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Public Stem Cell Research Funding

Boon or Boondoggle?

By Sigrid Fry-Revere and Molly Elgin

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Executive Summary

The United States Congress and more than 28 state legislatures have considered spending billions of taxpayer dollars on stem cell research over the next several years. The National Institutes of Health has already committed billions. And in 2004, California voters approved the Stem Cell Research and Cures Initiative, also known as the Proposition 71 bond measure, which authorized the state to raise \$3 billion over 10 years to fund such research. Though debates rage over the ethics of research using human embryonic stem cells, a more fundamental question has been ignored in this debate: Is stem cell research a sensible expenditure of taxpayer dollars? This is not a question of whether the research should be conducted, but whether *public* funding for it is justified.

Government programs, such as California's Proposition 71, are bureaucratic, wasteful, and mired in political controversy. And, because stem cell research is inherently speculative and politically controversial, the public would be best served if governments left it to the private sector. Each stem cell project is highly speculative, and it is not the place of government to gamble with taxpayers' money.

Unlike most cells in the human body, stem cells can develop into different types of cells and regenerate continuously. This suggests that stem cells may be broadly useful in treating a number of chronic and degenerative diseases. Adult stem cells are already being tested for the treatment of heart disease, rheumatoid arthritis, Parkinson's disease, type 1 diabetes, advanced kidney cancer, and spinal injury. Cord blood stem cell transplants are used in therapies for leukemias and lymphomas. And, in at least one experiment in mice, the onset of a form of Tay-Sachs disease was delayed by injecting the mice with stem cells taken from human embryonic stem cells.

However, at this point in time, no one knows how successful any of these lines of research may actually turn out to be or when any genuine medical treatments might become available. Embryonic stem cells are clearly the most versatile, but scientists have not yet been consistently able to control the growth of embryonic stem cells. Their interactions with other cells often cause unpredictable growth patterns, including tumors, and tissue rejection responses. Indeed, in a 2006 report, the U.S. National Academy of Sciences cautioned that research leading to the development of feasible therapies can take years or even decades. And, once the therapeutic applications are developed, those applications need to be tested to show that they are safe, which adds additional years to the development of viable treatment options. Consequently, politicians who promise cures in the near future for cancer and Parkinson's disease, lower future health care costs, and a booming biotechnology economy are being disingenuous.

Furthermore, there is little risk that stem cell research will go unfunded. Biotech companies, philanthropic organizations, and individuals have already invested billions of dollars in such research, and they show no sign of stopping. It is worth noting that the most important breakthrough in the field, the 1998

discovery of human embryonic stem cells and their unspecialized, self-renewing nature by University of Wisconsin professor James Thomson, was the result of privately funded research. And Thomson's research utilized embryos derived from in vitro fertilization (IVF) clinics, another private funding success story.

Just as public funding advocates argue now with regard to stem cell research, in the 1970s and 1980s, scientists lobbied the federal government to support research on new reproductive technologies, including IVF. Advocates insisted that funding IVF research was crucial for the United States to maintain its position as a leader in reproductive medicine, and they argued that infertile Americans would have to go abroad for the reproductive health care they should be receiving at home. However, public research funding advocates lost that debate. No human IVF research was ever federally funded, and there is no evidence that it has been ever funded by any U.S. state. Still, a number of IVF researchers continued their work with private funds. Within a short time, the United States became the global leader in reproductive medicine. Today in the United States, IVF for humans is estimated as a \$3 billion a year industry—all of it developed without any government funding.

Similarly, private sector investment in the biotechnology industry and generous philanthropic contributions from charitable foundations and individual donors have already pumped hundreds of millions of dollars into stem cell research in the United States alone. For example, while politics delayed the disbursement of Proposition 71 research grants, individual philanthropists donated more than \$250 million to California state universities to conduct stem cell research. And, in 2001, Harvard University, the Howard Hughes Medical Institute, the Juvenile Diabetes Research Foundation, and Boston IVF began a collaborative human embryonic stem cell research project; by early 2004 they had developed 17 new human embryonic stem cell lines without any government assistance.

More importantly, the politicized nature of the public debate over stem cell research threatens to spill over into and disrupt the research itself. The prospect of public funding so angers some Americans that it has spurred movements to restrict *private* stem cell research efforts. Under such circumstances, government funding for stem cell research is more hindrance than help to the advancement of science.

Californians were optimistic when Proposition 71 passed in 2004, but the initiative has been plagued by problems since its inception, and its implementation has left much to be desired. From 2004 to 2006, two lawsuits challenging the constitutionality of Proposition 71 prevented the disbursement of any public funds for stem cell research. In addition, disputes over how funds are to be disbursed, as well as how licensing and royalty agreements are to be structured, remain unresolved. The political nature of government funding means more delays to the already lengthy research process and makes financial returns on taxpayer dollars even more doubtful.

While political squabbles continue to stymie public funding for stem cell research, enterprising private companies, foundations, and individuals have invested or donated funds, not only for general stem cell research, but also for testing potential therapies and related products. Government programs, such as California's Proposition 71, are bureaucratic, wasteful, and mired in political controversy. As a result, the percentage of funds spent on actual research is low. Experience shows that it is possible to retain America's dominance in biotechnology without government funding, and current research continues to prove that private funding produces results more efficiently and effectively. No matter how much public funding proponents promise, the best way to make progress in stem cell research is to allow the private sector to grow, unimpeded by cumbersome regulation and political controversy.

