

## **Beyond the Low-Hanging Fruit: Stem Cell Research Policy in an Obama Administration**

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It has been widely expected that the installation of the Obama administration and an expanded Democratic majority in both houses of Congress would produce a major shift in federal human embryonic stem cell (hESC) research policy. During the Bush administration, hESC research was among the most controversial of scientific research topics, and the federal government's role in financing hESC research was limited both in scope and scale. Only certain embryonic stem cell "lines" were eligible for federal research support. Federal regulations prohibited the direct or indirect use of federal funds to finance research using other stem cell lines, so that laboratory space or equipment initially purchased with federal funds, for example, could not be used to support research on ineligible stem cell lines. Congressional attempts either to restrict this research further or to significantly expand the scope and scale of federal support were unsuccessful.

In response to this deadlock in Washington, stem cell advocates turned to state political systems—governors, legislatures, and bureaucracies—to continue pursuing their agendas, with varying degrees of success. These efforts have increased the amount of money devoted to hESC research and established infrastructure—laboratory space, training programs, and the like—that was not subject to federal spending restrictions. While both state and private funding have been adversely affected by the recent recession and the sharp decline in the stock market, states and private donors now spend more money than the federal government to support hESC research.

Many observers expected a major break in the Washington gridlock over stem cell research with the new administration. While a break has occurred, its significance is difficult to assess. President Obama has recently fulfilled his campaign promise to overturn executive orders that limited the scope and scale of federal stem cell funding, but he has also left action on other significant stem cell issues to the National Institutes of Health (NIH) and Congress.

This paper examines the current and likely future funding picture for hESC

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research. It outlines the Bush administration's regulatory and funding policies, inventories current state and private funding for stem cell research, and evaluates the factors likely to shape future stem cell funding. My conclusions are cautionary—while it seems likely that a new administration and Congress may well harvest low-hanging legislative fruit that has already passed Congress by substantial margins, the odds of a major shift in federal stem cell policy, at least in the short run, are low. Many ethical and political issues surrounding stem cell research remain controversial; furthermore, major problems with the national economy, health care, wars in Iraq and Afghanistan, and recent problems in the Middle East seem likely to consume much of the political attention and resources available to both President Obama and Congress. The administration has also committed to positions on other reproductive health issues which may complicate political progress on stem cell questions. The recently enacted economic stimulus package dramatically increases federal spending for biomedical research, but a major increase in stem cell funding seems unlikely. What does seem likely, even if state and private funding for stem cell research decline and federal funding increases, is that most serious policymaking around stem cell research will continue at the state level, rather than relocating to Washington.

### I. STEM CELLS—EMBRYONIC AND OTHERS<sup>1</sup>

Stem cell research is a complex scientific and political undertaking in which some aspects are extremely controversial and others are not. In the most general sense, stem cells are undifferentiated “blank” cells that do not have a specific physiological function, but which can, at least in theory, be turned into more specialized cells that perform desired functions. The development of therapies from these cells involves turning them into specialized types of cells that can replace those damaged or destroyed by disease, namely cells that cannot be replaced by natural processes. These specialized cells can then in turn be developed into specialized tissues that can be used in the treatment of disease. If stem cells can be turned into the specialized cells that produce dopamine, for example, they can be used to replace cells that have been damaged by Parkinson's disease.

Stem cell research uses a wide range of these types of cells, and only some of them are controversial. Scientists use a variety of animal stem cells, both embryonic and others, to study disease processes and to experiment with various techniques that may eventually have applications in the treatment of human disease—the techniques that were used to isolate human embryonic stem cells,

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1. For a basic overview of stem cell research science, see INT'L SOC'Y FOR STEM CELL RESEARCH, *STEM CELL FACTS: THE NEXT FRONTIER?* (2008), available at [http://www.isscr.org/public/ISSCR08\\_PubEdBroch.pdf](http://www.isscr.org/public/ISSCR08_PubEdBroch.pdf); and International Society for Stem Cell Research, FAQ, <http://www.isscr.org/public/faq.htm> (last visited Apr. 30, 2009).

for example, were first developed in animal models. Research using animal stem cells of different types is not controversial and has been routinely supported by the NIH.

Research using human stem cells is more politically complex. So-called “adult” stem cells,<sup>2</sup> which are typically irreversibly developed and more specialized in that they can generally only be converted into a limited range of more specialized cells, were initially isolated in the 1950s. These cells have come to be used as part of treatment regimes for some diseases, particularly those that require the replacement of the immune system. Hematopoietic stem cells, for example, which can be isolated from bone marrow, are regularly used to replenish the blood cells that are destroyed by treatments for leukemia and other forms of cancer. Research using these types of stem cells, which occur naturally in the body and can be isolated without any adverse effects, is not particularly controversial and is regularly funded by NIH and other organizations that support biomedical research.

By contrast, research using human embryonic stem cells has been extremely controversial. These cells, which were isolated in the late 1990s, form during the development of a fertilized human embryo and are extracted in the first few days of the embryo’s growth. These cells are, at least in theory, capable of being turned into all of the body’s specialized cell types and thus are potentially usable to treat a broader range of diseases than more specialized (less flexible) adult stem cells. The controversy surrounding research using these cells arises from the fact that the extraction of the stem cells destroys the embryo, which many critics find ethically unacceptable.<sup>3</sup>

Several recent scientific developments may allow the creation of stem cell lines without the destruction of embryos.<sup>4</sup> Most visibly, several groups have developed “induced pluripotent stem cells” (iPSCs) by using genetic manipulation to turn a skin cell into cells that closely resemble embryonic stem cells.<sup>5</sup> This ability to reverse the development of an existing cell and turn it into a

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2. The term “adult” is confusing, since these cells do not necessarily come from chronological adults. Some varieties of “adult” stem cells, in fact, can be isolated from the blood in the umbilical cords of new born infants or the pulp under baby teeth. The use of the term “adult” comes from the fact that these stem cells are found in tissue that has already developed.

3. *But see* PRESIDENT’S COUNCIL ON BIOETHICS, ALTERNATIVE SOURCES OF HUMAN PLURIPOTENT STEM CELLS 24 (2005), available at [http://www.bioethics.gov/reports/white\\_paper/alternative\\_sources\\_white\\_paper.pdf](http://www.bioethics.gov/reports/white_paper/alternative_sources_white_paper.pdf) (discussing techniques for removing cells from “live” embryos in a process similar to pre-implantation genetic diagnosis).

4. See Rajesh Rao, *Alternatives to Embryonic Stem Cells and Cloning: A Brief Scientific Overview*, 9 YALE J. HEALTH POL’Y L. & ETHICS 603 (2009).

5. M. William Lensch, *Breakthroughs in Stem Cell Biology: Human iPSC Cells*, STEM CELL BRIEFINGS (Int’l Soc’y for Stem Cell Research, Deerfield, Ill.), Feb. 27, 2008, <http://www.isscr.org/public/briefings/breakthrough.html>. For a more detailed explanation, see

stem cell, which may then be turned into an entirely different type of cell, has become politically controversial. Detractors of hESC research have argued that the availability of this and other alternative techniques to produce stem cell lines lessens or eliminates the need to support research using hESCs. Many scientists argue such a conclusion is premature, noting that iPSCs have not been demonstrated to be acceptable substitutes for hESCs, which will remain the “gold standard” for stem cell research for some time to come.<sup>6</sup>

## II. FEDERAL REGULATION AND FUNDING

In spite of considerable public attention to stem cell-related issues over the last fifteen years, there is little consensus about the appropriate scope and financing for hESC research.<sup>7</sup> Debate in Washington has generally not addressed the permissibility or legality of embryonic stem cell research, but it has rather focused on the narrower question of which stem cell “lines” should be eligible to receive federal financial support through the NIH and other federal agencies.<sup>8</sup> The Bush administration, together with some (though not all) religious and pro-life groups, argued consistently that human embryos have the same moral status as human life and that research destroying embryos should be restricted, if not entirely prohibited. Many Democrats, together with disease advocacy groups and some pro-life Republicans, have disputed this characterization of the moral status of the embryo and have argued that hESC research presents considerable potential for treating a wide range of diseases.

The use of federal funds to create, destroy, or harm embryos for research purposes has been routinely prohibited in appropriations bills since the mid-1990s through the so-called Dickey-Wicker Amendment.<sup>9</sup> Subsequent debate, however, has relied on arguments that this prohibition does not extend to

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Gretchen Vogel, *Breakthrough of the Year: Reprogramming Cells*, 322 SCIENCE 1766 (2008).

6. For a recent example of these competing positions, see Rob Stein, *Researchers Find Safer Way To Produce Stem Cell Alternative*, WASH. POST, Mar. 2, 2009, at A5.

7. For a history of federal policy in this area, see PRESIDENT’S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 21-52 (2004), available at [http://www.bioethics.gov/reports/stemcell/pcbe\\_final\\_version\\_monitoring\\_stem\\_cell\\_research.pdf](http://www.bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf).

