones, and bulk food stuffs. The application of the principles of engineering and technology to the life sciences.

Additional medical definition
Mosby's Medical Dictionary 09 (8th Edition, Elsevier)
biotechnology [-teknol′əjē] Etymology: Gk, *bios* + *techne,* art, *logos,* science 1 the study of the relationships between humans or other living organisms and machinery, such as the health effects of computer equipment on office workers or the ability of airplane pilots to perform tasks when traveling at supersonic speeds. 2 the industrial application of the results of biologic research, particularly in fields such as recombinant deoxyribonucleic acids (DNA) or gene splicing, which permits the production of synthetic hormones or enzymes by combining genetic material from different species. See also recombinant DNA.

Science dictionary definition: use of biological substances to solve an engineering problem
Science Dictionary 02 (The American Heritage, Published by Houghton Mifflin)
The use of a living organism to solve an engineering problem or perform an industrial task. Using bacteria that feed on hydrocarbons to clean up an oil spill is one example of biotechnology. The use of biological substances or techniques to engineer or manufacture a product or substance, as when cells that produce antibodies are cloned in order to study their effects on cancer cells. See more at genetic engineering.

Biotechnology can mean any technological application that uses biological organisms to make or modify products or processes ---- it can be divided up into several sub-categories depending on their application: red biotechnology is the medical use of biotechnology
Wenting 11 - Ph.D. at the Division of Cancer Stem Cell Research, Medical School of Xi'an Jiaotong University (Yang, "What is Biotechnology?", http://www.wmedicine.com/what-is-biotechnology~175)

Biotechnology is any technological application that uses biological systems, living organisms, or derivatives there of, to make or modify products or processes for specific use. One section of biotechnology is the directed use of organisms for the manufacture of organic products (examples include beer, milk-products, and skin). Naturally present bacteria are utilized by the mining industry in bioleaching. Biotechnology is also used to recycle, treat waste, clean up sites contaminated by industrial activities (bioremediation), and produce biological weapons. There are also applications of biotechnology that do not use living organisms. Examples are DNA microarrays used in genetics and radioactive tracers used in medicine.
Modern biotechnology is often associated with the use of genetically altered microorganisms such as E. coli or yeast for the production of substances like insulin or antibiotics. It can also refer to transgenic animals or transgenic plants, such as Bt corn. Genetically altered Mammalian cells, such as Chinese Hamster ovarian cells, are also widely used to manufacture pharmaceuticals. Another promising new biotechnology application is the development of plant-made

pharmaceuticals. There are number of jargon terms for sub-fields of biotechnology. **Red biotechnology is biotechnology applied to medical processes. An example would include an organism designed to produce an antibiotic, or engineering genetic cures to diseases through genomic manipulation**. White biotechnology, also known as grey biotechnology, is biotechnology applied to industrial processes. An example would include an organism designed to produce a useful chemical. White biotechnology tends to consume less resources that traditional processes when used to produce industrial goods. Green biotechnology is biotechnology applied to agricultural processes. An example would include an organism designed to grow under specific environmental conditions or in the presence (or absence) of certain agricultural chemicals. Green biotechnology tends to produce more environmentally friendly solutions then traditional industrial agriculture. An example of this would include a plant engineered to express a pesticide, thereby eliminating the need for external application of pesticides. The term blue biotechnology has also been used to describe the marine and aquatic applications of biotechnology, but its use is relatively rare.

Red biotechnology, or medical biotechnology, includes genetic engineering, genomics, pharmacogenics

UNECA 2 – United Nations Economic Commission for Africa (August, "Harnessing Technologies for Sustainable Development" "Tackling the Diseases of Poverty through Red Biotechnology", http://www.uneca.org/harnessing/chapters/chap4/chapter4_127_132.pdf)