Introduction

The United States Congress and more than 28 state legislatures have considered spending billions of taxpayer dollars on stem cell research over the next few years. The National Institutes of Health (NIH) has already committed billions. Though debates rage over the ethics of the work, a more fundamental question is being ignored: Is stem cell research a sensible expenditure of taxpayer dollars? This is not a question of whether the research should be conducted, but whether *public* funding for it is justified.

Because stem cell research is inherently speculative and politically controversial, the public would be best served if governments left it to the private sector. Politicians who promise cures in the near future for cancer and Parkinson's disease, lower future health care costs, and a booming biotechnology economy are being disingenuous. Each stem cell project is highly speculative, and it is not the place of government to gamble with taxpayers' money.

Furthermore, there is little risk that stem cell research will go unfunded—biotech companies, philanthropic organizations, and individuals have already invested billions of dollars in such research, and they show no sign of stopping. More importantly, the politicized nature of public debates over stem cell research threaten to spill over into and disrupt the research itself. The prospect of public funding so angers some Americans that it has spurred movements to restrict *private* stem cell research efforts. Under such circumstances, government funding for stem cell research is more hindrance than help to the advancement of science.

The Political Controversy

In November 2007, New Jersey voters rejected an initiative to borrow \$450 million to fund state-run stem cell research. Defeat should not have come as a surprise. New Jersey voters had the advantage of seeing how little California's 2004 stem cell funding initiative has accomplished at an extremely high cost. New Jerseyites have also seen the flourishing of private stem cell research efforts in their own backyard, evidence that such research need not depend on government funding. Moreover, it simply makes no sense for a state with the highest per-capita public debt in the nation to borrow still more money to spend on stem cell research.¹

Yet some New Jersey legislators remain eager to increase taxes and spending to finance stem cell research—and they are not alone. By the end of 2008, the National Institutes of Health will have spent over \$2.5 billion on stem cell research in just five years. Nine states, including California,

New Jersey voters were wise to learn from California's mistakes, and residents of others states would be wise to follow suit.

New York, and Connecticut, have committed to combined spending of over \$4.1 billion over the next 10 years.² Government funding advocates consistently downplay the significant financial risks involved in the research and the inefficiency of public programs in managing its progress. They also seem to ignore the fact that private companies are doing just fine conducting stem cell research without government help or interference.

New Jersey voters were wise to learn from California's mistakes, and residents of others states would be wise to follow suit. Most of the problems that arose in California are endemic to government-run efforts in general, such as wasted time and money and political squabbling over the fair distribution of funds. This is not to suggest that private initiatives cannot be wasteful, inefficient, or unsuccessful—many biotechnology firms fail because they are high-risk ventures. But in the private sector individuals make their investments voluntarily. If people find that they have been lured into investing their money under false pretenses, they have legal remedies available to address such injustices, including opportunities for reparations. There are no such remedies for mistakes made at the ballot box. Whether or not stem cell research proves a worthy investment on the whole, citizens of other states would be wise to follow New Jersey's example and reject any proposal for government funding of stem cell research.

What Are Stem Cells and What Can They Do?

To understand this issue, it is worth learning a little about the underlying science. Most cells perform only one function, and they can only produce other cells of the same type, which, like the original cells, will eventually mature and die. For example, newly divided muscle cells become mature muscle cells, and they can only produce new muscle cells. However, unlike most cells, stem cells can generate different types of cells and regenerate continuously. When a stem cell divides, one daughter cell becomes a specialized cell, such as a muscle or blood cell, while the other daughter cell remains a stem cell, which then can produce the same or another kind of cell, again leaving a daughter cell behind to continue the stem line.³ Thus, stem cells can give rise to both specialized and unspecialized cells.

Different types of stem cells differ in the variety of cells they can produce. Adult stem cells are already being tested for the treatment of heart disease,⁴ rheumatoid arthritis, Parkinson's disease, type one

diabetes, advanced kidney cancer, and spinal injury.⁵ Cord blood stem cell transplants are used in therapies for leukemias and lymphomas.⁶ And, in at least one experiment in mice, the onset of a form of Tay-Sachs disease was delayed by injecting the mice with stem cells taken from human embryonic stem cells.⁷ Embryonic stem cells are clearly the most versatile of stem cells, though research remains in a very early stage. Indeed, scientists have not yet been consistently able to control the growth of embryonic stem cells; their interactions with other cells often cause unpredictable growth patterns, including tumors, and tissue rejection responses.⁸ Efforts to reprogram adult cells to act more like embryonic stem cells give hope to those who oppose the use of human embryos in research, but the reprogramming of adult stem cells has implementation problems of its own.⁹

Scientists have worked with stem cells since the 1960s,¹⁰ but, in 1998, University of Wisconsin biophysics professor James Thomson discovered human embryonic stem cells and their unspecialized, self-renewing nature.¹¹ In December 1999, the journal *Science* declared human embryonic stem cell research “the breakthrough of the year.”¹² The potential applications of Thomson’s discovery stirred not only the imagination of the scientific community, but also that of millions of people who hoped embryonic stem cell therapies could help them or their loved ones overcome dreaded diseases.