8. See e.g., Ceci Connolly, *2 GOP Senators Defend Bush on Stem Cell Research*, WASH. POST, Aug. 13, 2004, at A2; Rick Weiss, *Approved Stem Cells’ Potential Questioned*, WASH. POST, Oct. 29, 2004, at A3; Rick Weiss, *Bill Renews Fight on Stem Cells*, WASH. POST, Feb. 17, 2005, at A6.

9. The original amendment can be found in the Balanced Budget Downpayment Act, Pub. L. No. 104-99 § 128, 110 Stat. 26, 34 (1996) (affecting NIH funding for FY 1996 contained in Pub. L. No. 104-91, 110 Stat. 7 (1996)). For subsequent fiscal years, the rider is found in Title V, General Provisions, of the Labor, HHS and Education appropriations acts. See JUDITH A. JOHNSON & ERIN D. WILLIAMS, CONGRESSIONAL RESEARCH SERV., CRS REPORT FOR CONGRESS: STEM CELL RESEARCH 2 n.7 (2005), available at <http://fpc.state.gov/documents/organization/51131.pdf>.

research on stem cell lines created using other funding sources.<sup>10</sup> The Clinton administration advocated an expansive view of this argument, which would have encouraged researchers to fund the creation of stem cell lines from other sources and then apply for federal funds to continue research on these “pre-existing” lines.<sup>11</sup> The Bush administration, by contrast, largely limited federal funding support to the small number of lines existing before 2001. The more recent development of techniques for devising stem cell lines that do not require the destruction of embryos led to an executive order signed in 2007, which expanded eligibility to stem cell lines developed “without creating a human embryo for research purposes or destroying, discarding or submitting to harm a human embryo or fetus.”<sup>12</sup> The NIH developed elaborate guidance for defining “harm” to an embryo or fetus, but this executive order was revoked by President Obama’s recent order.<sup>13</sup>

The Bush administration also adopted an unusually restrictive policy that prohibited the direct or indirect use of federal funds to support research on ineligible stem cell lines.<sup>14</sup> In order to avoid jeopardizing their federal funds, many universities and other research institutes found it prudent to build separate labs and purchase completely separate equipment to be used in hESC research. These facilities still draw on non-federal sources of funding, allowing research institutes to avoid charges that they are using, for example, lab equipment originally purchased with federal funds to indirectly support research on ineligible stem cell lines.<sup>15</sup>

Despite considerable effort, the federal policymaking process has not been successful in moving hESC research policy in any particular substantive direction. By one count, more than forty separate pieces of legislation have been introduced since 2001 in this general area, ranging from attempts to prohibit or

10. See JOHNSON & WILLIAMS, *supra* note 9; George Q. Daley, *Missed Opportunities in Embryonic Stem-Cell Research*, 351 NEW ENG. J. MED. 627 (2004).

11. See National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000) (guidelines under the Clinton administration).

12. Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007).

13. For details, see NAT’L INSTS. OF HEALTH, PLAN FOR IMPLEMENTATION OF EXECUTIVE ORDER 13435: EXPANDING APPROVED STEM CELL LINES IN ETHICALLY RESPONSIBLE WAYS (2007), available at <http://stemcells.nih.gov/staticresources/policy/eo13435.pdf>. For an explanation of the political context surrounding this executive order, see Rick Weiss, *Future of Stem Cell Tests May Hang on Defining Embryo Harm*, WASH. POST, July 29, 2007, at A8. For the revocation of this order, see Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

14. Roger G. Noll, *The Politics and Economics of Implementing State-Sponsored Embryonic Stem-Cell Research* 20-21 (Stanford Inst. for Econ. Policy Research, Discussion Paper 04-28, 2005), available at <http://www.stanford.edu/group/siepr/cgi-bin/siepr/?q=system/files/shared/pubs/papers/pdf/04-28.pdf>.

15. See, e.g., Claudia Driefus, *At Harvard’s Stem Cell Center, the Barriers Run Deep and Wide*, N.Y. TIMES, Jan. 24, 2006, at F2.

even criminalize all cloning research to efforts to expand the scope and scale of federal support for hESC research.<sup>16</sup> None of these initiatives has become law. Congress twice passed, and President Bush twice vetoed, legislation that would have expanded federal support to cell lines derived from embryos created, but not used, for *in vitro* fertilization.<sup>17</sup> There are large numbers of these unused embryos, most of which will likely be destroyed, currently being stored at fertility clinics. The bills Congress passed would have allowed researchers to use federal funds to develop stem cell lines from these embryos if the individuals who deposited them donated them for research. The Dickey-Wicker Amendment continues to limit federal funding for research that would entail the destruction of embryos;<sup>18</sup> however, current federal law imposes no restrictions on research funded by private or other non-federal funds.

As a result of these funding limits, federal support for hESC research has historically been small. Appendix A displays past and estimated funding levels by the NIH for hESC research and other kinds of stem cell research for the last six fiscal years. Total NIH funding for all kinds of stem cell research has increased over this period by approximately twenty percent, from \$553 million to \$938 million annually. Spending on hESC research, however, amounts to only about nine percent of this total, or slightly less than \$90 million annually. Other forms of stem cell research that are not particularly controversial attract more support and account for the bulk of growth in spending over this period. There are no limits on other stem cell research activities of the sort that have been attached to hESC research. Researchers have developed treatments using other types of human stem cells, and many of the techniques used to isolate or manipulate embryonic stem cells have been developed using animal cells. Direct federal support to date for hESC research has been limited. As Appendix A notes, spending for all forms of stem cell research is relatively small compared to NIH support in such areas as cancer, genetics, biotechnology, and cardiovascular research, and support for hESC research is roughly comparable to NIH spending on Alzheimer's disease, diagnostic radiology, and eye diseases.

### III. STATE ACTIONS AND FUNDING

While decisive federal action around hESC research has proven impossible to date, more than a few states have been able to establish coherent state research policies. As in numerous other areas, advocates frustrated by the deadlock in

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16. FRANCIS FUKUYAMA & FRANCO FURGER, *BEYOND BIOETHICS: A PROPOSAL FOR MODERNIZING THE REGULATION OF HUMAN BIOTECHNOLOGIES* 129 (2007).

17. *See* Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong. (2006); Stem Cell Research Enhancement Act of 2007, S. 5, 110th Cong. (2007).

18. Sheryl Gay Stolberg, *New Stem Cell Policy To Leave Thorniest Issue to Congress*, N.Y. TIMES, Mar. 9, 2009, at A1.

Washington have been able to move their agendas forward at the state level. While policymakers in many states have avoided becoming involved in the complex and controversial issues surrounding hESC research, others have been able to construct majorities around particular approaches to this research. Like the legislation proposed but not enacted at the federal level, the legislation actually enacted by states has been extremely diverse in scope and intent. These state laws range again from legislation to prohibit and even criminalize hESC research to active encouragement of hESC research inside state borders and authorization of considerable amounts of state funds to support it.<sup>19</sup> At the time of this writing, five states ban or restrict hESC research,<sup>20</sup> while as many as ten have supported it in some form.<sup>21</sup>

State financial support for stem cell research is particularly significant because few states have any experience with supporting biomedical research on a large scale. While some states have supported various kinds of targeted research initiatives at state universities to encourage other types of technology, almost no states have experience with operating competitive, peer-reviewed research programs in medicine or genetic research. Funding from the NIH and other federal agencies has been ubiquitous in biomedical research, so states have not previously felt compelled to support research in these areas.

In spite of this limited experience, several states have approved, and more have proposed, substantial spending from state sources to support stem cell research. A summary of state activity to date is presented in Appendix B. There is no authoritative source of comparable data on state spending on stem cell research, and it is frequently difficult to use publicly available information to

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19. For an excellent recent review of state activities, see generally Aaron D. Levine, *Policy Considerations for States Supporting Stem Cell Research: Evidence from a Survey of Stem Cell Scientists*, 68 PUB. ADMIN. REV. 681 (2008). Current and pending state legislation on these issues can be tracked at National Conference of State Legislatures, Stem Cell Research, <http://www.ncsl.org/programs/health/genetics/embfet.htm> (last visited Apr. 30, 2009).

20. These states are Arkansas, Indiana, Louisiana, North Dakota and South Dakota. See Dahleen Glanton, *A Stem Cell Battle Along State Lines*, L.A. TIMES, Mar. 13, 2009, at A21, available at <http://www.latimes.com/news/nationworld/nation/la-na-stemcells-states13-2009mar13,0,773884.story>; see also National Conference of State Legislatures, *supra* note 19 (listing states' restrictions on research with embryos and fetuses). Other states have begun considering enacting legislation in the wake of Executive Order 13,505. See Shaila Dewan, *After Change in Federal Policy, Some States Take Steps To Limit Stem Cell Research*, N.Y. TIMES, Mar. 13, 2009, at A9, available at <http://www.nytimes.com/2009/03/14/us/politics/14stem.html>.