Broadly defined, red biotechnology is a cluster of scientific techniques applied to the medical field that include genetic engineering, genomics, and pharmacogenics. Red biotechnology uses substances naturally produced in the human body, such as proteins and enzymes, to fight infections and diseases, or substances in plant and animal cells to produce medicines for human use (Europabio 2001). Biotechnology is an old science, used centuries ago to produce beer and cheese using micro-organisms. Modern biotechnology began in 1953 when biochemists James Watson and Francis Crick determined the structure of DNA (deoxyribonucleic acid), the molecule that encodes genetic information (PhRMA 2001). DNA contains all the information needed to build an entire organism, be it a bacterium, plant, or animal. Modern biotechnology mainly uses the genes of organisms. Modern techniques of genetic engineering and information provided by genomics enable scientists to use genes in new ways and with greater precision. As one researcher puts it, "in the past, we could look under the microscope and say a cell looks abnormal, but we didn't know what was going on inside it. Now, researchers can find genetic defects and attack cancer cells with substances naturally found in the body" (PhRMA 2001, p. 3). Red biotechnology applies genetic engineering techniques and genomics knowledge for medical or pharmaceutical purposes. Genetic engineering is the technique used to alter or move genetic material of living cells. It has evolved enormously thanks to advances in computerization and mechanical techniques and in the knowledge of genes. The technique is based on the artificial production of new genetic material by joining segments of DNA from different organisms, a process called recombination (Fell 1998). Such genetic manipulation allows scientists to change the genetic structure of an organism on the spot, quickly and more efficiently than with any other technique (Unilever 2001). Genomics is the study of the genome—the sum total of the genetic material in a particular organism—and how it affects the human body (Lea 2000). One of the most promising innovations for medical science today, genomics was made possible by the invention of the gene sequencer in 1975 and the development of rapid computer analysis of DNA in the early 1990s (Pontin 1998). Genomics makes it possible to understand the structural components of an organism, and thus of a disease caused by or affecting that organism, by sequencing the organism's genome (that is, determining the exact order of the base pairs in a segment of DNA). The landmark mapping of human genes recently completed promises further innovations in research

Genetic Enhancement:

Genetic enhancement distinct from gene therapy—refers to the practices of altering genes to improve capacities

Reference.MD 12 (Sources: NLM Medical, NIH UMLS, Drugs FDA, FDA AERS, http://www.reference.md/files/D024/mD024861.html)

The use of genetic methodologies to improve functional capacities of an organism rather than to treat disease. Not for therapeutic procedures (= Gene therapy).

Genetic enhancement distinct from therapy—different source

U.S. National Library of Medicine
(http://www.definitions.net/definition/genetic%20enhancement)
1. genetic enhancement The use of genetic methodologies to improve functional capacities of an organism rather than to treat disease.

Genetic Engineering:

Genetic engineering—DNA cell research
Collins English Dictionary 09 (Complete & Unabridged 10th Edition, William Collins Sons & Co. Ltd., Harper Collins Publishers)
— *n*
alteration of the DNA of a cell for purposes of research, as a means of manufacturing animal proteins, correcting genetic defects, or making improvements to plants and animals bred by man

Genetic engineering—scientific method
Dictionary.com 2012 *Unabridged*. Random House, Inc.
the development and application of scientific methods, procedures, and technologies that permit direct manipulation of genetic material in order to alter the hereditary traits of a cell, organism, or population. **2.** a technique that produces unlimited amounts of otherwise unavailable or scarce biological product by introducing DNA isolated from animals or plants into bacteria and then harvesting the product from a bacterial colony, as humaninsulin produced in bacteria by the human insulin gene.

Genetic Material:

Genetic material—materials that make up a cell
Biology-online.org 11 http://www.biology-online.org/dictionary/Genetic_material
Definition *noun* The genetic material of a cell or an organism refers to those materials found in the nucleus, mitochondria and cytoplasm, which play a fundamental role in determining the structure and nature of cell substances, and capable of self-propagating and variation. Supplement The genetic material of a cell can be a gene, a part of a gene, a group of genes, a DNA molecule, a fragment of DNA, a group of DNA molecules, or the entire genome of an organism.

Genes have properties of self-propagation and variation
McGraw-Hill Dictionary of Scientific and Technical Terms 03 (6th Edition, The McGraw-Hill Companies, Inc.)
genetic material [jə ¦ned·ik mə ′tir·ē·ə l] (genetics) The nuclear (chromosomal) and cytoplasmic (mitochondrial and chloroplast) material that plays a fundamental role in determining the nature of all cell substances, cell structures, and cell effects; the genes have properties of self-propagation and variation.

Germline Engineering:

Germline engineering—improving reproductive cells
PBS Biology Glossary (Public Broadcasting Station, http://www.pbs.org/faithandreason/biogloss/germln-body.html)
Germline engineering (or 'enhancement') involves making "improvements" in gametic (reproductive) cells. These changes will be passed on to subsequent generations.

