



Too Much To Ask

The States Simply Cannot Make Up for Federal Inaction on Stem Cell Research

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Introduction

The latest outcome in the ongoing national debate about human embryonic stem cell research is unprecedented in the history of science funding in the United States. President Bush's recent veto of the Stem Cell Research Enhancement Act means that a cutting edge field of scientific inquiry will soon receive its strongest support not from the federal government, but from the states.

Although Washington provides the majority of funding for stem cell research, it refuses to permit scientists to work with new and more effective lines of human embryonic stem cells. The states have moved to fill this gap in order to allow American scientists to use the best tools in the race for life-saving cures. Yet as important and admirable as these state initiatives are, they cannot replace the leadership that would be provided by the National Institutes of Health (NIH).

Nor is a decentralized research system as efficient as the federal structure that is already in place. The differing federal and state stem cell research policies have forced states to spend the bulk of their money on building infrastructure, purchasing equipment and training scientists, not on funding actual research projects. And contrary to the impression that state funding of this emerging field of science is substantial, our analysis demonstrates that allocated state funding—funding designated for specific purposes—is currently modest at best and not targeted towards research that is ineligible for federal funding.

States are supporting stem cell research to the best of their abilities, but only combining their efforts with stronger federal support will truly advance stem cell research. We need to pass the Stem Cell Research Enhancement Act and increase federal funding for embryonic stem cell research in order to remedy the situation and ensure the United States remains at the forefront of this major new scientific field – for the benefit of our science, our citizens, and our economy.

The Outdated Federal Funding Policy

On August 11, 2001, President Bush ordered that federal funding of research involving human embryonic stem (hES) cells be limited to stem cell lines derived as of that date. Nearly five years later, on July 19, 2006, the president vetoed legislation that would have made it possible



for federally funded research to be conducted with newer hES cell lines. For the foreseeable future, federally funded researchers will have to rely on a few outdated and potentially contaminated stem cell lines. Private, foreign, and state researchers, meanwhile, are using more efficacious lines, while the lack of federal support becomes more and more egregious.

Back in 2001, however, problems with the Bush policy were not immediately recognized because of the nascence of the science. The Bush administration policy was even received with a degree of enthusiasm and hope by some scientists. NIH Director Dr. Elias Zerhouni proclaimed that “the President’s policy has provided us the opportunity to be at the forefront of the latest groundbreaking discoveries in culturing, characterization and differentiation of stem cells, and I am confident that NIH will keep its premier place in this field for years to come.”¹

At the time of the announcement, the President said there were “more than 60 genetically diverse (human embryonic) stem cell lines”² deemed eligible for funding. Overestimations of available lines and the development of mutations in the older lines have caused that number to dwindle since then to 21.³ Access to these lines has thus become difficult for scientists, slowing research.⁴ Furthermore, concerns about contamination by the mouse feeder cells used to grow the lines and the genetic instability of older lines appear to make it unwise to transplant any derived cells from the approved lines into a human patient.

Scientists have since developed ways to derive more promising hES cell lines. Dr. James Thomson, credited with first isolating embryonic stem cells, explains the advantage of these lines in a recent article in *Biotechnology*. “Human-ES-cell lines derived in defined conditions would be more directly applicable to clinical use than are cell lines derived in the presence of animal products,” he notes. “Derivation and culture in serum-free, animal product-free, feeder-independent conditions mean that new human-ES-cell lines could be qualitatively different from the original lines, and makes current public policy in the United States increasingly unsound.”⁵

Even without eligibility for federal funding, these newer lines have proven far more popular. Since 2003, Harvard University has sent 667 batches of their newly derived lines to laboratories around the world, while the National Stem Cell Bank, the main distributor of federally funded lines, has sent just 246 batches.⁶

Despite these new developments, however, federal funding policy has not adapted to keep pace with science. The constraints of the current federal policy, coupled with the limitations of the federally approved lines, are becoming increasingly troublesome as scientists work toward developing tangible cures and conducting human trials.

The Potential of Human Embryonic Stem Cells

Scientists agree that hES cells are the most promising type of stem cells for medical therapy, drug development, and generation of new disease theories. Unlike adult stem cells, hES cells can develop into any cell in the body. Dr. Douglas Kerr’s use of transplanted embryonic stem



cell-derived motor neurons to help paralyzed rats regain moderate function after 6 months⁷ and the discovery by scientists at UCLA that they could coax hES cells to mature into T-cells (potentially leading to a cure for AIDS)⁸ are just two examples of the promise of embryonic stem cells.