21. These states are California, Connecticut, Illinois, Maryland, Massachusetts, Minnesota, New Jersey, New York, Ohio, and Wisconsin, as I will discuss here. For a continually updated listing of state activities related to stem cell research, see National Conference of State Legislatures, *supra* note 19 (noting additional support for adult stem cell but not embryonic stem cell research in Indiana and Virginia and activities by Washington that may enable future funding of stem cell research).

apportion various forms of state spending between hESC research and other forms of stem cell research.

By far the largest state initiative to date has been in California. In 2004, California voters approved an initiative to spend \$3 billion, financed by state general obligation bonds, over a period of ten years to support stem cell research. The California Institute for Regenerative Medicine (CIRM), the agency that manages the state's stem cell program, has already allocated over \$600 million in hESC research support, or more than five times what NIH is allocating annually to these activities.<sup>22</sup>

Other state allocations to date have been smaller. Ohio and Minnesota have made "one time" appropriations for adult stem cell research and capital construction, respectively. New Jersey, Illinois, and Connecticut have allocated research grants of varying sizes, and New Jersey has also approved funds for the construction of a stem cell laboratory, although a bond issue to support an ongoing research program was defeated in 2007.<sup>23</sup> Connecticut has approved ongoing support for stem cell research programs from tobacco settlement revenues,<sup>24</sup> and Maryland has made multiple awards supported by general state revenues.<sup>25</sup> Wisconsin has not made separate appropriations of state funds to support hESC research, but the state has been aggressively promoting stem cells as an economic development strategy.<sup>26</sup> University of Wisconsin is a major center for hESC research—the university is one of the places where hESCs were first isolated in the late 1990s—and the state holds important patents in hESC technology. The university also houses the National Stem Cell Bank, established

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22. See California Institute for Regenerative Medicine, Welcome, <http://www.cirm.ca.gov> (last visited Apr. 30, 2009) (detailing the California funding allocation and CIRM approval of more than \$693 million in grants to date).

23. For a description of the bond issue's defeat, see Richard G. Jones & Kareem Fahim, *Bid for Stem Cell Financing Was Late and Lukewarm, Organizers Concede*, N.Y. TIMES, Nov. 9, 2007, at B1, available at <http://www.nytimes.com/2007/11/09/nyregion/09abortion.html>.

24. The enabling legislation (Connecticut Public Act 05-149; Senate Bill 934) appropriated \$20 million from state general funds to support the first two years of research grants and also authorized the transfer of \$10 million annually from the state Tobacco Settlement Fund to the state's Stem Cell Research Fund for the next eight years (fiscal years 2008 to 2015). See 2005 Conn. Legis. Serv. No. 05-149 (West) (codified as amended at CONN. GEN. STAT. ANN. §§ 19a-32d to -32g (West 2006)); Connecticut Department of Public Health, Stem Cell Research Program – About CT's Program, <http://www.ct.gov/dph/cwp/view.asp?a=3142&Q=389690> (last visited Apr. 30, 2009).

25. For details on funding and financial resources for the Maryland program, see Maryland Stem Cell Research Fund, About Us, <http://www.mscref.org/content/aboutus/index.cfm> (last visited Apr. 30, 2009).

26. For a brief description of these efforts, see Press Release, Office of the Governor, Governor Doyle Announces \$1 Million for Stem Cell Start-Up Company (Oct. 10, 2006), available at [http://www.wisgov.state.wi.us/journal\\_media\\_detail.asp?prid=2362](http://www.wisgov.state.wi.us/journal_media_detail.asp?prid=2362).

by NIH to maintain and distribute many of the stem cell lines that could be researched using federal funds.<sup>27</sup>

Larger state stem cell programs are in the works. The FY 2008 New York State budget appropriated \$100 million in state funding to establish a stem cell research program, and there are plans for additional funding, although the potential source remains unclear.<sup>28</sup> The state has made two rounds of awards, has issued a strategic plan, and is soliciting applications for other funding. Massachusetts recently passed a \$1 billion life sciences initiative that includes an indeterminate amount for stem cell research.<sup>29</sup> Both states are major centers for hESC research, and there appears to be significant bipartisan political support for ongoing state funding. Both states have also taken care to spread initial spending broadly in terms of geography, thereby maximizing the number of areas and legislative districts with an economic stake in continued funding.

At least some of these state initiatives appear to be sustainable into the Obama administration. California's Proposition 71 authorized the disbursement of \$3 billion in research funds over ten years, and CIRM management has begun to lobby for additional funding sources past this time horizon.<sup>30</sup> Connecticut has earmarked \$100 million in state funds over a decade. Existing programs in New York and Massachusetts also contemplate ongoing funding for stem cell research. Although the New Jersey bond issue to support stem cell research was defeated, the state's governor has discussed plans to support this research by other means, and the state has made small economic development grants to biotech firms interested in stem cell therapies.<sup>31</sup> Maryland, by contrast, relies on annual state appropriations to support stem cell research. While annual appropriations are less reliable than earmarked bond proceeds, strong political support may produce stable funding. Recent budget problems may have reduced the size of programs in some states, but there is no evidence as yet that states are abolishing stem cell programs in response to financial difficulties. There have

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27. President Obama's executive order has now removed many line-based restrictions on federal funding for hESC research. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

28. See EMPIRE STATE STEM CELL BD., STRATEGIC PLAN 14 (2008), available at [http://stemcell.ny.gov/docs/NYSTEM\\_Strategic\\_Plan\\_FINAL.pdf](http://stemcell.ny.gov/docs/NYSTEM_Strategic_Plan_FINAL.pdf).

29. For a description of the Massachusetts initiative, see the website of the Massachusetts Life Sciences Center, the state agency which directs the program. The Massachusetts Life Sciences Center, <http://www.masslifesciences.com/mission.html> (last visited Apr. 30, 2009).

30. These efforts include pursuing funding from the Obama administration's economic stimulus plan and private placement of state bonds. For details, see the ongoing coverage in the California Stem Cell Report blog. California Stem Cell Report, <http://californiastemcellreport.blogspot.com> (last visited Apr. 30, 2009).

31. Alex Philippidis, *Corzine To 'Revisit' Stem-Cell Referendum as Calif. Company Expands to New Jersey*, BIOREGION NEWS, May 5, 2008, <http://www.genomeweb.com/bioregionnews/corzine-%E2%80%98revisit%E2%80%99-stem-cell-referendum-calif-company-expands-new-jersey> (free subscription required for access).

been public complaints about the failure of state programs to yield tangible results and a variety of issues raised about program management, particularly in California, but there have been no serious political challenges as yet to these programs' continued existence.<sup>32</sup>

Several states have begun to shift the form of support they offer away from research-oriented grants to universities and towards support of for-profit companies aimed at product development. California has recently awarded its first substantial grants to private companies<sup>33</sup> and is in the process of developing a loan program targeted at biotechnology companies involved in the development of stem cell therapies.<sup>34</sup> The Massachusetts Life Science Center, whose mandate includes support for stem cell research, has funded no stem cell activities to date beyond a registry of stem cell lines and a stem cell "bank." The Center's only "round" of funding to date, which did not involve any stem cell projects, supported joint projects by universities and private companies. This pattern suggests that further state support for stem cell research, when it comes, may be more "applied" or "translational" in nature rather than aimed at university-based research.<sup>35</sup>

In addition to providing significant financial support for stem cell research not eligible for federal funding, these state initiatives also have established centers of policymaking for stem cell research independent of federal influence. States that have established funding programs for stem cell research have been compelled to develop regulations governing the types of research that will be supported, acceptable sources and payment for stem cell lines to be used in funded research, intellectual property, an acceptable "return" to state governments on their research investment, and a variety of other complex issues. While most states appear to have relied heavily for many of these issues on model guidelines promulgated by the National Academy of Sciences and the International Society for Stem Cell Research,<sup>36</sup> state policies differ substantially.

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32. See, e.g., Thomas Lee, *Stem Cells: Time to Make Good on Promises*, MINNEAPOLIS STAR TRIB., Sept. 28, 2008, at 1D, available at <http://www.startribune.com/business/29828789.html>; Bernadette Tansey, *Obama Policy a Lift for Stem Cell Researchers*, S.F. CHRON., Nov. 29, 2008, at A1, available at <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2008/11/29/MN76147PBR.DTL>.

33. *Business Snags \$5.3 Million from CIRM*, California Stem Cell Report, Dec. 15, 2008, <http://californiastemcellreport.blogspot.com/2008/12/business-snags-53-million-from-cirm.html>.

34. *\$500 Million CIRM Lending Program Up on Wednesday; Details Missing*, California Stem Cell Report, Jan. 18, 2009, <http://californiastemcellreport.blogspot.com/2009/01/500-million-cirm-lending-program-up-on.html>.

35. See Ben Butkus, *Massachusetts LSC Awards \$3.7M to Spur Public-Private R&D Partnerships*, BIOTECH TRANSFER WEEK, Dec. 31, 2008, <http://www.genomeweb.com/biotechtransferweek/massachusetts-lsc-awards-37m-spur-public-private-rd-partnerships>.