Embryonic stem cell research holds extraordinary promise, but its potential therapeutic applications are still speculative. Until scientists can control the growth of stem cells and make them interact with other cells without causing tumors or rejection responses in patients, there is very little therapeutic use for embryonic stem cells.¹³ As the public liaison of the National Institute of Neurological Disorders and Stroke put it, “[embryonic stem cell] research is in its infancy. There are many technical and scientific hurdles to overcome, and it will probably be years before the results of any such studies in humans that may be developed are known. Currently, the usefulness of embryonic stem cells to treat disease, even in animal models, is still far from clear.”¹⁴

The Public Funding Movement

Following James Thomson’s discovery, funding stem cell research became not only politically feasible, but hugely popular. However, the use of embryos remains controversial, and the national debate has been

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deadlocked ever since. Current U.S. law does not prohibit any form of stem cell research, but the use of federal funds is restricted to 22 stem cell lines derived from embryos before August 9, 2001.¹⁵ In the absence of federal funding, private firms, charitable foundations, and, more recently, state governments have stepped in to create their own stem cell research programs. More than half of U.S. states have debated funding some form of stem cell research, but California was the first state to fund a major stem cell initiative.

In November 2004, Californians approved the Stem Cell Research and Cures Initiative, also known as the Proposition 71 bond measure, by a vote of 59 to 41 percent.¹⁶ The initiative amended the state constitution to guarantee a right to conduct stem cell research, and it authorized the state to sell bonds to raise \$3 billion over 10 years to fund such research. The initiative created the California Institute of Regenerative Medicine (CIRM) to disburse the funds to researchers through grants¹⁷—to be supervised by an Independent Citizens Oversight Committee. The initiative stipulates that California’s only statutory restriction on stem cell research is a five-year moratorium on human cloning by any researcher in the state, whether publicly or privately funded.¹⁸ Californians were optimistic when Proposition 71 passed in 2004, but the initiative has been plagued by problems since its inception, and its implementation has left much to be desired.

The Benefits of Proposition 71 Were Greatly Exaggerated

Proposition 71 stated that, “it is the intent of the people of California in enacting this measure to . . . improve the California health care system and reduce the long-term health care cost burden on California through the development of therapies that treat diseases and injuries with the ultimate goal to cure them.” Both proponents and critics of public funding for stem cell research agree that finding cures for diseases and reducing health care costs are noble goals, but Proposition 71 has very little hope of accomplishing these goals.

It Is Disingenuous to Imply that Cures are Imminent

Stem cell research is a brand new field; in any such frontier research, results cannot be predicted, and benefits are impossible to assess. At best, some stem cell research may lead to therapies that will help replace human cells and tissues that are no longer functioning properly, or help medicines

reach the market and patients more quickly by allowing scientists to target specific cells during drug testing.¹⁹ In the long run, such advances could prevent or treat long-term illnesses, and thereby reduce the costs of certain treatments, but those results are highly uncertain. Even in the best of circumstances, effective therapies developed from embryonic stem cell research are decades away.

The National Academy of Sciences (NAS) has noted the elusive nature of the claimed benefits of stem cell research. As NAS researchers explain, “what tend to be ‘over-promised’ are not only the potential outcomes of both embryonic and adult stem cell research, but also the time scales that are involved.” Research leading to the development of feasible therapies can take years or even decades. And, once the therapeutic applications are developed, those applications need to be tested to show that they are safe, which adds additional years to the development of viable treatment options.²⁰ It is worth noting that the lag time in the pharmaceutical industry between the funding of basic research and a new drug product reaching the market is an estimated average of 18 years.²¹ A stem cell therapy might take a shorter time to develop and test than a new drug, but it could just as easily take longer.

Given these realities, the campaign for passage of Proposition 71 was highly misleading. In an emotion-laden television ad, actor and Parkinson’s disease sufferer Michael J. Fox urged voters to support Proposition 71 because it could save millions of lives and find cures for serious diseases like cancer, diabetes, Alzheimer’s, and Parkinson’s. The widely used appeal to California voters claimed that Proposition 71 “could save the life of someone you love.”²² But, as Boston University bioethicist George Annas explains, “that’s a good argument, politically, but in reality that’s nuts.”²³ It is too early to predict what will come of stem cell research, and there is certainly no basis for the claim that the \$3 billion California taxpayers have devoted to stem cell research will save lives.

It is Misleading to Promise Reduced Health Care Costs

Promoters of the California initiative went beyond unrealistic medical promises. Advocates of Proposition 71 also argued that the massive stem cell spending would bring about certain financial gains. They told voters that Proposition 71 would “protect and benefit the California budget” by “funding scientific medical research that will significantly reduce state health care costs in the future” and provide “an opportunity for the state

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to benefit from royalties, patents, and licensing fees that result from the research.”²⁴

Even worse, several researchers at California universities made outlandish claims regarding the financial benefits of passing Proposition 71. For instance, University of California, San Diego, cell biologist Lawrence Goldstein told *Science* that, as a result of Proposition 71, cures for chronic diseases such as juvenile diabetes will save \$1 billion a year in health care costs in California.²⁵ Given the unpredictability of embryonic stem cell research, especially the present inability to prevent a patient’s immune system from rejecting the cells, such a claim is astounding. And, in a study sponsored by an organization called “Yes On 71,”²⁶ Stanford University health economist Laurence Baker and Bruce Deal of the consulting firm Analysis Group concluded that the state would save between \$6 billion and \$12 billion in health care costs.²⁷

