

2005

## The Impact of Current Policy and Regulation on Future Stem Cell Human Health Applications

Michael J. Malinowski

Louisiana State University Law Center, [mjmalin@lsu.edu](mailto:mjmalin@lsu.edu)

Follow this and additional works at: [https://digitalcommons.law.lsu.edu/faculty\\_scholarship](https://digitalcommons.law.lsu.edu/faculty_scholarship)



Part of the Law Commons

---

### Repository Citation

Malinowski, Michael J., "The Impact of Current Policy and Regulation on Future Stem Cell Human Health Applications" (2005). *Journal Articles*. 140.

[https://digitalcommons.law.lsu.edu/faculty\\_scholarship/140](https://digitalcommons.law.lsu.edu/faculty_scholarship/140)

This Article is brought to you for free and open access by the Faculty Scholarship at LSU Law Digital Commons. It has been accepted for inclusion in Journal Articles by an authorized administrator of LSU Law Digital Commons. For more information, please contact [kreed25@lsu.edu](mailto:kreed25@lsu.edu).

# THE IMPACT OF CURRENT POLICY AND REGULATION ON FUTURE STEM CELL HUMAN HEALTH APPLICATIONS

MICHAEL J. MALINOWSKI\*

## INTRODUCTION

My approach to bioethics is very much application centered, meaning in part that I prioritize reality and ongoing human experiences—the impact on lives in motion today—over theory, with appreciation that the two often work well together.<sup>1</sup> I use theory to assist in problem identification and analysis, but I favor a fact-based approach driven by what people are actually living through today.<sup>2</sup> While doing so, I also try to be thoughtful and think longer term and proactively.

I believe that those of us who invest our professional lives in bioethics and health policy have an obligation to be professionally self-aware and open. We must figure out what drives our thinking and why, identify where we stand on particular issues and why, and then disclose that information honestly when we enter debates. Otherwise, meaningful communication

---

\* Ernest R. and Iris M. Eldred Professor of Law and Associate Director, Program in Law, Science, and Public Health, Paul M. Hebert Law Center, Louisiana State University. The presentation for this live symposium on November 19, 2004 was derived from another given by the author on October 11, 2004 at National Academies, *Workshop on Guidelines for Human Embryonic Stem Cell Research* (Oct. 11-12, 2004, Washington, D.C.). The author would like to thank Professor R. Alta Charo for interactions in conjunction with the *Workshop* that contributed to this effort, Professor Nanette Elster for her thoughtful suggestion, and Daven Williams for her research assistance.

1. See Michael J. Malinowski, *Law, Policy, and Market Implications of Genetic Profiling in Drug Development*, HOUS. J. HEALTH LAW & POL'Y 31, 59-61 (2002). "One might argue, therefore, that there is a moral imperative in addition to a professional obligation to bridge law and policy with meaningful fieldwork.... in both life science R&D and health care delivery...." *Id.* at 61.
2. See generally *id.*

and dialogue are unlikely. Even if more often than not we end up agreeing that we disagree because our personal determinants on an issue are not aligned, we can do so with a baseline of communication and understanding, and relay the same to others in the debate.

Given this approach, today's topic certainly necessitates some disclosure by me at the outset. Therefore, I will begin by explaining my position on human embryonic stem cell research (hESCR) and my underlying rationale for my position. In Part II of this presentation, I will address the impact of current federal policy and regulation on hESCR in the context of ongoing basic research. In Part III, I will discuss the potential impact of existing federal policy and regulations on human health applications of hESCR. I will conclude in Part IV by sharing my overriding thoughts about the regulatory environment for hESCR in the United States. Given the chronic commingling of therapeutic and reproductive cloning since the late 1990s, I believe that assurance to quell discomfort with the notion of human cloning for reproduction is a prerequisite for significantly increasing support for hESCR in the near future. As I will explain, I believe that such assurance is possible only through more meaningful regulatory oversight and accountability in the field of assisted reproduction (AR) in the United States.

### I. OVERALL POSITION ON HESCR

My position on hESCR is influenced heavily by the state of AR in the United States, and I believe that these issues are fundamentally entangled. AR has become a burgeoning, multibillion-dollar industry annually in this country, and one that is growing exponentially.<sup>3</sup> Professor George Annas has done a wonderful job—in literature, in presentations, and in the popular media, including a PBS documentary entitled *Making Babies* that I have shown often in my classes<sup>4</sup>—drawing attention to the dearth of U.S. federal regulation in the field of AR.<sup>5</sup> Professor Annas has referred to AR in the

- 
3. See Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past—Present, and Future?*, 36 CONN. L. REV. 125, 179-97 (2003) (fully explaining the present state of regulation of AR in the U.S., including dependence upon voluntary reporting, and the market, social, and scientific factors driving extensive expansion of use of AR technologies). Cf. PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 54-63 (2004), available at [http://www.bioethics.gov/reports/reproductionandresponsibility/\\_pcbe\\_final\\_reproduction\\_and\\_responsibility.pdf](http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf) [hereinafter PRESIDENT'S COUNCIL, REPRODUCTION AND RESPONSIBILITY]. According to one report, AR constituted a \$4 billion industry annually as of 2001. See *id.* at 191.
  4. *Frontline: Making Babies* (PBS television broadcast, June 1, 1999).
  5. See generally George J. Annas, *The ABCs of Global Governance of Embryonic Stem Cell Research: Arbitrage, Bioethics and Cloning*, 39 NEW ENG. L. REV. 489 (2005).

United States as “the wild West”<sup>6</sup> of American medicine, and that pretty much captures it.<sup>7</sup>

The consequential reality is that we know, according to data released by the American Society for Reproductive Medicine (ASRM) on May 7, 2003, that we have more than 400,000 frozen embryos left over from AR procedures and derogated to what I will call “cryopreservation purgatory.”<sup>8</sup> These numbers are probably very low because they are based on self-reporting,<sup>9</sup> and AR has been burgeoning since 2003. Reality is that these embryos are the creation of medical intervention and their continued existence is wholly dependent upon the same. As we heard this morning from Dr. Suzanne Kadereit,<sup>10</sup> Harvard’s Boston Children’s Hospital is not going to pay to keep the embryos perpetuating forever, and we should not anticipate more from its sister institutions.