Patents:

Patent

Dictionary.com 2012 *Unabridged*. Random House, Inc.
The exclusive right granted by a government to an inventor to manufacture, use, or sell an invention for a certain number of years.

Pharmaceuticals:

Medical Definitions—
Dorland's Medical Dictionary for Health Consumers 07 (Sauders, an imprint of Elsevier, Inc.)
1. pertaining to pharmacy or drugs. **2.** a medicinal drug.

Stedman's Medical Dictionary 02 (The American Heritage by Houghton Mifflin Company, Published by Houghton Mifflin Company)
adj. Of or relating to pharmacy or pharmacists. n. A pharmaceutical product or preparation.

Regulation:

Regulation—law by authority prescribing conduct
"regulation." *Dictionary.com Unabridged*. Random House, Inc. 23 Apr. 2012. <Dictionary.com http://dictionary.reference.com/browse/regulation>.
noun 1. a law, rule, or other order prescribed by authority, especially to regulate conduct. 2. the act of regulating or the state of being regulated. 3. *Machinery* . the percentage difference in some quantity related to the operation of an apparatus or machine, as the voltage output of a transformer or the speed of a motor, between the value of the quantity at no-load operation and its value at full-load operation. 4. *Electronics* . the difference between maximum and minimum voltage drops between the anode and the cathode of a gast ube for a specified range of values of the anode current. 5. *Sports* . the normal, prescribed duration of a game according to the sport's regulations, exclusive of any extra innings,o vertime period, etc.: *The Knicks tied the score in the final seconds of regulation, sending the game into overtime. adjective* 6. prescribed by or conforming to regulation: *regulation army equipment*. 7. usual; normal; customary: *the regulation decorations for a Halloween party.*

Stedman's cites exactly that—it is a law with the purpose of controlling/governing conduct
Stedman's Medical Dictionary 02 (The American Heritage by Houghton Mifflin Company, Published by Houghton Mifflin Company)
The act of regulating or the state of being regulated. A principle, rule, or law designed to control or govern conduct. A governmental order having the force of law. The capacity of an embryo to continue normal development following injury to or alteration of a structure.

Regulations can include standards, government orders, and etc—anything that has the force of law and governs 'procedure or behavior'
Collins English Dictionary 09 (Complete & Unabridged 10th Edition, William Collins Sons & Co. Ltd., Harper Collins Publishers)
– ***n***
1.the act or process of regulating
2.a rule, principle, or condition that governs procedure or behaviour
3.a governmental or ministerial order having the force of law
4.*embryol* the ability of an animal embryo to develop normally after its structure has been altered or damaged in some way
5.(*modifier*) as required by official rules or procedure: *regulation uniform*
6.(*modifier*) normal; usual; conforming to accepted standards: *a regulation haircut*
7.*electrical engineering* the change in voltage occurring when a load is connected across a power supply, caused by internal resistance (for direct current) or internal impedance(alternating current)

Reprogenetics:

Reprogenetics involve the creation, use, manipulation, or storage of gametes or embryos

Parens and Knowles 2003 (Erik Parens, PhD Senior Research Scholar at The Hastings Center,and Lori P. Knowles, dependent consultant specializing in biotechnology law and ethics and Research Fellow at the Health Law Institute, University of Alberta Law School, "Reprogenetics and Public Policy Reflections and Recommendations," The Hasting Center Report, July-August 2003, The Hastings Center, http://www.thehastingscenter.org/pdf/reprogenetics_and_public_policy.pdf)

This report defines reprogenetics broadly, as the field of research and application that involves the creation, use, manipulation, or storage of gametes or embryos. The report also defines embryo broadly. It adopts the definition that Congress uses in its ban on funding for embryo research: "any organism . . . that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells." 4 Of course, there are alternative definitions that reflect the choices a society makes. 5 The techniques used to create, use, and manipulate embryos for reproductive purposes can also be put to nonreproductive purposes. For example, the somatic cell nuclear transfer (SCNT) or cloning technique can be used, in principle, for the reproductive purpose of creating a child or for the nonreproductive purpose of creating a source of embryonic stem (ES) cells (and ultimately transplantable tissue). Because the reproductive and nonreproductive uses of embryos are inextricably entwined, we must consider them together if we want to understand and anticipate the implications of our "big embryo experiment."