36. The National Academy guidelines are contained in COMM. ON GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH, GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH (2005), available at <http://www.nap.edu/openbook.php?isbn=0309096537>, with amendments

Some states restrict eligibility for funding to universities and other nonprofit research institutes, for example, while others contemplate grants to for-profit companies or consortia of companies and universities. Some state regulations prohibit the use of state funds to pay donors of eggs that will be used in developing stem cell lines; others require only assurances that the donation of eggs has been voluntary. While the potential for conflict between the policies of different states may complicate attempts for researchers to collaborate across state lines, several states have established a consortium (the Interstate Alliance on Stem Cell Research) to identify and ameliorate such conflicts.<sup>37</sup> The existence of state laws and regulations (or, in the case of California, covenants with bondholders) governing the expenditure of state funds for stem cell research may complicate any federal efforts to expand regulation of this research beyond those projects supported with federal funds.

A second reason for expecting state stem cell programs to persist is that they appear to have been effective tools for state economic development. Levine's recent work suggests that state funding and permissive state policies that place few limits on stem cell research have been effective in creating awareness among stem cell scientists of differences among states, causing permissive states to be seen as more attractive research environments.<sup>38</sup> Some states have been aggressively recruiting scientists from other states, which may continue to generate demands for support from medical schools and other institutions fearful of losing productive researchers.

#### IV. PRIVATE PHILANTHROPY AND STEM CELL RESEARCH

A second major source of funding for hESC research and other forms of stem cell research has been private philanthropy. While private support, even on a large scale, to support biomedical research is nothing new, private support for stem cell research in general, and hESC research in particular, has been unusual in two ways: it is large relative to the scale of the research enterprise and the level of federal support, and it has been used for a broader array of activities than has been typical.

While a comprehensive accounting of private contributions to stem cell research is impossible, a listing of some recent large, visible gifts is provided in Appendix C. This list is incomplete. Many national foundations which finance

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issued in 2007 and 2008. The International Society for Stem Cell Research guidelines are contained in INT'L SOC'Y FOR STEM CELL RESEARCH, GUIDELINES FOR THE CONDUCT OF HUMAN EMBRYONIC STEM CELL RESEARCH (2006), available at <http://www.isscr.org/guidelines/ISSCRhESCguidelines2006.pdf>.

37. For details, see the Alliance's website at Interstate Alliance on Stem Cell Research, Welcome, <http://www.iascr.org/> (last visited Apr. 30, 2009).

38. Levine, *supra* note 19.

research into particular diseases, such as the Juvenile Diabetes Research Foundation, the Michael J. Fox Foundation for Parkinson's Research, and the Leukemia and Lymphoma Society, fund stem cell research projects; other foundations and donors may also fund stem cell projects at individual institutions. The overall size of these donations is difficult to identify, although a *Wall Street Journal* article has claimed that private funding constitutes the primary source of support for hESC research.<sup>39</sup> This list also excludes investment by private companies and venture capital funds for stem cell-related projects. One published estimate places venture capital investment in stem cell companies of all types at \$1.1 billion between 1995 and 2007, a modest amount by venture capital standards.<sup>40</sup> This investment is almost certainly focused on products developed from adult stem cells, which have not been as controversial as embryonic stem cells. More recent anecdotal reports suggest that venture capital investment in adult stem cell companies may have accelerated as more products are developed, although many of these products are at the pre-clinical trial stage.<sup>41</sup>

While this list is incomplete, it reports gifts totaling some \$2.7 billion, a large amount given the current scale of federal funding and the overall size of the stem cell research enterprise. Itemizing the activities that these funds are intended to support, separating support for hESC research from other stem cell research funding, or identifying the time period over which these funds are to be spent is impossible with any degree of precision. It seems reasonable, however, to infer that much of this funding, particularly to institutions in California, Massachusetts, New York, and Maryland that are already major centers of hESC research, goes to support hESC research in various ways. Contributions to establish stem cell research centers at particular universities are common, which may mean that these funds support the acquisition of lab space and equipment, salaries for key center personnel, and other "overhead" or "start-up" functions as well as activities more directly related to biomedical research. The Harvard Stem Cell Institute, for example, has developed several hESC "lines" that are available to other researchers in addition to supporting its own research program.<sup>42</sup> The

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39. Robert J. Hughes, *Stem Cell Funding's Private Side*, WALL ST. J., July 28, 2006, at W2.

40. Lee, *supra* note 32 (citing an estimate by MoneyTree, Inc.).

41. See, e.g., Chuck Soder, *Stem Cell Progress Aiding Firms' Product Commercialization Plans*, CRAINS CLEVELAND BUS., Jan. 5, 2009, at 1; John Sterling, *Toucan Capital Holds Largest Portfolio of Stem Cell and Regenerative Medicine Companies*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS, Jan. 23, 2009, <http://www.genengnews.com/news/bnitem.aspx?name=48528449>. For examples of products that have been through initial clinical trials, see Amy Coombs, *Stem Cells for the Heart, a New Wave of Clinical Trials*, NATURE REP. STEM CELLS, Apr. 10, 2008, <http://www.nature.com/stemcells/2008/0804/080410/full/stemcells.2008.55.html>.

42. See *Approval Granted for Harvard Stem Cell Institute Researchers To Attempt Creation of Disease-Specific Embryonic Stem Cell Lines*, HARV. U. GAZETTE, June 6, 2006,

largest gifts in this Appendix, however, are donations of stock to the Stowers Research Institute in Missouri that cannot be allocated easily to any particular activity.<sup>43</sup>

One novel trend, at least in California, is the use of private money to directly support the activities of government agencies. CIRM management actively solicited donations amounting to some \$18 million from private parties to pay the organization's initial operating expenses, and the agency will occupy office space in downtown San Francisco rent- and utility-free for a decade as a result of private contributions.<sup>44</sup> Private donors also supported CIRM's research program through the purchase of low interest Bond Anticipation Notes,<sup>45</sup> which were repaid once the bond issue authorized by Proposition 71 was sold. A similar use of private placements has been suggested as a possible means of coping with the state of California's suspension of bond issues to address extremely severe budget problems.<sup>46</sup> The Massachusetts proposal for state support of stem cell research also includes \$250 million in private matching funds to be used in conjunction with state funding.<sup>47</sup>

The sustainability of private donations at this level to support stem cell research in general and hESC research in particular is unclear. Many disease foundations support stem cell research, including hESC research, as part of their

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<http://www.hno.harvard.edu/gazette/daily/2006/06/06-stemcell.html>.

43. The Stowers situation is complicated. As described in Institute publications, "far more" of the Institute's research program to date has involved adult and germ-line stem cells than embryonic stem cells. Institute management has attempted to expand its embryonic stem cell research program, but persistent attempts by the Missouri legislature to restrict or criminalize this research has made it difficult to attract researchers to the Institute's Kansas City campus. In response to the ongoing political debate in Missouri, the Institute has funded embryonic stem cell research underway at Harvard, which is listed in Appendix B, moved significant endowment assets from Missouri to a Delaware-based non-profit organization, and has recently announced it is putting further expansion plans in Missouri on hold until the political environment stabilizes. See William B. Neaves, *Why the Stowers Institute Supports Stem Cell Research*, STOWERS REP., Fall 2006, at 2, 2; Stephanie Simon, *Stem Cell Dissent Roils States*, L.A. TIMES, Aug. 1, 2007, at A12; Rob Roberts, *Stowers Puts Expansion Plans on Hold*, KANSAS CITY BUS. J., Jun. 28, 2007, <http://kansascity.bizjournals.com/kansascity/stories/2007/06/25/daily37.html>.

44. David Hamilton, *Donors Sustain Stem Cell Effort in California Amid Funding Battle*, WALL ST. J., Aug. 16, 2006, at A1.

45. See Karen Gullo & Rob Waters, *California's \$3 Bln Stem Cell Bonds Approved by Judge*, BLOOMBERG.COM, Apr. 21, 2006, <http://www.bloomberg.com/apps/news?pid=10000103&sid=aF7GZ7xaVaoY&refer=us>.

46. For details, see Ron Leuty, *State's Budget Crisis Could Strain Stem Cell Research Efforts*, SILICON VALLEY/SAN JOSE BUS. J., Dec. 19, 2008, [http://sanjose.bizjournals.com/sanjose/stories/2008/12/22/story7.html?jst=pn\\_pn\\_lk](http://sanjose.bizjournals.com/sanjose/stories/2008/12/22/story7.html?jst=pn_pn_lk).