For the purposes of argument, let us elevate the existence of these frozen embryos to a status much higher than what they actually are. Let us equate them with people with life histories who are dependent on medical intervention for their continued existence—for example, an eighteen-year-old who suffered severe brain trauma in an automobile accident or an eighty-six-year old with very advanced Alzheimer’s. It is basic, well

---

*See, e.g.,* Rosario M. Isasi & George J. Annas, *Arbitrage, Bioethics, and Cloning: The ABCs of Gestating A United Nations Cloning Convention*, 35 CASE W. RES. J. INT’L L. 397 (2003).

6. *See* Isasi & Annas, *supra* note 5, at 397.

7. *See* Malinowski, *supra* note 3, at 180-89.

8. *Id.* at 130 n.11 (citing American Society for Reproductive Medicine, *Vast Majority of Cryopreserved Embryos Slated for Future Family Building*, ASRM BULL., May 7, 2003, available at <http://www.asrm.org/Washington/Bulletins/vol5no30.html>).

9. The United States relies heavily upon voluntary reporting by those practicing AR. The Centers for Disease Control and Prevention (CDC) has contracted implementation of the Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. 102-493, 106 Stat. 3146 (1992), to the Society for Assisted Reproductive Technology (SART), which is part of the American Society for Reproductive Medicine (ASRM). Malinowski, *supra* note 3, at 182. The CDC compiles submitted data and publishes reports. *See, e.g.,* CTRS. FOR DISEASE CONTROL & PREVENTION, *2000 Assisted Reproductive Technology Report*, available at <http://www.cdc.gov/reproductivehealth/ART00/download.htm> (Dec. 20, 2002); CTRS. FOR DISEASE CONTROL & PREVENTION, *2001 Assisted Reproductive Technology Success Rates*, available at <http://www.cdc.gov/reproductivehealth/ART01/download.htm> (Dec. 2003).

10. Suzanne Kadereit & Pamela J. Hines, *An Overview of Stem Cell Research*, 39 NEW ENG. L. REV. 607 (2005). *But see* Miller v. Am. Infertility Group, No. 02-L-7394 (Cir. Ct. Cook County, Ill., County Dep’t Law Div., Feb. 4, 2005) (memorandum opinion and order) (on file with author) (holding that a couple whose frozen embryos were accidentally destroyed at a fertility clinic has the right to file a wrongful death lawsuit).

established law and policy in the United States and in many other industrialized countries that, when a person is incompetent and wholly dependent upon medical intervention for his or her continued existence, and that person has not expressed wishes to the contrary before becoming incompetent, the family or guardian of that person has the right to make decisions about withdrawing medical intervention.<sup>11</sup> Often, the decision to withdraw treatment is accompanied by a decision to donate the person's physical existence for use in organ transplantation or research to benefit others.<sup>12</sup>

When the life lost is a frozen embryo rather than an incompetent person, however, President Bush's policy on stem cell research greatly impedes the ability of "family members" to mitigate the loss of life by making potentially significant health contributions. Under the Bush policy, the option to donate cryopreserved embryos is limited to research with private money and removed from academic institutions, which understandably makes that option much less appealing to many people.<sup>13</sup> The policy also creates a significant disincentive and, at the least, major administrative transaction costs for the thousands of academic institutions and researchers who receive some of the many billions of taxpayer dollars

- 
11. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 1379-1446 (5th ed. 2004); TIMOTHY STOLTZFUS JOST, *READINGS IN COMPARATIVE HEALTH LAW & BIOETHICS* 299-326 (Carolina Academic Press 2001) (discussing the right to die).
  12. See FURROW ET AL., *supra* note 11, at 1315-43. Cf. UNIF. DETERMINATION OF DEATH ACT § 1, 12A U.L.A. 593 (1980). The act has been expanded to encompass "brain death" in the definition of death and, generally, to make it easier to donate organs for transplantation. FURROW ET AL., *supra* note 11, at 1321.
  13. Fact Sheet, The White House, Embryonic Stem Cell Research (Aug. 9, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>. On August 9, 2001, President Bush declared federally funded research permissible on hESCs already extracted from embryos at that time. *Id.*; see also Address to the Nation on Stem Cell Research, 2 PUB. PAPERS 953 (Aug. 9, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>. Soon after, access to and the quality of these lines were called into question. See, e.g., Sheryl Gay Stolberg, *Ruling by U.S. Widens Study of Stem Cells*, N.Y. TIMES, Aug. 7, 2002, at A1. Recently, these lines have been declared probably useless for human medicinal applications because they were created with mouse feeder cells, a reflection of the state of science at that time, and many are of poor quality. See Karen Kaplan, *Study Says All Stem Cell Lines Tainted*, L.A. TIMES, Jan. 24, 2005, at A1. This issue also was raised and discussed several times at a public workshop held at the National Academy of Sciences on October 11-12, 2004 in Washington D.C. See generally NAT'L ACAD. OF SCIS., *Guidelines for Human Embryonic Stem Cell Research: A Public Workshop*, at <http://dels.nas.edu/bls/stemcell.html> (last visited Feb. 15, 2005) [hereinafter NAT'L ACAD. OF SCIS., *Public Workshop*].

the federal government invests in biomedical research each year.<sup>14</sup> This policy also contributes to the decision reached by the many thousands of people who have received AR services and who do not want biological offspring beyond their own families to simply make no decision or an affirmative decision to allow the cryopreservation of their leftover embryos to linger on—perhaps at the discretion of an AR clinic.<sup>15</sup> Consequently, the numbers of embryos derogated to cryopreservation with no chance of implantation for reproduction should rise in the United States in conjunction with advancement and use of AR services.<sup>16</sup>