These reports were widely circulated and quoted in the campaign for Proposition 71. Critics have pointed out the weakness of this argument, which fails to account for the time required to develop the promised cures and whether they are even possible. Embryonic stem cell therapies could take decades to develop—if they ever materialize at all. If cures are found, the lengthy research and clinical trial process will reduce projected revenues considerably, by about 65 percent according to some calculations.²⁸

In addition, royalties are not as lucrative for research institutions as proponents of Proposition 71 have implied. Surveys by the Association of University Technology Managers of revenue for fiscal years 2000 to 2004 indicate that licensing income from research constitutes only about 6.6 percent of overall research expenditures for hospitals and research institutions in the University of California system, and just 2.1 percent of all university research.²⁹ University of California, Berkeley, economics professor Richard Gilbert points out that, if one accounts for an average of eight years between research expenditures and revenues from research-related products, the actual ratio of income to expenditure is closer to 4.5 percent. According to Gilbert, this means that for every \$100 a state spends on stem cell research, it can expect less than \$5 in revenue.

To make things worse, state licensing and royalty requirements may be too onerous to attract industry partners to bring state-funded discoveries to fruition. Three years into the project, as of July 2008, a dispute between CIRM and the California legislature regarding the terms

of licensing and royalty agreements remains unresolved.³⁰ Some legislators believe that CIRM's proposed royalty and licensing fees are too low to generate the promised revenue, while CIRM argues that any higher demands will scare away potential research and development partners, causing them to seek funds and development agreements elsewhere.³¹ The inevitable compromise will make Proposition 71's promises of future royalties and more affordable health care tenuous at best.

Promises of potential royalties also fail to account for the challenges associated with the unresolved issue of patenting human embryonic stem cell technologies. The issues involved are at the cutting edge of intellectual property law, and the legal status of patents for stem cell lines and related products has been in flux for almost a decade.³² Because the patentability of stem cell technologies remains legally uncertain, potential stem cell research revenues are entirely hypothetical.³³

In this regard, James Thomson's discovery is important legally, as well as scientifically. He filed a patent application in 1998 before publishing his discovery of the unspecialized and self-renewing nature of embryonic stem cells.³⁴ The resulting patents granted were so broad that the Wisconsin Alumni Research Foundation (WARF), to which Thompson transferred the patents, arguably holds ownership rights over *all* U.S. human embryonic stem cell products, regardless of how they are derived. This fact undermines claims of an immediate financial windfall for California. WARF first said it would require CIRM to pay for the use of its patents and demand royalties from CIRM grantees, but it agreed in January 2007 not to challenge CIRM's use of its patents because CIRM is a non-profit entity. In the short term, WARF's decision to allow CIRM free use of its technologies worked to CIRM's advantage by putting off any decision about the scope of the patents. But the lingering patent question will make it more difficult for CIRM to collect similar licensing fees on any potential discoveries in the future.

An April 2007 decision by the U.S. Patent and Trademark Office that upheld a challenge to Thomson's patents further complicates the issue.³⁵ Thomson's patents on the human embryonic stem cells are in question because they are similar to earlier patents on mouse cells. WARF is challenging the decision, but the legal confusion surrounding the patents and related licensing fees makes potential gains through patenting and licensing stem cell discoveries highly tentative. Nevertheless, Proposition 71's supporters still made claims of likely cures and health care cost savings unflinchingly throughout their campaign.

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It Is Disingenuous to Promise Economic Growth

In addition to exaggerating the direct revenue gains from the initiative; Proposition 71 advocates portrayed the stem cell program as a boost to the state's overall economy. The initiative itself stated that it would "benefit the California economy by creating projects, jobs, and therapies that will generate millions of dollars in new tax revenues."³⁶ Proponents claimed that the influx of government revenue—\$3 billion in taxpayer money—would provide an economic stimulus. However, spending public money (whether from bond financing or current tax revenue) to build labs and offer research stipends merely diverts that money from one use to another. It can only stimulate the California economy if the value of any resulting discoveries is greater than that of the alternative uses, or if they were to attract private investment from outside the state from investors who would not come otherwise. But, given the highly speculative nature of stem cell research, and the wasteful mandatory expenditures on intermediaries such as CIRM and the Independent Citizens Oversight Committee, that eventuality is far from assured. Money put into more certain ventures with less built-in waste would be expected to yield much higher returns. That is one reason why the financing of stem cell research is better left in private hands.

Proponents of Proposition 71 have many questions to answer. The campaign generated so much excitement about the prospects of stem cell research and its possible benefits that voters authorized the state, despite a heavy load of existing debt, to borrow \$3 billion to invest in stem cell research over the next 10 years—money that must be repaid along with accrued interest. The California Legislative Analyst's Office estimates that the total cost of the initiative will be \$3 billion in principal *and another \$3 billion in interest* paid off over 30 years.³⁷ Thanks to battles in the courts and in the legislature, California taxpayers will have to wait even longer to see if there is a payoff to their investment. From 2004 to 2006, two lawsuits challenging the constitutionality of Proposition 71 prevented the disbursement of any public funds for stem cell research. And, in 2006, lawmakers unsuccessfully tried to pass legislation to make CIRM's activities more transparent.³⁸ The political nature of government funding just means more delays to the already lengthy research process and makes financial returns on taxpayer dollars even more doubtful.