47. Commonwealth of Massachusetts, *Massachusetts Life Sciences Initiative Strategy*, [http://www.mass.gov/Agov3/docs/mass\\_life\\_sciences\\_strategy.rtf](http://www.mass.gov/Agov3/docs/mass_life_sciences_strategy.rtf) (last visited Apr. 30, 2009).

ongoing research funding activities, and total hESC research funding from this source may well exceed funding by the federal government. While disease foundations typically do not report funding amounts for stem cell or any other particular line of research in their annual reports or financial statements, the Juvenile Diabetes Research Foundation, one of the larger disease foundations, by itself spent approximately \$4.9 million in FY 2008 on hESC research.<sup>48</sup> Even if support from other individual disease foundations is smaller, it would not be difficult for total foundation support to exceed federal funding. As noted in Appendix C, several universities have also established large fundraising campaigns to support hESC and other stem cell research, which may be successful to some degree in establishing a stable flow of funds for individual campuses. In addition, the recent decline in the stock market may have significantly reduced the net worth of many foundations and lessened their ability to continue to support research at this level. While there may be fewer large grants to establish new research programs or build labs independent of the current NIH funding restrictions, there may be enough ongoing support for foundations and other private donors to continue to outspend NIH on hESC research.

While a conclusive accounting appears impossible, the available evidence strongly suggests that both state governments and private foundations are outspending the federal government in the support of hESC research and have become major policymakers around stem cell research. California has been particularly active in this regard: the state is currently the largest supporter of hESC research in the world and has been actively seeking collaborative relationships with funding agencies in other countries. Because the federal government has limited its support of stem cell research, it has exercised significantly less influence in stem cell research policy than in other scientific areas. Some observers have suggested that this regulatory picture may change with the Obama administration and a new Congress. I now turn to an examination of the likely future of hESC research policy and funding.

#### V. OBAMA'S EXECUTIVE ORDER AND THE OUTLOOK FOR STEM CELL FUNDING

Some observers expected this picture to change dramatically with a new administration and a new Congress.<sup>49</sup> The picture has clearly changed, but it is

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48. Juvenile Diabetes Research Foundation, Stem Cell Facts, [http://advocacy.jdrf.org/files/General\\_Files/Advocacy/2009/Stem\\_Cell\\_Therapies.pdf](http://advocacy.jdrf.org/files/General_Files/Advocacy/2009/Stem_Cell_Therapies.pdf) (last visited Apr. 30, 2009); see also Hughes, *supra* note 39.

49. See, e.g., Carl Hulse, *Democrats Weigh Methods To End Stem Cell Ban*, N.Y. TIMES, Jan. 3, 2009, at A11; Gautam Naik & Robert Lee Hotz, *Obama's Promise on Stem Cells Doesn't Ensure New War on Disease*, WALL ST. J., Nov. 25, 2008, at A9, available at <http://online.wsj.com/article/SB122757360662054989.html>.

still uncertain how dramatic the change will prove to be. After some pressure from advocates, President Obama recently signed an executive order that repealed the Bush administration's restrictions on the stem cell lines that federal funding can be used to support, eliminated the requirement that federally supported research be segregated from that on ineligible lines, and revoked Bush's recent executive order allowing federal support for research only on lines created by means that did not destroy or harm an embryo.<sup>50</sup> The order was, however, narrowly drawn and articulated no particular standards to govern the origins of lines that would qualify for federal funds. The only standard referenced in the order is "to the extent permitted by law." To fill this gap, the NIH were directed to issue "guidance on such research" within 120 days.<sup>51</sup> The President has not called for the abolition of the Dickey-Wicker amendment, and his chief domestic policy advisor has been quoted to the effect that the administration will have no position on the issue.<sup>52</sup> In similar fashion, the administration has not called explicitly for an expansion of funding for embryonic stem cell research and has not endorsed more controversial means of producing embryonic stem cells such as somatic cell nuclear transfer.<sup>53</sup>

This failure on the part of the President to endorse any particular standard for stem cell lines, the transfer of responsibility for promulgating standards to NIH (thus effectively delaying a decision on the administration's stem cell policy), and the staging of the event at which the order was signed provide circumstantial evidence for the prediction that the administration is unlikely to seek more than incremental change in stem cell policy in the short run. The event was announced at a time when it was unlikely to attract major media attention, and the signing of the executive order was coupled with the signing of a presidential memorandum on scientific integrity rather than being the sole subject of the presidential appearance. The President's statement at the signing took some care to acknowledge opposing views on stem cell research and promised "strict guidelines, which we will rigorously enforce" in the conduct of stem cell research.<sup>54</sup>

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50. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

51. For an explanation, see Rob Stein, *Obama's Order on Stem Cells Leaves Key Questions to NIH*, WASH. POST, Mar. 10, 2009, at A1, available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/03/09/AR2009030903156.html>.

52. See Stolberg, *supra* note 18.

53. Somatic cell nuclear transfer is a technique in which the nucleus of a fertilized egg is replaced with the nucleus of a somatic cell from a potential patient and then allowed to develop to the point where stem cells can be collected. It has the potential virtue of producing cells and tissues that are compatible with the patient's body and will not be attacked by the patient's immune system. For details, see Richard Mollard, *Somatic Cell Nuclear Transfer (SCNT) or Therapeutic Cloning*, International Society for Stem Cell Research, [http://www.isscr.org/public/therapeutic\\_cloning.pdf](http://www.isscr.org/public/therapeutic_cloning.pdf) (last visited Apr. 30, 2009).

54. *Transcript: Obama's Remarks on Stem Cell Research*, N.Y. TIMES, Mar. 9, 2009,

These circumstances suggest that the administration policy and the NIH guidelines, when they appear, are likely to focus on incremental modifications to existing policy. Perhaps the most obvious candidate for such changes would involve standards proposed in bills which Congress has already passed twice which expand the number of stem cell lines eligible for federal financial support.<sup>55</sup> These standards would expand eligible lines to include cells derived from embryos initially created but no longer needed for reproductive purposes, which would otherwise have been destroyed; these embryos will need to have been donated under appropriate standards for informed consent.

While the elimination of the Bush administration's restrictions and expansion of eligible lines along the lines Congress has already approved are not trivial, these changes will not directly expand federal support for stem cell research of any sort or significantly expand the heretofore limited federal role in the governance of this research. It is uncertain, however, whether the administration and its congressional allies will seek more than incremental changes in stem cell funding or substantial legislative changes that would significantly alter the existing decentralized stem cell governance structure. It might be argued that there are substantial reasons for the Obama administration, and for stem cell allies more generally, not to push for more serious changes in federal stem cell policy in the short run.

Perhaps the most obvious reason for *not* pursuing more dramatic change in stem cell policy is the demand for political capital and attention from other equally or more pressing problems. The Obama administration and new Congress have inherited wars in Iraq and Afghanistan, flare-ups in the Middle East, extremely expensive and divisive ongoing repairs to the country's financial system and overall economy, controversial anti-terrorism policies, and increasing problems with health care coverage and global warming, among other difficulties. Dealing with these issues, which are more or less mandatory items on the national agenda, is likely to prove protracted and controversial, making it possible that a new Congress and President simply will not have the time or energy to address the complex, controversial, but non-crisis issues associated with significantly altering the federal role in stem cell research. An executive order or legislation of the scope described above would address issues that have already been discussed and debated at some length before being passed twice by

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<http://www.nytimes.com/2009/03/09/us/politics/09text-obama.html> (not published in the print edition).

55. See *supra* note 17. As this Article was going to press, NIH issued draft guidelines expanding the number of stem cell lines eligible for federal funding along the lines suggested here. After a period of public comment, final guidelines will be issued in the summer of 2009. Draft National Institute of Health Guidelines for Human Stem Cell Research Notice, 74 Fed. Reg. 18,578 (proposed Apr. 23, 2009). For an explanation of the political context, see Ceci Connolly, *Compromise Rules Issued on Embryonic Stem Cells*, WASH. POST, Apr. 18, 2009, at A4.

Congress. While likely to attract strenuous protest from stem cell detractors, this particular set of changes already has a pre-existing majority that has determined that supporting it is in its political interest. Other changes have not received this level of prior attention from the political process and may well be more controversial and harder to resolve, raising the real possibility that a stem cell reform bill could become gridlocked in Congress.

Several other factors contribute to the likelihood of congressional gridlock around stem cell research. One is that a number of important issues around this research remain politically controversial, and a congressional majority in favor of reform cannot be assumed. The last two congressional elections have produced significant Democratic majorities in both the House and the Senate, but many Democratic gains have been in districts and states traditionally held by Republicans, which means that the Democrats newly occupying these seats may have to worry about electorates who are more dubious about the benefits of stem cell research than those from traditionally Democratic areas. The Dickey-Wicker amendment has been attached to every Department of Health and Human Services appropriations bill since 1996,<sup>56</sup> but there has been little serious discussion of this restriction and no serious attempt to abolish it. There is no ready-made majority for eliminating this restriction, as there may be for expanding the number of stem cell lines eligible for federal funding.

Beyond debate over funding research involving the destruction of embryos, controversy exists over the question of payment for eggs. Infertile couples are currently allowed to offer payment for others' eggs for use in reproductive therapies, but payment for eggs for *research* purposes is currently illegal in most states (although payment for expenses and lost wages is sometimes permissible).<sup>57</sup> Researchers and advocates have increasingly complained that the lack of embryos from which to extract stem cells constitutes a major barrier to research progress and that efforts to solicit donations of eggs have largely proved unsuccessful. Legislative efforts to allow the use of federal funds to pay egg donors, however, are likely to prove quite controversial with at least some groups. Interested parties particularly include women's health advocacy groups that support stem cell research, but express strong concern about the risks associated with egg extraction procedures and the vulnerability of lower-income women to offers of significant amounts of cash.<sup>58</sup>

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56. See JOHNSON & WILLIAMS, *supra* note 9, at 2 n.7.