President Bush has stated repeatedly that his policy on human embryonic stem cell research is rooted deeply in respect for embryos and human life,<sup>17</sup> and the same is said by Leon Kass who chairs the President's Council on Bioethics and is reflected in the Council's position.<sup>18</sup> It seems terribly inconsistent to me to be creating embryos without foresight about their fate, without any meaningful and direct government oversight, and placing them in cryopreservation purgatory for extended periods of time

- 
14. The National Institutes of Health (NIH) alone was a conduit for a federal budget of \$28 billion in 2004, and NIH's budget for 2005 is \$28.6 billion. Jonathan Weisman, *2006 Cuts in Domestic Spending on Table*, WASH. POST, May 27, 2004, at A1; *Drug Development: Medicine Price Hike Highlights Controversy of Government Funding Drug Research*, MED. LETTER ON CDC & FDA, June 20, 2004, available at 2004 WL 55170701.
  15. See *supra* note 10 and accompanying text (comments of Dr. Kadereit). Resistance to putting one's embryos up for donation in this context is not surprising, for many seek AR services rather than adoption because of the value they place on biological ties to offspring. For case studies that illustrate this point, see *18 Ways to Make a Baby* (PBS television broadcast, Oct. 9, 2001). See also *Miller*, No. 02-L-7394.
  16. Expanding use of AR services in the United States is driven by many influences, including demographic and cultural trends resulting in delays in reproduction and acceptance of AR, the number of AR service providers and their marketing efforts, the profitability of providing AR services, and increasing scientific capabilities, including preimplantation genetic diagnosis (PGD) that allows genetic selection among available embryos before implantation. See generally Malinowski, *supra* note 3; John A. Robertson, *Extending Preimplantation Genetic Diagnosis: The Ethical Debate*, 18 HUM. REPROD. 465 (2003).
  17. Heather L. Fowler, *Misapplied Ethical Considerations: U.S. Federal Stem Cell Mandates Lack Global Focus and Market Foresight*, 36 CORNELL INT'L L.J. 521, 534 (2004); Tommy G. Thompson, *Why Bush's Stem Cell Policy is Reasoned—and Why It's Working*, USA TODAY, Aug. 16, 2004, at 11A, available at [http://www.usatoday.com/news/opinion/editorials/2004-08-15-stem-cells\\_x.htm](http://www.usatoday.com/news/opinion/editorials/2004-08-15-stem-cells_x.htm). See generally *supra* note 13.
  18. See LEON R. KASS, *LIFE, LIBERTY AND THE DEFENSE OF DIGNITY: THE CHALLENGE FOR BIOETHICS* 130 (Encounter Books 2002). For the Council's position on this issue and others, see <http://www.bioethics.gov>. See also PRESIDENT'S COUNCIL, *REPRODUCTION AND RESPONSIBILITY*, *supra* note 3.

without any intention of using them when there are potential medical benefits to existing living, breathing people. The Bush Administration and supporters of his policy question this potential and suggest alternatives to hESCR.<sup>19</sup> Doing so necessitates speculation in the negative about the outcome of ongoing and future scientific research with hESCs, which is a mirror reflection of the Administration's major criticism of advocates for hESCR—that they are speculating (in the positive) when they identify potential clinical applications.<sup>20</sup> The fact is that the vast majority of Nobel Laureates in science recognize human health potential in hESCR and support U.S. federal funding of it.<sup>21</sup> Presumably, the visionaries excited about hESCR are hyping the potential clinical use, but the funny thing about science is that you never really know unless you try. I have seen accomplishments in science during the last decade, including completion of a map of the human genome ahead of schedule and under budget, that I was told by many top medical and science people in the early 1990s would not happen.<sup>22</sup> The division between the pragmatists in medicine and visionaries in science<sup>23</sup> now has shifted beyond mapping the human genome to making medical sense out of it, and we are all debating how quickly that will come.

## II. ONGOING BIOMEDICAL RESEARCH AND DEVELOPMENT (R&D)

My position on hESCR now established, let us sketch a regulatory picture for the future development of stem cells in application—and do that with some cautious skepticism about how quickly these applications are going to come. When I contemplate applications, I do not view the future

---

19. Research with adult stem cells is frequently pointed to as an alternative that is showing more scientific advancement. For example, President Bush has and continues to make this argument. *See, e.g.*, Address to the Nation on Stem Cell Research, *supra* note 13. *See generally infra* note 21.

20. Associated Press, *First Lady Joins Stem Cell Debate* (Aug. 9, 2004), *available at* <http://www.cbsnews.com/stories/2004/07/28/politics/printable632432.shtml>.

21. Letter from Nobel Laureates to President Bush (Feb. 21, 2001), *available at* <http://www.washingtonpost.com/ac2/wp-dyn/A37117-2001Feb21?language=printer>. *See generally* COMMITTEE ON THE BIOLOGICAL AND BIOMEDICAL APPLICATIONS OF STEM CELL RESEARCH, STEM CELLS AND THE FUTURE OF REGENERATIVE MEDICINE (Nat'l Acad. Press 2002) (discussing stem cell research and its potential to improve human health); ANN B. PARSON, THE PROTEUS EFFECT: STEM CELLS AND THEIR PROMISE FOR MEDICINE (Joseph Henry Press 2004). *See also* Harvey Fineberg, Remarks at the National Academy of Sciences Public Workshop (Oct. 12, 2004) (transcript on file with author); NAT'L ACAD. OF SCIS., *Public Workshop*, *supra* note 13.

22. Michael J. Malinowski, *Separating Predictive Genetic Testing from Snake Oil: Regulation, Liabilities, and Lost Opportunities*, 41 JURIMETRICS J. 23, 26 (2000).