Non-embryonic or “adult” stem cells have provided many important cures, but they have less medical potential than embryonic stem cells. Adult stem cells are derived from sources such as umbilical cords and bone marrow in developed humans, as opposed to embryos. Because they have already experienced a certain amount of specialization into particular cell types, there is doubt whether they can be coaxed into the full range of human cells. In addition, adult stem cells are more difficult to isolate and grow in the laboratory.

Some supporters of adult stem cell research ignore these problems. White House Deputy Chief of Staff Karl Rove went as far as to claim that adult stem cells are more promising than embryonic stem cells.⁹ To make this case, opponents of hES cell research exaggerate the successes of adult and cord blood stem cells, claiming that these stem cells have been used to treat 65 different diseases. However, a recent analysis by noted stem-cell researchers Shane Smith, Steven Teitelbaum, and William Neaves determined that these stem cells have only been used to treat nine different diseases.¹⁰

Federal Funding Climate for Stem Cell Research

Federal funding for hES cell research is crucial to the success of the field. The federal government is the driving engine behind scientific research in the United States, and NIH is the primary agency by which the federal government conducts research to help “prevent, detect, diagnose, and treat diseases and disability.”¹¹ One of the main roles of the NIH is to conduct basic biomedical research and provide a foundation for developing new medical advances.¹²

“The reality is that the federal government, the National Institutes of Health, is the funding that drives basic research and research into new therapies in this country,” Dr. Thomson explains, “And if you exclude that, then you’re basically stuck.”¹³

In the 2006 fiscal year, NIH spent \$28.5 billion on biomedical research.¹⁴ The largest private funding source, the Howard Hughes Medical Institute, provided only about \$600 million.¹⁵ NIH has a unique ability to fund long-term, high risk research that has the potential to offer substantial medical benefits, such as deep brain stimulation and HIV/AIDS vaccines. NIH also has established structures for reviewing and regulating grants and provides a cohesive network of both research and researchers that encourages collaboration and limits research overlap.

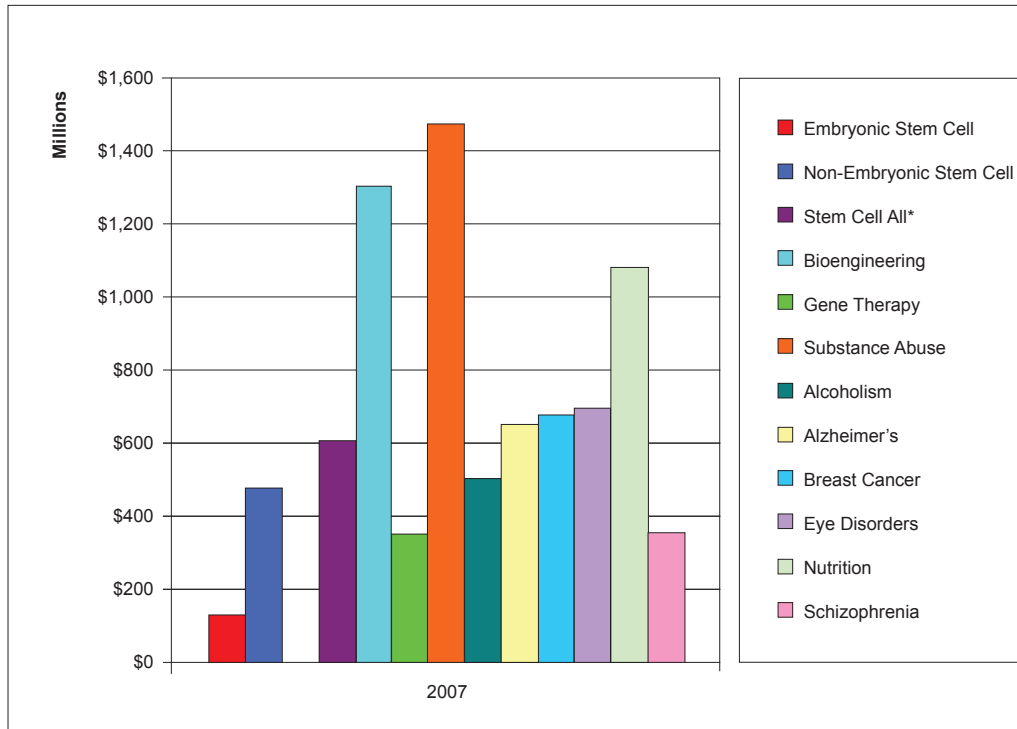
Despite the promise of stem cell research, federal funding is scarce. In 2007, NIH designated only \$608 million toward all types of stem cell research. This figure actually represents a decrease of funding from the 2005 and 2006 designations of \$609 million. While this decrease may not seem substantial, it is noteworthy that funding has remained relatively stagnant for the last 3 years despite major recent advances in embryonic stem cell research.