In a state with a \$14 billion deficit projected for 2008 alone,³⁹ more deficit spending on an extremely speculative investment is unwise.⁴⁰ If new discoveries generate little or no income, then additional taxes will be

needed to cover the debts incurred to pay for the research. Taxpayers will then have to ante up still more money to prevent research programs from closing down. Lowering taxes and reducing regulatory burdens in ways that would encourage private research institutions to move to California would be a better way to stimulate the economy than spending more tax money the state does not have.

Leadership. . . in Spending

Most state statutes funding stem cell research declare a legislative intent to propel the state to the forefront of research. Eleven states have initiated funding for stem cell research programs, and 28 have considered some form of such funding. Unfortunately, state action is more likely to hinder cutting-edge biotechnology research than it is to produce important scientific or medical breakthroughs.

Promises of World Leadership

Proposition 71 was promoted as a measure that would “advance the biotech industry in California to world leadership, as an economic engine for California’s future.”⁴¹ “If you look at the high-tech boom in the Silicon Valley as an example,” said California Governor Arnold Schwarzenegger (R) just two weeks before the November 2004 vote on Proposition 71, “you know that had billions of dollars of impact on state revenue and certainly you want to preserve California’s position for the oncoming industry.”⁴²

Similarly, in announcing New York’s funding initiative, then-Lieutenant Governor (now Governor) David Paterson claimed: “Stem cell research offers New York profound economic opportunities and this funding commitment by the state will help position New York as a world leader in the field.”⁴³ However, it is unclear how the buildup of costly state bureaucracies in pursuit of speculative gains will lead states into anything but further debt. It is sobering to consider that nine out of 10 new biotech firms fail,⁴⁴ as do nine out of 10 new pharmaceutical products in clinical trials.⁴⁵ There is little to suggest that government-run research programs could offer a better track record, and good reason to believe they would be worse.

Hindering, not Fostering, Research

State policy makers say they want their states to lead the world in stem cell research, but exorbitant building expenditures and burdensome research

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restrictions belie their stated goal. Because of political considerations, state politicians are spending 85 percent of funds allotted for stem cell research to build infrastructure and train state science students to become stem cell researchers, leaving only about 15 percent of funds for actual *research*.⁴⁶ Though a similar comprehensive study of private industry is unavailable, a quick survey of six of the estimated 40 publicly traded companies conducting stem cell research shows that, for the companies selected, the percentage of total operational expenditure spent on research and development trends towards the 70 percent range, significantly higher than that of state governments. Although these data are not conclusive, it appears that states could produce much greater gains by enticing private sector investment in the biotechnology industry than by funding stem cell research directly.

Further complicating matters, investment in stem cell research is risky because of *political*, as well as scientific, uncertainty. Many states have passed, or are considering, laws restricting various aspects of stem cell research—in language sometimes so vague that it is difficult to know what is and what is not allowed. Almost half of U.S. states have passed legislation to restrict stem cell research. While California amended its