23. *Id.* at 24 n.3, 25 n.4 and accompanying text.

from only a clinical delivery standpoint. Rather, my perspective, shaped by years of law practice and other commercial sector experience, is very much from the laboratory bench to market. Many important commercial applications are research tools to enable other basic research in human health and corollary applications.<sup>24</sup>

The timing of jolting, fundamental advancements in hESCR during the late 1990s has been politically problematic for the field. The isolation of human stem cells reported in 1998 by Geron Corporation and the University of Wisconsin<sup>25</sup> came almost literally on the tail of Dolly—the first successfully cloned mammal.<sup>26</sup> Dolly triggered an immediate reaction of fear of cloning for human reproduction, and human cloning and reproduction have been extensively commingled in the popular press, public mindset, and legislative activity ever since.<sup>27</sup> This cloning override between therapy and reproduction is not entirely unfair because, in fact, the science does carry over. If one develops techniques such as somatic cell nuclear transfer<sup>28</sup> to engage in hESCR for patient-tailored medicinal applications, presumably those could be used in AR. In fact, the technique was developed in the process of cloning mammals for reproduction—Dolly. The human reproduction concern “has legs” from a pragmatic point of view because the U.S. federal government does not regulate AR in a comprehensive, direct manner.<sup>29</sup> At the very least, drawing this connection

- 
24. Consider the myriad compounds that have been patented and, through licenses and commercial royalty arrangements, used in diverse clinical applications. *See generally* BOSTON CONSULTING GROUP, *THE PHARMACEUTICAL INDUSTRY INTO ITS SECOND CENTURY: FROM SERENDIPITY TO STRATEGY* 38-39 (Jan. 1999).
  25. Terry Devitt, *Wisconsin Scientists Culture Elusive Embryonic Stem Cells* (Nov. 5, 1998), at <http://www.news.wisc.edu/3327.html>.
  26. For more information, visit the web site of the Roslin Institute in Edinburgh, Scotland, where Dolly was created, at <http://www.roslin.ac.uk/public/cloning.html>. *See also* *Dolly the Sheep*, in WIKIPEDIA ENCYCLOPEDIA, at [http://en.wikipedia.org/wiki/Dolly\\_the\\_sheep](http://en.wikipedia.org/wiki/Dolly_the_sheep) (last modified Feb. 2, 2005).
  27. *See* Paul Lesko & Kevin Buckley, *Attack of the Clones ... and the Issues of Clones*, 3 COLUM. SCI. & TECH. L. REV. 1 (2002), at <http://www.stlr.org/cite.cgi?volume=3&article=3>; Meredith Lewis, Book Note, *Age of Human Cloning and the Constitutional Crisis that May Result*, 6 J.L. & FAM. STUD. 171 (2004); Shawn E. Peterson, Note, *A Comprehensive National Policy to Stop Human Cloning: An Analysis of the Human Cloning Prohibition Act of 2001 with Recommendations for Federal and State Legislatures*, 17 NOTRE DAME J.L. ETHICS & PUB. POL'Y 217, 217-18 (2003).
  28. STEM CELL NETWORK, *What is Somatic Cell Nuclear Transfer (SCNT)?*, at <http://www.stemcellnetwork.ca/guide/focus.php?id=174> (last visited Feb. 10, 2005); *see* COMMITTEE ON THE BIOLOGICAL AND BIOMEDICAL APPLICATIONS OF STEM CELL RESEARCH, *supra* note 21, at 10-12.
  29. *See supra* notes 4-7 and accompanying text; *see also infra* notes 73-76 and



is not unreasonable, illogical, irrational or unfair. Similarly, baseline moral and religious objections to destroying embryos stirs the issues of cloning for therapy and cloning for reproduction into each other.

Even with the reelection of President Bush and absent a change in federal policy on hESCR, it is certain that hESCR is going to continue. The research will move forward primarily as a private market endeavor. In fact, NIH is encouraging this by grant funding efforts to make cell lines available for private research and development.<sup>30</sup> On a personal note, as a taxpayer and as one who has spent the vast majority of his career practicing law and engaging in scholarship in the area of technology transfer and development in biotechnology, I find the Administration's position to be hypocritical and generally troubling. It is no consolation to me to hear that the Administration's position on hESCR is tempered by the fact that NIH, in addition to putting up \$25 million for direct support of this research, is also putting up \$25 million to deal with the transaction cost of complying with its own restrictive policy on federal funding.<sup>31</sup> Rather, it seems awfully hypocritical to me to put so much government money allegedly committed to research into lowering transaction costs created because the Bush Administration does not want to support that research in an open way—though implicitly the Administration acknowledges the importance of hESCR enough to grant fund efforts to “Coase around”<sup>32</sup> its own policy.

Even without NIH funding to bridge transaction costs created by President Bush's policy, the biomedical establishment that is dependent upon federal funding is committed to doing this research, and is going to find a way to do some of it—there is no question. We are seeing that happen now. Notably, there are few instances where major universities—Harvard<sup>33</sup> and Stanford<sup>34</sup>—have shadowed the arrangement between Geron

---

accompanying text. See generally Malinowski, *supra* note 3.