Funding for stem cell research has not reflected its promise to treat a whole host of diseases, since it receives similar amounts of funding as research into alcoholism, Alzheimer's disease and eye disorders, and less than 50% of the funding for bioengineering (see Figure 1).¹⁶

Figure 1

NIH funding to various areas of research in FY 2007



The lack of funding is even more striking for embryonic stem cell research, which receives less than a third of the funding as that of adult stem cell research (see Table 1). Of the \$608 million designated for stem cell research in 2007, only \$135 million was earmarked for embryonic stem cell research, while the remaining \$473 million went to non-embryonic stem cell research. Funding for embryonic stem cell research alone was less than half of funding for gene therapy. The conclusion is clear: the federal government is not adequately funding or supporting embryonic stem cell research.

Table 1

NIH Funding for Stem Cell Research (in millions)

Year	Embryonic Stem Cell Research	Non- Embryonic Stem Cell Research	All Stem Cell Research
2003	133	383	517
2004	113	439	553
2005	137	472	609
2006	135	474	609
2007	135	473	608



Lack of substantial federal funding has allowed other nations to catch up with American researchers. As scientists in other countries aggressively pursue stem cell research using the newest and most promising lines, there is significant concern about the diminishing U.S. dominance in the field. A recent study of embryonic stem cell research publications found that in 2002, about one-third of the ten articles published on embryonic stem cell research were from the U.S.; by 2004 that percentage had dropped to around a quarter of the 77 articles published.¹⁷

Furthermore, according to that same study, “forty-four newly derived human embryonic stem cell lines that are not approved for U.S. federal funding were used in (other) recent research.”¹⁸ While the U.S. is still the leading nation in embryonic stem cell research, this could change as American scientists pursue research in other countries, young U.S. scientists opt for other areas of research, and foreign scientists continue receiving substantial funding to work with newer stem cell lines.

Federal policy slows not only hES cell research but all types of stem cell research. The restrictive funding climate discourages scientists from entering the field and limits basic research. Worries over funding or possible restrictions on the research itself makes promising young scientists loathe to pursue stem cell research. Testifying before a Senate sub-committee, Dr. James Battey, Chair of the NIH Stem Cell Taskforce, stated, “Young people are now electing to stay away [from human embryonic stem cell research].”¹⁹ Dr. Elizabeth Nabel, Director of the National Heart, Lung and Blood Institute, agrees: “the restricted access [to embryonic stem cells] will hamper the NIH’s ability to recruit young scientists.”²⁰

The slowing of basic hES cell research also hurts other areas of stem cell research. Scientists believe that a lot that can be learned about non-embryonic stem cells from embryonic stem cells. “If we study the embryonic stem cells, we learn the basic science,” explains Dr. Thompson. “That knowledge is just as likely to be applied to adult stem cells as to the embryonic stem cells.”²¹

Researchers need the same skills and equipment to study both hES and adult stem cells. Slowing research in one area of stem cell research – particularly one that will help scientists understand the early stages of cell development – stymies the entire field.

State Funding Climate for Stem Cell Research

While the federal government has floundered, several states have worked to become leaders in stem cell research, providing both funding and political support. The day after President Bush vetoed legislation to expand federal funding eligibility to include new hES lines, Governor Schwarzenegger of California loaned \$150 million to the California Institute of Regenerative Medicine for stem cell research and Governor Blagojevich of Illinois promised \$5 million in additional funds for stem cell research.