Table 1. Stem Cell Research Expenditures of the Top Six Companies

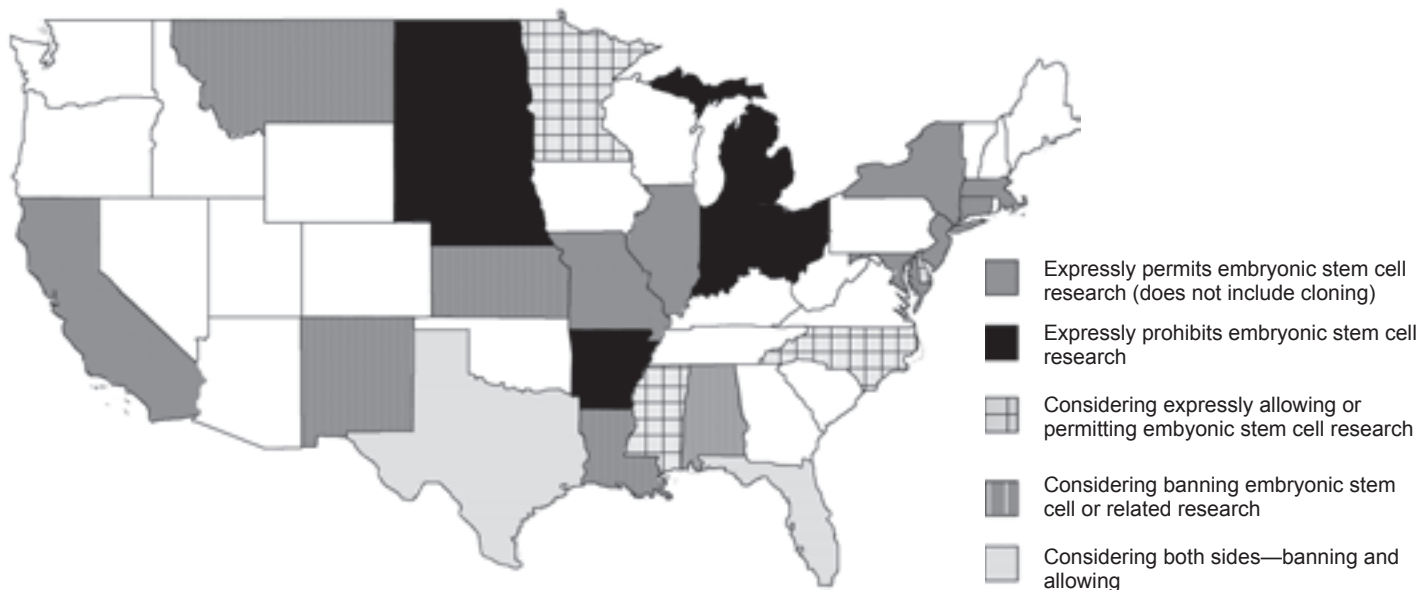
Company	Total Operational Expenditure 2007	R&D Expenditure 2007	Total Operational Expenditure 2006	R&D Expenditure 2006	Total Operational Expenditure 2005	R&D Expenditure 2005	R&D as percentage of total operational expenditure*
<i>Expenditure in millions.</i>							
Aastrom	\$20.2	\$11.4	\$18.6	\$9.5	\$13.3	\$7.2	56.4%
Geron Corp.	\$70.5	\$54.6	\$50.6	\$41.2	\$43.9	\$35.1	77.4%
Stemcells, Inc.	\$28.6	\$19.9	\$21.5	\$13.6	\$16.6	\$8.2	69.6%
Osiris Therapeutics, Inc.	\$57.8	\$50.9					88.1%
Viacell			\$78.8	\$14.0	\$61.0	\$13.7	17.8%
Advanced Cell Technologies	\$23.6	\$17.8	\$12.7	\$9.0			70.9%
* Percentages calculated from 2007 numbers; Viacell was acquired by PerkinElmer in 2007, so the percentage shown for Viacell is calculated using 2006 numbers.							

constitution to protect stem cell research—including embryonic stem cell research—from bans or restrictions that might be imposed in the future by the state legislature or local governments, the state nevertheless enacted legislation prohibiting so-called reproductive cloning.⁴⁷ Eleven states have enacted outright bans on embryonic stem cell research, 10 have prohibited the related procedure of cloning, and at least five are considering some form of restriction on other stem cell-related research.⁴⁸

Each state has its own set of definitions, rules, and regulations. Some draw distinctions based on the source of the stem cells, or add restrictions based on the purpose for which the research is conducted. Furthermore, several states have yet to decide what to allow or to restrict, and new legislation is constantly being proposed. Even states that appear to have settled on a position have policies that remain in flux. After the people of Missouri passed a ballot initiative in November 2006 to amend the state constitution to protect stem cell research, state lawmakers continue to fight for bans on certain types of research.⁴⁹ In June 2007, this “persistent negative political climate” led prominent stem cell research philanthropists Jim and Virginia Stowers to cancel a planned \$300 million expansion of their Kansas City-based Stowers Institute for Medical Research and redirect some of their money into a new philanthropic enterprise incorporated in Delaware.⁵⁰

Figure 1. State Stem Cell Laws

Source: Lexis-Nexis website, www.lexis.com, *Legislation by State*, key word “stem cell” and the National Conference of State Legislatures Genetics Legislation Database, <http://www.ncsl.org>.¹



Notes: ¹ Cloning in this instance refers to human cloning. In the case of Nebraska,

Private funding continues to be vital to stem cell research. In fact, the most important breakthrough in the field, James Thomson’s discovery of the nature of human embryonic stem cells, was the result of privately funded research.

There is a Better Way

Given the risks and questionable benefits, why are state governments rushing to fund stem cell research? Some argue that, precisely because of the risky nature of the work, private companies will either not pursue it or will only focus on the more immediately profitable aspects. These claims are false. The riskiness of cutting-edge research methods and technologies is standard in the biotechnology industry and is therefore unlikely to intimidate investors whose financing of the biotech industry totaled over \$20 billion in 2005.⁵¹ The more pressing risks hindering greater private investment are political controversy and the threat of stifling regulation.

Private funding continues to be vital to stem cell research. In fact, the most important breakthrough in the field, James Thomson’s discovery of the nature of human embryonic stem cells, was the result of privately funded research.⁵² And Thomson’s discovery utilized embryos derived from *in vitro* fertilization (IVF) clinics, another private funding success story.

A Historical Success Story

To understand the possibilities of private research funding, an actual historical success story provides a good illustration. In the 1970s and 1980s, scientists lobbied the federal government to support research on new reproductive technologies, but ethical concerns regarding experimentation on human embryos stymied their efforts. Research advocates spent millions of dollars trying to convince the President, Congress, and the National Institutes of Health that funding research involving *in vitro* fertilization techniques was crucial for the United States to maintain its position as a leader in reproductive medicine. Advocates of public funding for IVF argued that a “brain drain” would ensue, and that infertile Americans would have to go abroad for the reproductive health care they should be receiving at home.