30. O. Carter Snead, *Keynote Address: Preparing the Groundwork for a Responsible Debate on Stem Cell Research and Human Cloning*, 39 NEW ENG. L. REV. 479 (2005).
31. See *id.* A similar message was issued by a James Battey, Director, National Institute on Deafness and Other Communication Disorders, on October 12, 2004 at *Guidelines for Human Embryonic Stem Cell Research*, a workshop organized and hosted by the National Academy of Sciences, October 12-13, 2004, Washington, D.C., in which the author participated.
32. See generally Ronald Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1 (1960).
33. Harvard's effort is the Harvard Stem Cell Institute, which announced in March 2004 that it had developed seventeen new embryonic stem cell lines. See *Harvard Stem Cell Institute*, HARV. GAZETTE, Apr. 22, 2004, available at <http://www.news.harvard.edu/gazette/2004/04.22/science.html>.
34. Stanford has established the Institute for Cancer/Stem Cell Biology and Medicine, information about which is available at <http://med.stanford.edu/institutes/>.

and the University of Wisconsin that produced the 1998 fundamental hESCR advances.<sup>35</sup> These universities have put up administrative divisions and created separate entities to engage in hESCR without federal funding.<sup>36</sup> The problem is that there are not too many schools in the position of Harvard and Stanford. I teach at Louisiana State University, a good school with some A-level science through the Pennington Biomedical Research Center, AgCenter, School of Veterinary Medicine, Health Sciences Center, and so forth, but LSU is not positioned financially or politically to create a quasi-private entity for hESCR. Even with state support, doing so would be extremely difficult, though LSU does receive a significant amount of federal funding to support research projects throughout the LSU System. LSU is representative of a considerable portion of the research university community, and mechanisms created by a few of the most renowned private institutions, even if successful and duplicated, are unlikely to offset the loss of meaningful access to tens of billions of dollars in federal funding annually for an entire field of science.

In conjunction with private universities, a few states are getting directly involved in hESCR. Most notably, California has committed \$3 billion over ten years.<sup>37</sup> Without putting up the same billions of dollars, New Jersey too has taken a positive stand.<sup>38</sup> Nevertheless, other states as diverse as Massachusetts and Louisiana have either seen supportive legislative initiatives fail or actually considered legislative proposals to move in the opposite direction.<sup>39</sup> Moreover, California's financial support

---

35. For information about this arrangement, visit the site of the Wisconsin Alumni Research Foundation, at <http://www.warf.ws>, which holds composition of matter patents in stem cell lines—a potential basis for property claims to all stem cell lines.

36. See *supra* notes 31-32 and accompanying text.

37. John M. Broder & Andrew Pollack, *Californians to Vote on Spending \$3 Billion on Stem Cell Research*, N.Y. TIMES, Sept. 20, 2004, at A1; Dan Vergano, *Embryonic Imbroglio*, USA TODAY, Oct. 27, 2004, at D6.

38. Wesley Chang, Comment, *Arrested Development: Patent Laws, Embryonic Stem Cell Research, and the Organ Black Market*, 10 SW. J.L. & TRADE AM. 407, 424-25 (2004).

39. Louisiana already recognizes the embryo as a juridical person. LA. REV. STAT. ANN. §§ 121-33 (West 2004). A legislative proposal to ban human cloning that would have effectively prohibited hESCR research in the state regardless of the source of funding was circulated in 2004. See H.R. 803, 2004 Sess. (La. 2004). Massachusetts, though in a heated biotech race with California, was unable to enact proposed legislation supporting stem cell research. However, Thomas M. Finneran, the former Speaker of the House, who opposed that legislation, is now supportive in his role as Chief Executive Officer of the Massachusetts Biotechnology Council. See Mark Zimmerman, *An Odd Job for Tom Finneran*, BOSTON GLOBE, Oct. 3, 2004, at D10 (letter to the editor); Scott S. Greenberger & Frank Phillips, *Stem Cell Bill Tops Agenda as Legislature Convenes*, BOSTON GLOBE, Jan. 6, 2005, at A1; John

cannot offset the tens of billions of dollars NIH invests annually in biomedical research and the associated, potentially enormous opportunity cost.<sup>40</sup> As we witnessed through the Human Genome Project, meaningful support from the U.S. government in areas of research can have a distinctive effect in terms of establishing prioritization, “critical mass” participation, and focus throughout the global science community.

### III. FUTURE HUMAN HEALTH APPLICATIONS

So what is the opportunity cost in terms of human health applications? Throughout this symposium,<sup>41</sup> the NAS’s forum last month,<sup>42</sup> and the scientific and popular literature,<sup>43</sup> many potential human health applications of ongoing hESCR have been identified. Some of the more dramatic applications are a cure for diabetes, effective treatment for Alzheimer’s, and spinal cord repair.<sup>44</sup> President Bush’s policy of restricted funding for hESCR is premised on the assumption that the applications of the technology are years in the future. However, there are immediate and certain applications of hESCR that refute this assertion. Deeper knowledge about cell differentiation could have a profound impact on basic biomedical research. Consider creation of cell lines free of non-human animal cultures, an abundance of cell lines tailored to genetic characteristics of specific disease populations, novel vectors, and other biomaterials which, through material transfer and development agreements, become valuable tools used in many areas of biomedical research. If human experience in biomedical R&D is any indication, incremental clinical applications in the process of moving from the present towards effective therapies are actually probable with meaningful investment in hESCR. For example, consider use of cell manipulation techniques to conduct much more precise toxicity testing—perhaps to better isolate adverse events associated with pharmaceuticals

---

Strahinich, *Finneran Now Backs Stem Cell*, BOSTON HERALD, Nov. 10, 2004, at 42.

40. See *supra* note 14 and accompanying text (noting that the NIH has a budget of \$28.6 billion in 2005).

41. See generally Symposium, *Stem Cell Research to Human Cloning: Where Do We Draw the Line?*, 39 NEW ENG. L. REV. 477, 477-714 (2005).

42. See NAT’L ACAD. OF SCIS. *Public Workshop*, *supra* note 13.

43. See, e.g., COMMITTEE ON THE BIOLOGICAL AND BIOMEDICAL APPLICATIONS OF STEM CELL RESEARCH, *supra* note 21; PARSON, *supra* note 21.