57. For further details and a listing of state restrictions on the purchase or sale of human tissue, see National Conference of State Legislatures, *supra* note 19.

58. See, e.g., *The Implementation of Proposition 71, the Stem Cell Research and Cures Act: Joint Informational Hearing of the S. Subcomm. on Health, S. Subcomm. on Stem Cell Research Oversight, and the Assembly Comm. on Health*, 2005 Leg., 2005-2006 Sess. 74 (Ca. 2005) (statement of Francine Coeytaux, Pro-Choice Alliance for Responsible Research), available at [http://senweb03.senate.ca.gov/committee/standing/health/PROP\\_71\\_OVERSIGHT\\_TRANSCRIP](http://senweb03.senate.ca.gov/committee/standing/health/PROP_71_OVERSIGHT_TRANSCRIP)

Proposals to expand federal control over stem cell research to projects not supported by federal funds are also likely to prove controversial. NIH has no experience with research oversight on the scale required to enforce uniform federal guidelines, and federal rules might well conflict with state laws, regulations, and, in the case of California, covenants with bondholders. Some scientists have supported an expanded NIH role in the oversight of stem cell research while others have argued that the combination of local, state, and federal agency oversight currently in place is sufficient to ensure adequate attention to outstanding scientific, ethical, and legal questions.<sup>59</sup>

Proposals to dump a lot of additional federal money into stem cell research may be similarly divisive. While the recently enacted economic stimulus package contains increased funding for NIH as a whole, it seems unlikely that this increase will produce anything more than incremental funding for stem cell research, particularly hESC research. Opposition will come from the same groups that have opposed this research all along and will likely even come from elsewhere in the scientific community. After doubling between 1999 and 2003,<sup>60</sup> NIH's overall budget has remained flat and even declined in real terms in recent years.<sup>61</sup> As a result of these financial pressures, overall grant success rates have fallen from thirty percent to less than twenty percent, and as low as ten percent in some fields.<sup>62</sup> Scientists who are having trouble supporting their own research are likely to protest vehemently if their stem cell colleagues, who already receive money from states and private foundations, now get additional support from NIH as well. Funding for stem cell research in general, or hESC research in particular, does not have a separate budgetary identity inside NIH, but is scattered across the separate budgets of the NIH's component institutes that fund research on a range of different diseases. NIH officials in some of these institutes may find it more sensible to steer new funding away from stem cell research to other research areas that do not have substantial state or private foundation support. The odds of

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T.doc; Judy Norsigian, *Egg Donation for IVF and Stem Cell Research: Time To Weigh the Risks to Women's Health*, DIFFERENT TAKES, Spring 2005, at 1, available at <http://www.sc.edu/healthycarolina/pdf/risksofeggdonation.pdf> (statement by the Executive Director of Our Bodies Ourselves);

59. See Michael Warner & Hans Smith, *Oversight from Bench to Bedside*, SCI. PROGRESS, Aug. 25, 2008, <http://www.scienceprogress.org/2008/08/oversight-from-bench-to-bedside>.

60. National Institutes of Health, *The NIH Almanac – Appropriations*, <http://www.nih.gov/about/almanac/appropriations/part2.htm> (last visited Apr. 30, 2009).

61. *Id.* (showing that from 2003-2007 the NIH budget increased \$196 million, while keeping pace with inflation would have required an increase of \$221 million).

62. For reviews of NIH's recent funding problems, see David Korn et al., *The NIH Budget in the "Postdoubling" Era*, 296 SCIENCE 1401 (2002); Joseph Loscalzo, *The NIH Budget and the Future of Biomedical Research*, 354 NEW ENG. J. MED. 1665 (2006); David G. Nathan & Alan N. Schechter, *NIH Support for Basic and Clinical Research: Biomedical Researcher Angst in 2006*, 295 JAMA 2656 (2006).

a lot of additional federal money being devoted to stem cell research seem low. Even if NIH is able to expand support for stem cell research incrementally, it will only be one payer among many, and not even the largest one.

A final factor complicating the prospects for non-incremental changes in federal stem cell policy is continued scientific uncertainty around important questions. One is the availability of alternative procedures, such as the production of induced pluripotent stem cells (iPSCs) for producing embryonic stem cell lines that do not require the destruction of embryos. The existence of alternatives to hESCs would make stem cell research much less controversial, but as discussed earlier in this Article, most stem cell scientists appear unconvinced that iPSCs are reliable substitutes.<sup>63</sup> While studies comparing the two are underway in several places, it seems unlikely that the political controversy around hESCs will be resolved anytime soon, particularly if iPSCs prove to be less than optimal replacements for hESCs.

Another scientific uncertainty with political consequences is the outcome of the first clinical trial of a product derived from hESCs. Almost immediately after President Obama's inauguration, the Food and Drug Administration approved an application from Geron, a California company, to begin a Phase I clinical trial of a hESC-based therapy for severe spinal cord injuries.<sup>64</sup> Phase I trials are only intended to gauge treatment safety, and the Geron trial will only include eight to ten patients, but it might be expected that both stem cell detractors and supporters will attempt to use the results of this trial as ammunition to support their respective positions. In short, there are both political and scientific reasons to expect incremental, rather than far-reaching, changes in federal stem cell policy and funding over the short term.

Even if stem cell supporters are successful in expanding federal hESC funding, it seems unlikely that states will diminish their funding efforts. As noted above, many states have legally obligated funds with an extended time horizon, over which it may be difficult to divert funds from their intended uses. If the NIH funding picture remains tight, scientists and universities in some states may push to institutionalize or expand state stem cell programs as an alternative source of research funding. A second factor that is likely to encourage states to persist is competition both among states and between states and several foreign countries that have begun stem cell initiatives of their own. States see themselves, at least rhetorically, as competing with one another for jobs, tax revenue, economic development, and in the case of hESC research, research talent and prestige. After the passage of Proposition 71 in California, much of the public rhetoric in support of state funding for hESC research has focused on the need for states to

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63. See, e.g., Hulse, *supra* note 49.

64. See Andrew Pollack, *F.D.A. Approves a Stem Cell Trial*, N.Y. TIMES, Jan. 23, 2009, at B1, available at <http://www.nytimes.com/2009/01/23/business/23stem.html>.

remain “competitive” and to attract or retain scientific talent and prestige.<sup>65</sup>

There is evidence that state efforts to make themselves more attractive to stem cell researchers through permissive rules and funding have been successful.<sup>66</sup> A recent report from the California Institute for Regenerative Medicine, the state agency that manages the state’s stem cell initiative, claims that at least forty-five senior scientists have relocated to California from elsewhere,<sup>67</sup> and there is some systematic evidence that stem cell researchers have recently received more job offers than other types of scientists.<sup>68</sup> The Republic of Singapore, among other countries, has also mounted a highly publicized stem cell program of its own, which has recruited American and other scientists with subsidized lab space, ready access to stem cell lines, and other inducements.<sup>69</sup> While it is easy to overstate the effectiveness of such efforts, it seems clear that many state politicians have found concerns over “brain drains” to California or other more congenial locations to be effective arguments in pressing for state support for hESC and other forms of stem cell research.

#### CONCLUSION

What seems most likely, in short, is that the immediate future will be like the recent past, with the federal government being a relatively minor player and states and private funders continuing to carry the major funding and policy development burdens. hESC research will continue to be heavily supported in some states and illegal in some others, with states weighing in with hESC research funding programs of widely varying sizes. Competition among states is good for hESC research supporters—more governors and gubernatorial candidates may find it in their political interest to support state financing for this research if they can claim that state support will keep their state from “falling behind.” While state financial problems may handicap state efforts to initiate or expand stem cell programs, the evidence to date suggests these programs will continue, albeit on a less well-funded basis. There will be increasingly vocal debates over royalties, product pricing, and other research management issues that will be resolved in a wide range of ways, and conflicts between the rules that apply to collaborating researchers located in different states. This system is less efficient and more administratively difficult than a single funding source and set

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65. For an example of this rhetoric, see Deval L. Patrick & Therese Murray, *The Promise of Biotech*, BOSTON GLOBE, May 9, 2007, at A9.

66. See Levine, *supra* note 19.

67. LAURENCE BAKER & BRUCE DEAL, CIRM – INTERIM ECONOMIC IMPACT REVIEW (2008), [http://www.cirm.ca.gov/pub/pdf/EcoEval\\_091008\\_rpt.pdf](http://www.cirm.ca.gov/pub/pdf/EcoEval_091008_rpt.pdf).

68. Aaron D. Levine, *Research Policy and the Mobility of US Stem Cell Scientists*, 24 NATURE BIOTECHNOLOGY 865 (2006).

69. For an example of the coverage of the Singapore program, see Terri Somers, *Singapore Makes Investment in its Survival*, SAN DIEGO UNION-TRIB., Dec. 18, 2006, at A1.