Eventually, public research funding advocates lost that debate. No human IVF research was ever federally funded, and there is no evidence it has been funded by any U.S. state. But, as the divisive debate over experimenting on human embryos and the ethical merits of “test-tube babies” raged in the headlines, a number of researchers quietly continued their work with private funds. Far from suffering a brain drain, within a short time, the United States overtook the United Kingdom, its leading competitor in IVF research. Today in the United States, IVF for humans is estimated as a \$3 billion a year industry⁵³—all of it developed without any government funding.⁵⁴

Private Funding is Versatile

Opponents of reliance on private-sector funding for research fail to recognize that private financing can come from multiple sources, for multiple motivations, and be intended to pursue multiple goals. For one, both for-profit and not-for-profit private organizations are engaged in medical research. Some private donors are venture capitalists or large, publicly held corporations; others are private educational institutions, foundations, or even individual philanthropists. Every day, individuals vote with their wallets to support research through efforts such as the March of Dimes, which was Dr. Jonas Salk's primary financial patron for the research leading to his discovery of the polio vaccine.⁵⁵

The amount of individual charitable giving in the United States is astounding. Of voluntary donations given to non-profit organizations in 2005, 83.2 percent were from individuals, 11.5 percent from charitable foundations, and 5.3 percent from corporations.⁵⁶ Some analysts predict that, given current U.S. economic growth, voluntary donations will quadruple or even sextuple over the next 45 years.⁵⁷ Duke University Law Professor Joel Fleishman writes: “[I]t does appear that America is in for a golden age of philanthropy.”⁵⁸ Given the strength of individual philanthropy in the United States, the speculative nature of stem cell research, and the reservations of some over the ethics of such research, allowing private but not public funding, as happened with the development of new reproductive technologies such as IVF, is a viable compromise. It is also politically attractive because it does not require citizens opposed to stem cell research to support the work with their tax dollars.

More Is Not Necessarily Better

Some proponents of government funding of stem cell research argue that more is better, and that there is no reason not to pursue both federal and private funding simultaneously. However, there is evidence that government spending “crowds out” private contributors. The Congressional Budget Office (CBO) made exactly this point in a report on research and development in the pharmaceutical industry. “Even as it produces substantial social benefits,” the CBO observed, government spending “on basic research and development can also discourage private investment.” Government can discourage private investment directly, “as when the government sponsors research that the private sector would otherwise have conducted,” or indirectly, as when “the government

Opponents of reliance on private-sector funding for research fail to recognize that private financing can come from multiple sources, for multiple motivations, and be intended to pursue multiple goals.

Public funding can actually have a negative influence, if the political repercussions lead to increased and confusing regulation and limitations.

competes for trained scientists and other scarce resources and bids up their prices.”⁵⁹ The results are reduced private investment and lower long-term growth.⁶⁰

In fact, public funding can actually have a negative influence, if the political repercussions lead to increased and confusing regulation and limitations. For example, a bill in Nebraska banning cloning for reproductive purposes has been amended to include bans on cloning for research purposes, which would essentially outlaw human embryonic stem cell research regardless of how it is funded. Nebraska Right to Life Executive Director Julie Schmit-Albin expressed concern that the original bill “could have emboldened private sector cloning labs to come into Nebraska and we are thankful it was removed.”⁶¹ In Missouri, the Stowers Institute for Medical Research feared the imposition of restrictions enough to put on hold its planned expansion in Kansas City and invest in other states instead. Reliance on private funding alone would tend to de-politicize the process.

Privately Funded Researchers Are Already Hard at Work

Compared to the troubles facing public funding, privately funded stem cell research has an impressive record of proven successes and breakthroughs. Before Thomson’s discovery, human embryo research relied exclusively on private funding because no public funding was available. Yet, Thomson was not the only one doing research on human embryonic stem cells in the 1990s, and many more entered the field after he published his findings in 1998. For example, in 2001, Harvard University, the Howard Hughes Medical Institute, the Juvenile Diabetes Research Foundation, and Boston IVF began a collaborative human embryonic stem cell research project, and by early 2004 they had developed 17 new human embryonic stem cell lines without any government assistance.⁶² They began their research months before President Bush allowed very limited funding for research on existing stem cell lines, four years before California’s stem cell funding initiative was even on the ballot, and almost seven years before California issued the first bonds authorized by Proposition 71.

While the California Institute for Regenerative Medicine deals with disputes over the disbursement of funds, private contributions by investors and philanthropists continue to advance stem cell research. The adult stem cell product market—which experienced an increase of over 100 percent from 2006 to 2007—is testament to the quicker and more effective results

produced by private industry. Today, the most politically controversial form of stem cell research, embryonic stem cell research, is still almost exclusively supported by private funds.⁶³ But substantial amounts of private funding are also available for adult stem cell and cord blood stem cell research.

Some private companies have managed to avoid the political entanglements that cause investors to hesitate by concentrating their operations in states that, at least for now, expressly permit or are neutral on the subject of stem cell research. The advances some of these companies have made are impressive. For example, when Geron Corporation, Inc. scientists injected human cardiac cells derived from embryonic stem cells into a damaged rat heart, the cells not only survived, but improved cardiac function.⁶⁴ Geron is currently testing six different therapies derived from embryonic stem cells on non-human subjects, and it could begin Phase I regulated human trials⁶⁵ if the results indicate the therapies are safe and effective.