44. Research endeavors for human health applications include muscular dystrophy, autoimmune disorders (lupus, multiple sclerosis, and deafness), cells for drug testing, replacement salivary gland cells for patients treated with radiation for cancers of the head and neck, teeth regeneration, infertility, baldness, depression, neurogenesis, fortification of heart muscle, immune system tolerance for organ transplant patients, bone regeneration, breast reconstruction, Parkinson’s disease, making organs and other bio-structures, spinal cord injury, and aging. PARSON, *supra* note 21, at 219-32.

already on the market and commonly used:

Take the example of a Geron team's having turned human ES [embryonic stem] cells into what it believes are hepatocytes, the liver's primary specialized cell. If hepatocytes could be mass produced from ES cells, drugmakers, who must show that a new drug has no adverse effects on the liver, would have vast quantities of liver cells. Currently, a chief source of liver cells for drug tests are cadavers.<sup>45</sup>

As this example suggests, cellular differentiation techniques might help to modify or at least make better choices among a range of existing treatments in areas such as oncology. The capability to readily and cost-effectively grow particular kinds of cells may even enable some patient-tailored toxicity testing.

The hESC lines in existence on August 9, 2001—those which may be used in federally funded research under the Bush Administration's policy<sup>46</sup>—were created with exposure to mouse cultures, are limited in their genetic diversity, generally are of questionable vitality and quality, and in many instances are encased with proprietary interests.<sup>47</sup> Use of mouse feeder cells in the creation of these lines, reflective of the state of science at that time, introduces a muddle of xenotransplantation complications if these lines are to be the basis for human health applications.<sup>48</sup> In January 2005, a study was issued by researchers at the University of California San Diego and the Salk Institute for Biological Studies in La Jolla, indicating that the lines probably are too innately contaminated to ever serve as the basis for human health applications.<sup>49</sup>

Assuming we see meaningful human health applications from hESCR over the next several years in spite of limitations on federal financial support, are existing regulations and regulatory regimes for human health products sufficient to handle them? I do believe that the FDA, in collaboration with sister agencies as necessary under the Coordinated

---

45. *Id.* at 223.

46. *See supra* note 13 and accompanying text.

47. *See* Malinowski, *supra* note 3, at 184 n.301.

48. R. Alta Charo, *Existing Federal, State and Voluntary Regulation of Embryonic Stem Cell Research* (Oct. 2004), available at <http://dels.nas.edu/bls/stemcells/charo.pdf> (distributed at the NAT'L ACAD. OF SCIS., *Public Workshop*, *supra* note 13). For more information about xenotransplantation and related science and regulatory issues, see CENT. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., *Xenotransplantation Action Plan*, at <http://www.fda.gov/cber/xap/xap.htm> (last modified June 29, 2004).

49. *See* Kaplan, *supra* note 13.

Framework,<sup>50</sup> can rise to the occasion of sufficiently regulating products developed through hESCR. I say that fully aware that we have a very troubling time in front of us regarding the FDA. I was directly involved in the modernization of the FDA through scholarship and industry representation.<sup>51</sup> A lot of good was done to increase the crossover of new science into commercial applications. User fees have greatly expanded the FDA's resources, and also created much more dialogue among the FDA, industry, and academia.<sup>52</sup> Ultimately, you end up in a world where a very thick and long-standing wall was taken down between industry and the government through regulatory reform. While razing this wall arguably was necessary to fuel the genomics revolution,<sup>53</sup> accountability mechanisms must be added in its place to ensure some regulatory checkpoints.<sup>54</sup> The ongoing Cox-2 controversy, coupled with incidents such

- 
50. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986). Under this policy, federal regulatory entities are supposed to collaborate to regulate biotechnology products and not subject those products to added regulation just because biotechnology processes are used to make them. See Michael J. Malinowski, *FDA Regulation of Biotechnology Products for Human Use*, in *ENCYCLOPEDIA OF ETHICAL, LEGAL AND POLICY ISSUES IN BIOTECHNOLOGY* 215 (Thomas H. Murray & Maxwell J. Mehlman eds., 1999).
  51. This modernization refers to implementation of the Food and Drug Administration Modernization Act of 1997. Pub. L. No. 105-115, 111 Stat. 2296 (codified throughout 21 U.S.C.) [hereinafter FDAMA].
  52. Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (codified throughout 21 U.S.C.) [hereinafter PDUFA I]. PDUFA I was reauthorized (PDUFA II) in the context of FDAMA. Prescription Drug User Fee Act of 1994, Pub. L. No. 102-571, 106 Stat. 4491 (codified in scattered sections of 21 U.S.C.), renewed as an addendum to the FDAMA. The FDAMA renewed the user fee program for five years and introduced new performance goals and other fundamental adjustments. See Malinowski, *supra* note 50; Prescription Drug User Fee Amendments of 2002, Pub. L. No. 107-188, 116 Stat. 687 (codified throughout 21 U.S.C.) [hereinafter PDUFA III] (extending the program to Sept. 30, 2007). See generally *FOOD & DRUG ADMIN., PDUFA III Five-Year Plan*, available at <http://www.fda.gov/cc/pdufa3/2003plan/default.html> (July 2003).
  53. For support of federal technology transfer policy and practice, see generally NAT'L INSTS. OF HEALTH, *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, available at <http://www.nih.gov/news/070101wyden.htm> (July 2001); GEN. ACCOUNTING OFFICE, *REPORT TO CONGRESSIONAL COMMITTEES: TECHNOLOGY TRANSFER, ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES*, GAO/RCED-98-126 (May 1998), available at <http://www.gao.gov/archive/1998/rc98126.pdf> [hereinafter GAO REPORT].
  54. See generally Timothy Caulfield, *Globalization, Conflicts of Interests and Clinical Research: An Overview of Trends and Issues*, 8 WIDENER L. SYMP. J. 31 (2001); Janet Fleetwood, *Conflicts of Interest in Clinical Research: Advocating for Patient*

as the alleged failure of Lilly to disclose troubling clinical data for Prozac which has been on the market for years, may end up being the “thalidomide of 2005” that triggers some major reform.<sup>55</sup>

With that being said, the FDA has been extremely resourceful and dynamic responding to many scientific and other challenges during the last decade, and they have made some administrative changes that position them well to handle hESCR product applications. Most notably, they have been developing a “tissue products track” and have centered review for all drugs, including biologics, in the Center for Drug Evaluation and Research (CDER).<sup>56</sup> At least in theory, by centralizing pharmaceuticals in CDER, the Agency opened up the Center for Biologics (CBER)<sup>57</sup> to focus on areas like hESCR. Unfortunately, as I learned through a conversation at the NAS workshop,<sup>58</sup> the Agency also has gutted a great deal of CBER’s resources and human talent, and that simply has to be corrected.