XI. Appendix: Additional Research Resources

A1. Patent Law Resources

Georgetown University

- Genetics and the Law (LAWJ-935-08), Gail H. Javitt, J.D., M.P.H.
- Course Materials: P. Kuszler, K. Battuello, and S. O'Connor, Genetic Technologies and the Law: Cases and Materials, Carolina Academic Press (2007) (hereinafter Casebook).
- Other Resources: Genetics & Public Policy Center Website, www.dnapolicy.org
- Genetic Science Learning Center Website, http://gslc.genetics.utah.edu
- President's Council on Bioethics, www.bioethics.gov
- Secretary's Advisory Committee on Genetics, Health, and Society,
- http://www4.od.nih.gov/SACGHS.HTM
- National Human Genome Research Institute, www.genome.gov
- U.S. Department of Energy, Genome Programs, http://doegenomes.org/
- Dolan DNA Learning Center, http://www.dnalc.org/
- To learn more, check out this excellent website: http://www.dnaftb.org/dnaftb/
- Javitt, G. 2007. In Search of a Coherent Framework: Options for
- FDA_Oversight_ofGenetic Tests. *Food and Drug Law Journal* 62: 617-652
- http://www.dnapolicy.org/resources/Javitt_FDLJ.pdf
- Javitt, G., and K. Hudson. 2003. Regulating (for the benefit of) Future Persons: A
- Different Perspective on FDA's Jurisdiction to Regulate Human Reproductive Cloning. *Utah Law Review* 4:12011229.
- Gelsinger, P. Jesse's Intent, Parts 1&2, http://www.jesse- gelsinger.com/jesses-intent.html
- Judson, HF. 2006, The Glimmering Promise of Gene Therapy, MIT Technology Review
- http://www.technologyreview.com/Biotech/18096/
- Sharon F. Terry, *Learning Genetics,* 22 Health Affairs 166-171 (2003)
- Washington University v. Catalona
- *Tilousi v. Arizona State Univ. Bd. of Regent*

A2. Reproductive Health Resources

Portland State University

Link: http://kie.georgetown.edu/nrcbl/documents/sylb/se0614.pdf

Reproductive health care of undocumented immigrants readings:

- Donohoe MT. Trouble in the fields: Effects of migrant and seasonal farm labor on women's health and well-being. Medscape Ob/Gyn and Women's Health 2004;9(1): posted 3/4/04. http://www.medscape.com/viewarticle/470445 Oregon Center for Public Policy.
- Undocumented workers are taxpayers, too. Posted 4/10/07. Available at http://www.ocpp.org/2007/issue070410immigranttaxeseng.pdf

- DuBard CA, Massing MW. Trends in emergency Medicaid expenditures for recent and undocumented immigrants. JAMA 2007;297:1085-92.

University of Pennsylvania
Link: http://kie.georgetown.edu/nrcbl/documents/sylb/se0624.pdf
Reproductive health ethics readings:

- Marquis D. Why Abortion is immoral. In: Ethical Issues in Modern Medicine, Part Four, Section 1, pgs. 463-470.
- Thomson JJ. A Defense of Abortion. In: Ethical Issues in Modern Medicine, Part Four, Section 1, pgs. 483-491.
- Steinbock B. Using PGD to Save a Sibling: The Story of Molly and Adam. In: Ethical Issues in Modern Medicine, Part Four, Section 2, pgs. 544-545.
- Ethical Issues Related to Prenatal Genetic Testing. Council on Ethical and Judicial Affairs, American Medical Association. In: Ethical Issues in Modern Medicine, Part Four, Section 2, pgs. 513-522.

Georgetown University
Link: http://kie.georgetown.edu/nrcbl/documents/sylb/se0618.pdf
Assisted reproduction readings:

- Case Study: What is Wrong with Commodification?
- John D. Arras et al., Ethical Issues in Modern Medicine, 6 ed. (New York, NY: McGraw Hill, 2003). 615-24, 595-6144
- Barry R. Furrow et al., Bioethics: Health Care Law and Ethics, 4 ed. (St. Paul, MN: West Group, 2001). 103-26, 143-47
- Barry R. Furrow et al., Supplement to Bioethics: Health Care Law and Ethics, 4 ed. (St. Paul, MN: Thompson-West, 2003). 5-11, 12-16