Another private company, Osiris Therapeutics, Inc., has developed an adult stem cell treatment to repair gastrointestinal damage caused by radiation. The drug, Prochymal, has been granted Fast Track status by the Food and Drug Administration and is currently undergoing Phase III clinical trials.⁶⁶ The results look so promising that the Department of Defense recently awarded Osiris a two-stage \$224.7 million contract for the treatment that provides \$4.2 million in current research funding coupled with an option to purchase up to 20,000 doses upon FDA approval.⁶⁷ Yet another private company, StemCyte, Inc., is marketing stem cells derived from donated umbilical cord blood to treat blood diseases such as rare forms of leukemia. To date, these have been used in more than 600 patients in over 30 countries.⁶⁸

There are many more examples of a burgeoning stem cell research market. A sampling of private companies working on stem cell research (see Table 2) clearly shows that, contrary to some government funding proponents' claims, private companies are investing heavily in stem cell research. These companies, unlike state-funded organizations like CIRM, do not have to worry about their money being held up by political maneuverings or legal issues. The amount of money spent is determined by calculations of risk and potential gain, not by the wishes of politicians and special interest groups.

A sampling of private companies working on stem cell research clearly shows that, contrary to some government funding proponents' claims, private companies are investing heavily in stem cell research.

Table 2. Sample of What Some Private Companies are Doing

Company Name	R&D Expenditure 2007			Product Development
<i>(In millions, rounded to hundred thousands)</i>				
Aastrom	\$11.4	\$9.5	\$7.2	Bone Repair Cells to treat patients with degenerative bone diseases or traumatic bone injuries
Geron Corp.	\$54.6	\$41.2	\$35.1	Stem cells that improve cardiac function; acute spinal cord injury therapy
Stemcells, Inc.	\$19.9	\$13.6	\$8.2	
Osiris Therapeutics, Inc.	\$50.9			Prochymal treats gastrointestinal damage caused by radiation and graft-versus-hosts disease
Viacell		\$14.0	\$13.7	Viacord, preservation and storage of cord blood stem cells for related use
Advanced Cell Technologies ¹	\$12.7	\$9.0		Retinal Pigment Epithelium (RPE) program successfully restored visual function in rats
StemCyte	<i>(Privately-held)</i>			Stem cells used to treat blood diseases such as rare forms of leukemia.
¹ <i>Scientific American</i> , News Scan Briefs leader, March 2007.				

Individual benefactors is another significant source of private funding. For example, while politics delayed the disbursement of Proposition 71 research grants, philanthropists donated more than \$250 million to California state universities to conduct stem cell research.⁶⁹ Californians are not alone; individuals around the country have donated large sums to fund stem cell research as well.

Were stem cell research to be conducted exclusively in the private sector, those who see its funding as important could donate their own money and urge others do the same. At the same time, those who discount the urgency, see such research as a waste of resources, or consider it immoral, can try to convince others not to support it. Best of all, such debates can take place without getting bogged down in political struggles over whether or not it is appropriate for government to provide financial support for the research. A free market of ideas, with a plurality of private funding sources, in the long run will result in less waste and more funds being directed to those most vested in solving shared research concerns.

Table 3. Sample of Private Giving to Stem Cell Research Efforts

Amount	Donor	Recipient Institution
\$40 million (\$100 million target) ¹	Howard Hughes Medical Institute, Juvenile Diabetes Research Foundation, Harvard, various philanthropists	Harvard Stem Cell Institute
\$100 million ²	Michael Bloomberg	Johns Hopkins University
\$985 million ³	James and Virginia Stowers	Stowers Medical Institute
\$25 million ⁴	Anonymous patient	University of Texas Health Sciences Center – Houston
\$50 million ⁵	Starr Foundation	Rockefeller University; Cornell Medical School; Memorial Sloan-Kettering Cancer Center
\$50 million	John and Tashia Morgridge	Wisconsin Institutes of Discovery
\$10 million ⁶	Leon Black	Mount Sinai School of Medicine Black Family Stem Cell Institute
\$15 million ⁷	Shahla and Sushang Ansary	Cornell Medical School Center for Stem Cell Therapeutics
\$5 million ⁸	Harriet Heilbrunn	Rockefeller University
\$3 million ⁹	Chuck Brunie	Columbia University Medical Center

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Conclusion

While political squabbles continue to stymie public funding for stem cell research, enterprising private companies, foundations, and individuals have invested or donated funds, not only for general stem cell research, but also for testing potential therapies and related products. With the private sector taking such great strides, it is futile and self-defeating to go through tortuous efforts to secure government funding.

Government programs, such as California's Proposition 71, are bureaucratic, wasteful, and mired in political controversy. As a result, the percentage of funds spent on actual research is low. Besides being wasteful, government programs can deter progress in the private sector. Unnecessary and often onerous legislation and regulations impede the work of stem cell researchers and only add years to an already lengthy therapeutic development process.

Experience shows that it is possible to retain America's dominance in biotechnology without government funding, and current research continues to prove that private funding produces results more efficiently and effectively. No matter how much public funding proponents promise, the best way to make progress in stem cell research is to allow the private sector to grow, unimpeded by cumbersome regulation and political controversy.

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