Now, stepping beyond regulatory oversight, the privatized, extreme commerce approach<sup>59</sup> President Bush is taking with hESCR will have a significant impact on how and the extent to which hESCR is applied—both in biomedical research and in human health markets. Immediate experience

*Subjects*, 8 WIDENER L. SYMP. J. 105 (2001); Patricia Kuszler, *Curing Conflicts of Interest in Clinical Research: Impossible Dreams and Harsh Realities*, 8 WIDENER L. SYMP. J. 115 (2001); Michael J. Malinowski, *Academic-Industry Collaborations in the Clinic*, 8 WIDENER L. SYMP. J. ii (2001); Michael J. Malinowski, *Institutional Conflicts and Responsibilities in Anage of Academic-Industry Alliances*, 8 WIDENER L. SYMP. J. 47 (2001); Pilar N. Ossorio, *Pills, Bills and Shills: Physician-Researcher's Conflicts of Interest*, 8 WIDENER L. SYMP. J. 75 (2001); Cynthia Robbins-Roth, *From Alchemy to IPO: The Businesses of Biotechnology*, 8 WIDENER L. SYMP. J. 153 (2001); Erica Rose, *Financial Conflicts of Interest: How Are We Managing?*, 8 WIDENER L. SYMP. J. 1 (2001).

55. Ken Belson, *Lilly Shares Fall on Report About Prozac Documents*, N.Y. TIMES, Jan. 1, 2005, at C2; Alex Bernson, *An Industry in Poor Health*, N.Y. TIMES, Dec. 18, 2004, at A1; Barnaby J. Feder, *The Fallout from Celebrex*, N.Y. TIMES, Dec. 18, 2004, at B1; Gina Kolata, *A Widely Used Arthritis Drug is Withdrawn*, N.Y. TIMES, Oct. 1, 2004, at A1; Barry Meier, *A Top Republican to Offer Drug Data Bill*, N.Y. TIMES, Dec. 10, 2004, at C3; Anahad O'Connor & Denise Grady, *Problems May Send Many Patients Back to Good Old Aspirin*, N.Y. TIMES, Dec. 18, 2004, at B1. Several major pharmaceuticals, in an effort to preempt government mandates, are now posting much more clinical data voluntarily. Meier, *supra*.
56. See CENT. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., at <http://www.fda.gov/cder> (last updated Feb. 18, 2005). See generally Charo, *supra* note 48.
57. See CENT. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., at <http://www.fda.gov/cber> (last updated Feb. 1, 2005).
58. NAT'L ACAD. OF SCIS., *Public Workshop*, *supra* note 13.
59. See generally Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 NEW ENG. L. REV. 665 (2005).

with hESCR is telling. When President Bush issued his policy on hESCR on August 9, 2001, my immediate reaction was, "Does he assume these cell lines are free of intellectual property entanglements—that they are subject to free use?" I knew Geron had licenses from the University of Wisconsin and had exercised rights over a lot of the better lines.<sup>60</sup> Sure enough, Geron was pulled into negotiations with NIH representatives soon after, and the result was that the lines are accessible via licenses, but on terms that many researchers find unfavorable.<sup>61</sup>

What are the costs of a wholly privatized approach in the field of hESCR? Well, one of the costs is that extensive proprietary interests, an extension of the source of funding, results in a loss of derivation cell lines that would potentially make a significant impact in the field. Again, given the proprietary nature of the research and related information, you also end up with a loss of public awareness and accountability. Companies need only disclose to the extent necessary to obtain patents, and they usually go to great extremes to shroud invention with confidentiality and disclosure agreements and other secrecy measures to maintain patentability and competitive advantages, and to avoid public relations problems.<sup>62</sup> In fact, the U.S. government is sacrificing a major entitlement to information in hESCR under standard federal technology transfer law and policy. Even a small amount of federal funding entitles the U.S. federal government to receive reports about resulting inventions.<sup>63</sup> The government also receives a non-exclusive right to use inventions that come out of your taxpayer dollars in its own internal research,<sup>64</sup> and the U.S. government engages in

---

60. For more information about these licenses, visit the sites of Geron Corporation, at <http://www.geron.com/>, and the Wisconsin Alumni Research Foundation, at [www.warf.ws](http://www.warf.ws).

61. See O'Connor, *supra* note 59.

62. This is the author's observation based upon years of experience and practice in the field. See also Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987).

63. See Patent Rights in Inventions Made with Federal Assistance, Pub. L. No. 96-517, 94 Stat. 3019 (1980) (codified at 35 U.S.C. §§ 200-212) (the Bayh-Dole Act); Technology Innovation Act, Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified at 15 U.S.C. §§ 3701-3717) (the Stevenson-Wydler Technology Innovation Act); Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (1986) (codified at 15 U.S.C. §§ 3710a-d); Exec. Order No. 12591, 52 Fed. Reg. 13,414 (Apr. 10, 1987); American Technology Preeminence Act of 1991, Pub. L. No. 102-245, 106 Stat. 7 (1992) (codified in scattered sections of 15 U.S.C.); National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, 110 Stat. 775 (1996) (codified in scattered sections of 15 U.S.C.).