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of rules would be, but it is an accurate reflection of the conflicting and diverse national public and political views about hESCs, which do not show any sign of going away anytime soon.

**APPENDIX A. ESTIMATES OF NIH FUNDING FOR STEM CELL RESEARCH, FEDERAL FISCAL YEARS 2004 TO 2008, IN MILLIONS<sup>70</sup>**

	FY 2004 Actual	FY 2005 Actual	FY 2006 Actual	FY 2007 Actual*	FY 2008 Estimate
Stem Cell Research Total	\$553	\$609	\$643	\$968	\$938
Human Embryonic	\$24	\$40	\$38	\$74	\$88
Non-Human Embryonic	\$89	\$97	\$110	\$120	\$150
Human Non-Embryonic	\$203	\$199	\$206	\$226	\$297
Non-Human Non- Embryonic	\$236	\$273	\$289	\$400	\$497

\*In FY 2007, NIH restructured its categorization of disease research. These figures are using the new structure, although NIH also released information for FY 2007 using the historical method of categorizing diseases.

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70. National Institutes of Health, Research Portfolio Online Reporting Tool, <http://report.nih.gov/rcdc/categories/Default.aspx> (last visited Apr. 30, 2009) (noting that estimates of funding for FY 2009 and 2010 will be displayed upon transmittal of the President's budget request).

**APPENDIX B. STATE GOVERNMENT SUPPORT FOR STEM CELL RESEARCH, IN MILLIONS**

State	Allocated to Date	Appropriated or Authorized But Not Allocated*
California <sup>71</sup>	\$693	\$3,000
Connecticut <sup>72</sup>	\$30	\$100
Illinois <sup>73</sup>	\$15	--
Maryland <sup>74</sup>	\$38	\$18
Massachusetts <sup>75</sup>	\$20.2	\$980
Minnesota <sup>76</sup>	\$15	--
New Jersey <sup>77</sup>	\$5	\$280

71. California Institute for Regenerative Medicine, *supra* note 22; *Around the Regions: With State Finances Squeezed, California Stem Cell Funding Agency Eyes Contingency Plan*, BIOREGION NEWS, Jan. 5, 2009, <http://www.genomeweb.com/bioregionnews/around-regions> (free subscription required for access).

72. Press Release, Conn. Dep't of Pub. Health, State of Connecticut Prepares to Allocate \$9.8 Million in Stem Cell Research Funds (Apr. 1, 2009) <http://www.ct.gov/dph/cwp/view.asp?Q=437842&A=3659> (noting this is the third installment of grants).

73. Governor Blagojevich announced \$10 million in grants in April 2006 and \$5 million in August 2006. *See* Press Release, Ill. Regenerative Med. Inst., Gov. Blagojevich Announces Recipients of \$5 Million in New State Stem Cell Research Funding (Aug. 17, 2006), [http://www.idph.state.il.us/irmi/news\\_081706.html](http://www.idph.state.il.us/irmi/news_081706.html); Press Release, Ill. Regenerative Med. Inst., Gov. Blagojevich, Comptroller Hynes Announce \$10 million in State Stem Cell Research Grants (Apr. 24, 2006), [http://www.idph.state.il.us/irmi/news\\_042406.html](http://www.idph.state.il.us/irmi/news_042406.html).

74. The Maryland Stem Cell Research Fund had a budget of \$15 million in FY 2007, \$23 million in FY 2008 and \$18 million in FY 2009. *See* Press Release, Md. Stem Cell Research Fund, Maryland Stem Cell Commission Announces that 24 Grant Agreements Have Been Signed (Jan. 22, 2008), *available at* [http://www.mscref.org/\\_media/client/pdf/mscrcommission/publicnotices/stemcellannualreport2007press.pdf](http://www.mscref.org/_media/client/pdf/mscrcommission/publicnotices/stemcellannualreport2007press.pdf); Press Release, Md. Stem Cell Research Fund, Maryland Stem Cell Research Commission Receives 147 Applications for Funding (Jan. 16, 2009), *available at* [http://www.mscref.org/\\_media/client/pdf/MSCRFApplications-AnnualReport-Final.pdf](http://www.mscref.org/_media/client/pdf/MSCRFApplications-AnnualReport-Final.pdf).

75. The Massachusetts Life Sciences Initiative (\$1 billion) is not solely for stem cell research. *See* The Massachusetts Life Sciences Center, *supra* note 29. The Center awarded \$8.2M to the University of Massachusetts for a stem cell bank and \$12M in matching funds. Press Release, Univ. of Mass. Med. Sch., Massachusetts Life Sciences Center Awards \$8.2 Million to UMass Medical School for Stem Cell Bank and International Registry, \$12M for Matching Grants (Oct. 29, 2007), [http://www.umassmed.edu/10\\_26\\_07.aspx](http://www.umassmed.edu/10_26_07.aspx).

76. This was a capital grant by University of Minnesota to Minnesota Stem Cell Institute. University of Minnesota, Stem Cell Institute, About Us, <http://www.stemcell.umn.edu/stemcell/about/home.html> (last visited Apr. 30, 2009).

77. New Jersey authorized \$5 million in one round of research grants in 2005. The

State	Allocated to Date	Appropriated or Authorized But Not Allocated*
New York <sup>78</sup>	\$118.3	--
Ohio <sup>79</sup>	\$27.4	--

\*Dashes in this column indicate that the quantity of non-allocated funds is unknown or zero.

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appropriated/authorized amount includes \$10 million for research grants and \$270 million for stem cell lab construction. State of New Jersey Commission on Science & Technology, Stem Cell Research in New Jersey, <http://www.state.nj.us/scitech/stemcell> (last visited Apr. 30, 2009).

78. New York State Stem Cell Science, Grants and Contracts Awarded, [http://stemcell.ny.gov/research\\_support\\_grants\\_awards.html](http://stemcell.ny.gov/research_support_grants_awards.html) (last visited Apr. 30, 2009). In November of 2008, the Health Department deferred payment of \$9 million in stem cell spending. See Alex Philippidis, NY Gov.'s FY '10 Budget Would Cleave \$5.2B from Life-Science-Related Programs, BIOREGION NEWS, Nov. 17, 2008, <http://www.genomeweb.com/bioregionnews/ny-gov%E2%80%99s-fy%E2%80%9910-budget-cuts-would-cleave-52b-life-science-related-programs> (free subscription required for access).

79. Separate allocations for non-embryonic stem cell research were made in 2003 and 2006 to the Center for Stem Cell & Regenerative Medicine. National Center for Regenerative Medicine, Center for Stem Cell & Regenerative Medicine, <http://www.thestemcellcenter.org> (last visited Apr. 30, 2009).

### APPENDIX C. EXAMPLES OF PRIVATE DONOR RESEARCH SUPPORT FOR STEM CELL RESEARCH

State	Recipient	Donors	Amount Donated (Millions)	Comments
California <sup>80</sup>	California Institute for Regenerative Medicine (CIRM); various universities	Variety of foundations and individual donors	\$955	
California <sup>81</sup>	CIRM	Bond anticipation notes “purchased by foundations and private parties”	\$45	Proceeds used for research grants; repaid from bond proceeds
Maryland <sup>82</sup>	Johns Hopkins University	Michael Bloomberg	\$100	Amount for hESC research is unclear

80. See, e.g., LAURENCE BAKER & BRUCE DEAL, ANALYSIS GROUP, CIRM – INTERIM ECONOMIC IMPACT REVIEW, ADDENDUM 1: ECONOMIC EFFECT OF CIRM FACILITIES AND EQUIPMENT GRANTS ON TAX REVENUES AND JOBS (SEPTEMBER 10, 2008), available at [http://www.cirm.ca.gov/pub/pdf/EcoEval\\_091008\\_Addendum.pdf](http://www.cirm.ca.gov/pub/pdf/EcoEval_091008_Addendum.pdf); Richard C. Paddock, Broads Donate \$25 Million for Stem Cell Research Lab, L.A. TIMES, Dec. 18, 2008, at B3; Terri Somers, *Donations Add Muscle to Bid for Stem Cell Institute Funds*, SAN DIEGO UNION-TRIB., Feb. 29, 2008, at C-1; Richard C. Paddock, *Broads Donate \$25 Million for Stem Cell Research Lab*, L.A. TIMES, Dec. 18, 2008, at B3; Terri Somers, *Stem-Cell Researchers Celebrate \$30 Million Donation*, SAN DIEGO UNION-TRIB., Sept. 16, 2008, <http://www.signonsandiego.com/news/metro/20080916-1858-bn16stems.html>; Oliver Staley, *Stanford Gets \$75 Million for Stem Cells Research from Lokey*, BLOOMBERG.COM, Oct. 6, 2008, <http://www.bloomberg.com/apps/news?pid=20601103&sid=aH.JjGHbrwA4&refer=us>; *UCSF Snags \$25 Million Stem Cell Donation*, California Stem Cell Report, Dec. 18, 2008, <http://californiastemcellreport.blogspot.com/2008/12/ucsf-snags-25-million-stem-cell.html>.