Montclair State University
Link: http://kie.georgetown.edu/nrcbl/documents/sylb/se0595.pdf
Fertility frontiers: IVF, sperm & egg donation, and surrogacy readings:

- Amy Harmon, “Are You My Sperm Donor? Few Clinics Will Say” New York Times, Jan 20, 2006
- Amy Harmon, “Hello, I’m Your Sister. Our Father is Donor 150” New York Times, November 20, 2005

Feminist & GLBT perspectives on reproductive biotechnology readings:

- Chritine Stolba, “Overcoming Motherhood” (online at: http://www.policyreview.org/DEC02/stolba_print.html)
- Suzanne Holland, “Beyond the Embryo: A Feminist Appraisal of the Embryonic Stem Cell Debate.”
- Susan Dominus, “Growing up with Mom and Mom” The New York Times, October 24, 2004

Haverford College
Link: http://kie.georgetown.edu/nrcbl/documents/sylb/se0569.pdf
New genetic and reproductive technologies readings:

- Russ Rymer, *Genie*, *The Wild Child*, HarperPerenial, 1993.
- Barbara Katz Rothman, *The Book of Life*, Beacon Press, 2001. Pages 13-41, 111-137, 161-250.
- Arlene Judith Klotzko, Medical Miracle or Medical Mischief?, Hastings Center Report, May-June 1998, 5-8.

A3. Biotechnology and Transhumanism Resources

This is a very awesome article to get some background information on biotechnology and transhumanism with cool videos:
http://stream.aljazeera.com/story/engineering-human-evolution-0022143

Cites from University Curriculums:

Johns Hopkins University
Link: http://kie.georgetown.edu/nrcbl/documents/sylb/se0656.pdf
Biotechnology Readings:

- Korobkin R. and Munzer S.R. (2007) Stem Cell Century: Law and Policy for a Breakthrough Technology. Yale University Press, New Haven.
- Mathieu M (Ed.). (2004). Biologics Development: A Regulatory Overview. PAREXEL International: Waltham, MA
- Sherlock, R. and Morrey, JD (Eds.). (2002). Ethical Issues in Biotechnology. Rowman & Littlefield Publishers, Inc.: Lanham, MD.

Montclair State University
Link: http://kie.georgetown.edu/nrcbl/documents/sylb/se0595.pdf
Building "Better" Humans: Genetic Manipulation & Enhancement And Cloning Rights and Regulation Readings:

- Leon Kass, "The Age of Genetic Technology Arrives," Ch 4. Life, Liberty, and Defense of Dignity
- Beyond Therapy: Biotechnology and the Pursuit of Happiness
- Carson Strong, "Cloning and Infertility"; Glen McGee and Ian Wilmut, "A Model for Regulating Cloning"; Justine Burley and John Harris, "Human Cloning and Child Welfare" in The Human Cloning Debate

XII. Appendix: Sample Course Syllabus in Bioethics
BIE 709: Ethics of Health Communication
Spring 2012
Tuesdays, 6:30-9:00

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Course Background

Teaching and research in the area of the ethics of health communication transcends the formal discipline of communication studies and is registered in a host of other disciplines such as philosophy, religion, political science, psychology, sociology, feminist and cultural studies, law, medicine, and business administration. The importance of the ethics of health communication is easily justified by considering a simple question: What would life be like if ethics had no role to play in our everyday communication with others? I think it is fair to say that life would be much more of an ordeal than it already is.

The birth of scientific medicine was born with the help of the ethics of communication and public moral argument. Trained by the Sophists of their day, Hippocratic physicians involved themselves in this communication and rhetorical process when defining and defending their *techne* during public debates and while treating patients in the patients' homes or in the physicians' workshops. For these first men of scientific medicine, public moral argument served the important purpose of calling into being a "medical public" that, owing to its new scientific education, could stand with the Hippocratic physicians in their initial fight against traveling sophistic lecturers and those quack doctors whose practice still admitted the use of magical charms. As noted in the Hippocratic text *Decorum*, the wisdom that these healers possess and that they must constantly seek as their first priority makes them "the equal of a god. Between wisdom and medicine there is no gulf fixed." The point is put another way in the Hippocratic *Law*: "There are in fact two things, science and opinion; the former begets knowledge, the latter ignorance."