64. See the federal technology transfer policy, which consists of the authority cited *supra* note 63.

significant research in its NIH,<sup>65</sup> FDA,<sup>66</sup> and other laboratories. Keeping federal taxpayer dollars removed from hESCR means that we as taxpayers will not have standard entitlement to access inventions in the field of hESCR unless that access is acquired through government contracts or other measures.<sup>67</sup>

As a point of comparison, consider the United Kingdom's policy on hESCR. The United Kingdom government has implemented a mandatory licensing approach for all hESCR in conjunction with endorsing hESCR and making government financial support accessible.<sup>68</sup> Consequently, relative to the United States, the U.K. government knows much more about what hESCR is taking place on its soil even if much of that information remains proprietary. Moreover, with government support and a favorable regulatory environment, the United Kingdom has become an attractive professional destination for those engaged in hESCR, and perhaps investors also. This leads to yet additional possible U.S. cost consequences of the Bush policy—consequences that bring us back to basic research. First, science is global, and, if one believes in market forces, then talent and money in the field of hESCR are likely to shift to where there is the greatest opportunity. Second, continued investment of many billions of dollars in basic research on an annual basis is a reflection of public and political support of biomedical research. Many human health applications are particularly attributable to that investment including, at least historically, significant support for curiosity-driven research. Few private investors are attracted to curiosity-driven research, so we can assume that much of that has been driven out of hESCR under the Bush policy.

#### CONCLUDING THOUGHTS

I would like to close by making a “big picture” conclusion about U.S. policy and sentiment regarding hESCR. To do so, I ask you to step back to the announcement in 1998 by Geron Corporation and the University of Wisconsin that they had successfully isolated human embryonic stem cells.<sup>69</sup> This was a threshold event for the field which, subsequently, has

---

65. For information about the NIH's laboratories, see <http://www.nih.gov>.

66. For information about the FDA's laboratories, see <http://www.fda.gov>.

67. The author's understanding, based upon experience practicing in the field, is that the United States has not exercised these licenses in a meaningful manner thus far.

68. Anne McLaren, University of Cambridge, Address at *Guidelines for Human Embryonic Stem Cell Research: A Public Workshop* (Oct. 12, 2004) (explaining the United Kingdom's approach to hESCR). This address was part of a workshop hosted by the National Academy of Sciences. See NAT'L ACAD. OF SCI., *Public Workshop*, *supra* note 13.

69. Press Release, Geron Corp., *First Derivation of Human Embryonic Stem Cells* (Nov.



been advancing in exciting and often unpredictable ways.<sup>70</sup> There certainly is a before and an after in terms of scientific and public debate over hESCR.

Again, this timing was unfortunate from an hESCR policy perspective, for it came while the world was absorbing news of Dolly the sheep and contemplating cloning for human reproduction as a possible reality.<sup>71</sup> Therapeutic and reproductive cloning have been commingled in legislative and public debate since, and that debate has been extensive—in the media and in federal and state legislatures.<sup>72</sup>

In fact, as mentioned earlier,<sup>73</sup> the present state of regulation of AR in the U.S. makes it impossible to provide assurances to quell ongoing concern that advances in hESCR will spill over into human reproduction.<sup>74</sup> When I teach Bioethics: Law and Policy as I did again this semester, as an assignment, I send my students onto the Internet with the instruction to pretend that they are seeking AR services and to bring back a summary of what they find. It is amazing to shock the “MTV generation,” and yet it happens every time. What they find is aggressive commercialism in the most fundamental area of medicine from a humanity and society perspective. Although the United States does have a model compliance program for AR clinics written up by the Centers for Disease Control and Prevention (CDC) over a decade ago, no states have adopted it. The United States depends on a contract between CDC and SART—the professional society that oversees assisted reproduction—and the voluntary information that they generate,<sup>75</sup> as recognized by the President’s Council on Bioethics.<sup>76</sup> Although I am fairly comfortable with reporting by highly responsible institutions such as the Harvard-affiliated Brigham and

---

5, 1998), available at <http://www.geron.com/pressview.asp?id=561&print=yes>; see also John Miller, Comment, *A Call to Legal Arms: Bringing Embryonic Stem Cell Therapies to Market*, 13 ALB. L.J. SCI. & TECH. 555 (2003).

70. See NAT’L ACAD. OF SCI., *Public Workshop*, *supra* note 13.

71. See *supra* notes 22-24.

72. See generally Richard Guerra, Comment, *Therapeutic Cloning As Proper Subject Matter for Patent Eligibility*, 43 IDEA 695 (2003); Duane Nash, *Recommended Response for Human Cloning Patent Applications*, 42 IDEA 279 (2002); Peterson, *supra* note 26; Suzanne H. Rhodes, Comment, *The Difficulty of Regulating Reproductive and Therapeutic Cloning: Can the United States Learn Anything from the Laws of Other Countries?*, 21 PENN. ST. INT’L L. REV. 341 (2003); David M. Smolin, *Should a Ban on Reproductive Cloning Include a Ban on Cloning for Purposes of Research or Therapy?*, 32 CUMB. L. REV. 487 (2002).

73. See *supra* notes 5-8 and accompanying text.

74. See generally Malinowski, *supra* note 3.

75. See *supra* note 7 and accompanying text.

76. See PRESIDENT’S COUNCIL, REPRODUCTION AND RESPONSIBILITY, *supra* note 3, at 54-63.

Women's Hospital and Boston's Children's Hospital, these institutions are not necessarily representative of the hundreds of for-profit clinics across the country providing the majority of AR services.

So, at the end of the day, I believe that U.S. policy on hESCR is as entangled with Dolly and fears about human cloning in reproduction as therapeutic and reproductive cloning have been coupled in legislative and public debate.<sup>77</sup> I support hESCR passionately, while also recognizing that it is asking a lot of the public simply to trust without having some kind of assurance that the science will not be carried over into human reproduction and misused. Accordingly, in my opinion, debate over hESCR and U.S. law-policy should be shifted in the direction of providing that assurance.

---

77. See *supra* note 72 and accompanying text.