81. BAKER & DEAL, *supra* note 67, at 9.

82. Sonya Geis, *Rich Donors Help Calif. Fund Stem Cell Research*, WASH. POST, Dec. 19, 2006, at A2, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/12/18/AR2006121801080.html> (noting that this donation was “largely for stem cell research”); Winnie Hu, *New York: Bloomberg Donates \$100 Million to University*, N.Y. TIMES, Feb. 3, 2006, at B4.

State	Recipient	Donors	Amount Donated (Millions)	Comments
Maryland <sup>83</sup>	Johns Hopkins University Institute for Cell Engineering	Anonymous donor	\$58.5	
Massachusetts <sup>84</sup>	Harvard Stem Cell Institute	Howard Hughes Medical Institute; Juvenile Diabetes Research Foundation; Harvard; other philanthropists	\$40	\$100 million target <sup>85</sup>
Massachusetts <sup>86</sup>	Funds provided in conjunction with state life sciences initiative	Unspecified	\$250	Unclear if donations already made or contingent on state support
Massachusetts <sup>87</sup>	Two Harvard professors: Kevin Eggan and Chad Cowan	Stowers Medical Institute	\$10	
Missouri <sup>88</sup>	Stowers Medical Institute	James and Virginia Stowers	\$2,000	Unrestricted donation of stock and cash reserve

83. Press Release, Johns Hopkins Univ. Sch. of Med., Hopkins Launches Cell Engineering Institute with \$58.5 M. Gift (Jan. 30, 2001), available at <http://www.hopkinsmedicine.org/press/2001/JANUARY/010130.HTM>.

84. HARVARD STEM CELL INST., CONNECTIVITY: HARVARD STEM CELL INSTITUTE ANNUAL REPORT 32 (2006), available at [http://www.hsci.harvard.edu/files/HSCI\\_Annual\\_Report\\_2006.pdf](http://www.hsci.harvard.edu/files/HSCI_Annual_Report_2006.pdf).

85. *Campaigning for Stem Cells*, NEW ATLANTIS, Spring 2004, at 93, 94; *Harvard Stem Cell Studies Raise Eyebrows*, FOXNEWS.COM, Apr. 12, 2005, <http://www.foxnews.com/story/0,2933,153130,00.html>.

86. Commonwealth of Massachusetts, *supra* note 47, at 2 (projecting "\$250 million in private sector matching funds for capital, research grants, fellowships, and workforce training").

87. See Constance Holden, *States, Foundations Lead the Way After Bush Vetoes Stem Cell Bill*, 313 SCIENCE 420 (2006).

88. Stowers Institute for Medical Research, Fact Sheet, <http://www.stowers-institute.org/MediaCenter/docs/FactSheet.pdf> (last visited Apr. 30, 2009).

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State	Recipient	Donors	Amount Donated (Millions)	Comments
New York <sup>89</sup>	The Rockefeller University; Weill Medical College of Cornell University; Memorial Sloan-Kettering Cancer Center	Starr Foundation	\$50	
New York <sup>90</sup>	Rockefeller University	Harriet Heilbrunn	\$5	
New York <sup>91</sup>	Memorial Sloan-Kettering Cancer Center	Geoffrey Beene, LLC	\$101.9	Total donations including company shares; funds not specifically allocated to stem cell research
New York <sup>92</sup>	Mount Sinai School of Medicine—Black Family Stem Cell Institute	Leon D. Black	\$10	

89. Press Release, Mem'l Sloan-Kettering Cancer Ctr., Stem Cell Research in New York City Receives Pivotal Boost from The Starr Foundation (May 23, 2005), <http://www.mskcc.org/mskcc/html/57616.cfm>.

90. Press Release, Rockefeller Univ., Rockefeller University Establishes Stem Cell Research Center (Aug. 3, 2004), <http://runews.rockefeller.edu/index.php?page=engine&id=42>.

91. Press Release, Mem'l Sloan-Kettering Cancer Ctr., New Geoffrey Beene Gift to Memorial Sloan-Kettering Puts Total Support Over \$100 Million (Oct. 9, 2008), <http://www.mskcc.org/mskcc/html/87852.cfm>.

92. *Mount Sinai School of Medicine Establishes Stem Cell Institute*, MED. NEWS TODAY, May 6, 2005, <http://www.medicalnewstoday.com/articles/23926.php>.

State	Recipient	Donors	Amount Donated (Millions)	Comments
New York <sup>93</sup>	Columbia University Medical Center	Various private philanthropists	\$25	Total \$50 million goal
New York <sup>94</sup>	Weill-Cornell's Ansary Center for Stem Cell Therapeutics	Shahla and Hushang Ansary	\$15	
New York <sup>95</sup>	Post-doctoral research fellows	New York Stem Cell Foundation (supported by Stanley and Fiona Druckenmiller, The Shelley & Donald Rubin Foundation, and an anonymous donor)	\$5	Foundation also established a "safe haven" lab
New York <sup>96</sup>	University of Rochester	Jack Erdle	\$1	

93. Press Release, Columbia Univ. Med. Ctr., Columbia University Medical Center Launches Multi-Year Campaign To Support Stem Cell Research (June 15, 2005), [http://www.cumc.columbia.edu/news/press\\_releases/stem\\_cell\\_initiative.html](http://www.cumc.columbia.edu/news/press_releases/stem_cell_initiative.html).

94. Robert Kolker, *The California Stem-Cell Gold Rush*, N.Y. MAG., Dec. 27, 2004, available at <http://nymag.com/nymetro/health/features/10755/index3.html>.

95. Press Release, New York Stem Cell Found., The New York Stem Cell Foundation Commits More than \$5 Million in Fellowships for New York Scientists Engaged in Human Embryonic Stem Cell Research (June 28, 2007), available at [http://www.nyscf.org/images/pdf/pr\\_fellowship\\_07\\_28\\_07.pdf](http://www.nyscf.org/images/pdf/pr_fellowship_07_28_07.pdf); see also The New York Stem Cell Foundation, Fellowships & Grants, [http://www.nyscf.org/fellowshipsgrants/fellowships\\_grants.html](http://www.nyscf.org/fellowshipsgrants/fellowships_grants.html) (last visited Apr. 30, 2009).

96. Press Release, Univ. of Rochester Med. Ctr., Medical Center Receives Gift for Stem Cell Research (Aug. 10, 2006), <http://www.urmc.rochester.edu/PR/news/story.cfm?id=1201>.

## STEM CELL RESEARCH POLICY IN AN OBAMA ADMINISTRATION

State	Recipient	Donors	Amount Donated (Millions)	Comments
New York <sup>97</sup>	Albert Einstein College of Medicine Yeshiva University	Ruth and David Gottesman	\$15	
Texas <sup>98</sup>	University of Texas Health Sciences Center at Houston	Anonymous patient	\$25	
Washington <sup>99</sup>	University of Washington Stem Cell Institute	Multiple donors	\$17	\$100 million campaign <sup>100</sup>
Wisconsin <sup>101</sup>	University of Wisconsin	Wisconsin Alumni Research Foundation (WARF)	\$50	WARF is the primary investor in embryonic stem cell research in Wisconsin

97. Albert Einstein College of Medicine, Einstein Receives \$25-Million Gift to Support Stem Cell and Epigenomic Research and Clinical Skills Training, <http://www.aecom.yu.edu/home/fullstory.asp?id=198> (last visited Apr. 30, 2009) (noting that “\$15 million will be used to establish the Ruth L. and David S. Gottesman Institute for Stem Cell and Regenerative Medicine Research”); see also New York City Bioscience Initiative, Funding for Stem Cell Research, [http://www.nycbiotech.org/stem\\_cell.html](http://www.nycbiotech.org/stem_cell.html) (last visited Apr. 30, 2009).

98. Amber Buckley, *Anonymous Donor Pledges \$25 Million to Stem Cell Research*, DISTINCTIONS (Univ. Tx. Health Sci. Ctr., Houston, Tx.), May 2004, <http://publicaffairs.uth.tmc.edu/distinctions/archive/2004/May/25.html>.

99. See Tom Paulson, *Private Funds Keep Stem Cell Research Viable in Seattle*, SEATTLE POST-INTELLIGENCER, Sept. 29, 2007, at A1, available at [http://www.seattlepi.com/local/333633\\_stemcells29.html](http://www.seattlepi.com/local/333633_stemcells29.html).

100. Estimates of the amount sought by the University of Washington campaign vary between \$50 million, *id.*, and \$100 million, Eric Engleman, *\$100M Stem-Cell Push: UW Counters Rivals*, PUGET SOUND BUS. J., Mar. 10-16, 2006, at 1.

101. See Tom Still, *Wisconsin's Private Funding of Stem Cell Research Bucks Coastal Models*, WIS. TECH. NETWORK NEWS, Sept. 8, 2008, <http://wistechnology.com/articles/5003>.