The sustained good health of the body politic—especially if the *hoi polloi*, the public, yearn for a democratic life-style— presupposes the inventive use of discourse to educate others (e.g., physicians, patients, the general public) and to have them educate us about what we all need to do to improve our lives. "Discursive openings" need to be created between people so that they have a place to be with and for each other, to make known and share their knowledge and opinions, to argue about the real and potential consequences of their judgments, decisions, and actions, and to stay in touch with the joys and the sorrows that others are feeling and that require sustained attention if the truth that they reveal is to be genuinely acknowledged. The ethics of health communication necessarily entails a consideration of

such openings—"dwelling places" (*ethos*; pl. *ethea*)—where conscience and the acknowledgment of others can work together for the betterment of humankind. The dwelling places for the ethics of health communication include, for example, doctors' offices, hospital facilities, patient's homes, public forums, and our media saturated society.

General Course Objectives

At the completion of this course students will be familiar with key concepts, theories, and critical methods for addressing and analyzing issues in the ethics of health communication. The empirical orientation of the class will also ensure that students can construct theory "from the ground up."
The ontological foundations of communication ethics and their impact on the physician-patient-family member relationship will thus be a significant concern of the course.

Required Textbooks

Anatole Broyard (1992). *Intoxicated by My Illness (and Other Writings on Life and Death).* New York: Fawcett Columbine.

Arthur W. Frank (1995). *The Wounded Storyteller: Body, Illness, and Ethics. The University of Chicago Press.*

Michael J. Hyde (2008). *Perfection, Postmodern Culture, and the Biotechnology Debate* (The Carroll C. Arnold Distinguished Lecture). New York: Pearson/Allyn & Bacon. (Note: Copies of this monograph will be handed out in class at no cost.)

Nancy M. P. King and Michael J. Hyde (Eds.) (2012). *Bioethics, Public Moral Argument, and Social Responsibility*. New York: Routledge. Selected essays will be distributed in class. Titles of essays are listed on the last page of this syllabus.)

Sign Up for "Google Alert"

Assignments

1. Formal Presentations: Each student will do two 30 minute presentations on class readings. Procedures for doing the presentations will be discussed in class.

2. Research Paper: You will write a 10-15 page research paper. For the research paper you will select a topic that is related to the ethics of health communication. You can examine any of the topics emphasized in the course. Guidelines for the paper will be provided later in the semester.

3. Class Participation (In-class and Internet): Participation in this class is vital. Your participation grade will be based on your overall involvement in class discussion and Internet discussion. Your attendance will count toward your participation grade.

"Write as if you were dying. At the same time, assume you write for an audience consisting solely of terminal patients. That is, after all, the case. What would you begin writing if you knew you would die soon? What could you say to a dying person that would not enrage by its triviality?"

"Why are we reading, if not in hope of beauty laid bare, life heightened and its deepest mystery probed?"

(Annie Dillard, *The Writing Life*)

Schedule for BIE 709

Topic	Week	Chapters	Assignment
Introduction	**1**	**Communication Ethics (Hyde/King, p. 157)** **History and Current Issues**	
A Classic Case	**2**	**Broyard**	**2 page review**
Illness Stories: The Body, The Person, and Ethics.	**3**	**Frank, chapters 1-3** **Health Com. Essays**	
Illness Stories: The Body, The Person, and Ethics	**4**	**Frank, chapters 4-8** **Health Com Essays**	**Presentations**
Educating the Citizenry: Public Moral Argument	**5**	**Zarefsky; Moreno; The President's Commission on Bioethics; Hyde**	**Presentations**
Family Perspective Social Support	**6**	**Dresser** **"The Cruzan Case" (essay)** **"The Schiavo Case" (essay)**	**Presentations**

The Language and Rhetoric of Bioethics	**7**	**Churchill; Condit; Juengst; Parrott**	**Presentations**
The Medical System	**8**	**Keranen "The Doctor" (movie)**	
The Media, Health, and Law	**9**	**Giles and Krcmar; Gianelli; Coughlin, et. al.**	**Presentations**
Another Classic Case Study	**10 and 11**	**"Mother's Last Request"**	**4 page review**
The Future of Bioethics	**12**	**Elliott; Lundberg and Smith**	
President's Obama Health Care Speech	**13**	**Read and Critique Speech**	
Discuss Final Papers	**14**	**In-Class Proposals**	
Course Summary	**15**	**Tying Together Loose Ends**	

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