To date, seven states have adopted measures that provide funding for stem cell research (see Table 2), and legislation and ballot initiatives have been proposed in many other states across



the country. The total promised funds for stem cell research are over \$3.65 billion, with the significant bulk of that money coming from California, which designated around \$3 billion for stem cell research, and from Wisconsin, which has designated approximately \$486.5 million.²²

State initiatives have been greeted with substantial enthusiasm, and correctly so. Some prominent scientists, such as Dr. Nabel, believe NIH has ceded leadership in the field²³ and now must take the back seat in one of the most promising areas of medical research.²⁴ Enthusiasm for the state initiatives has even prompted some politicians and political pundits to go so far as to question whether researchers need federal sources of funding.²⁵

Table 2

State Funding for Stem Cell Research through 2016 (in millions)

	Embryonic	Non-embryonic	General/unknown	Total
CA	0	0	3,000	3,000
CT	0	0	100	100
IL	4.4	5.4	5	14.8
MD	15	0	0	15
NJ	2	3	15	20
OH	0	19.5	0	19.5
WI	0	0	486.5	486.5

Though states have performed admirably in their support for stem cell research, the faith in the capacity of states to fill the federal research gap is not well founded. States have significantly less money to devote to stem cell research than the federal government. The NIH budget for 2006, for example, is around a quarter of the entire state budget for California.²⁶

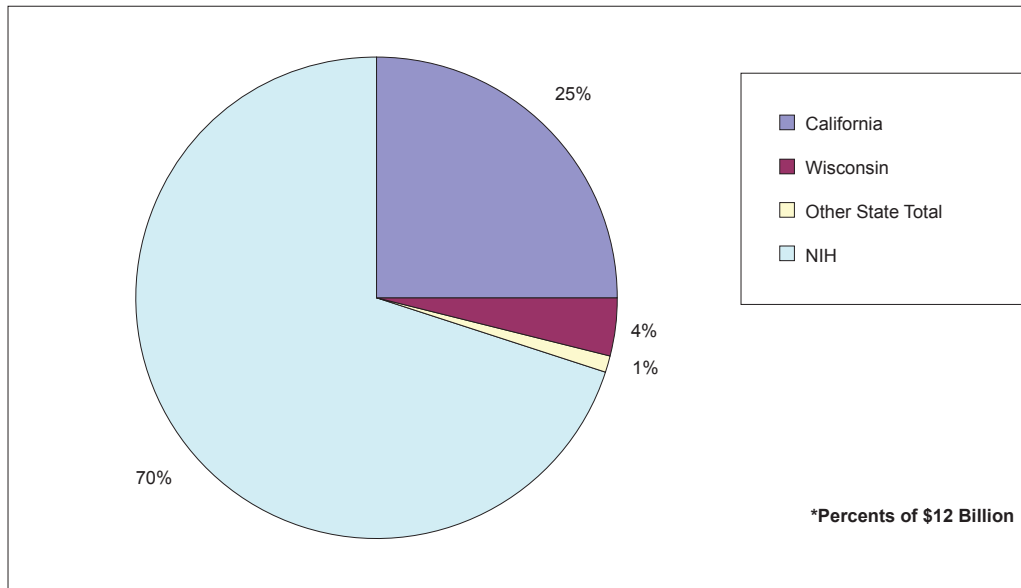
Moreover, state funds are specially allocated monies that are not renewed every year like the NIH budget, making them a less reliable source of funding. Worse still, the promised money for most state stem cell initiatives will be paid out over an extended period of time, usually five to ten years, so the impressive initial figures amount to less substantial yearly funding. Case in point: Connecticut has promised to spend \$100 million on stem cell research, but this amount will be paid out over ten years.

Although state funding accounts for 30% of all designated funds through 2016 (see Figure 2), it encompasses only 10% of allocated public spending on stem cell research to date (see Figure 3). Even in 2006, with state funding at its peak to date, state funds account for only 15% of total funds. And the total amount of public spending in 2006 on stem cell research, both in the states and by NIH, is roughly equal to the amount NIH alone spent on breast cancer or eye disorders in that same year. States simply cannot match the funding power of NIH.



Figure 2

Total Funds for Stem Cell Research by NIH and States (2003-2016)

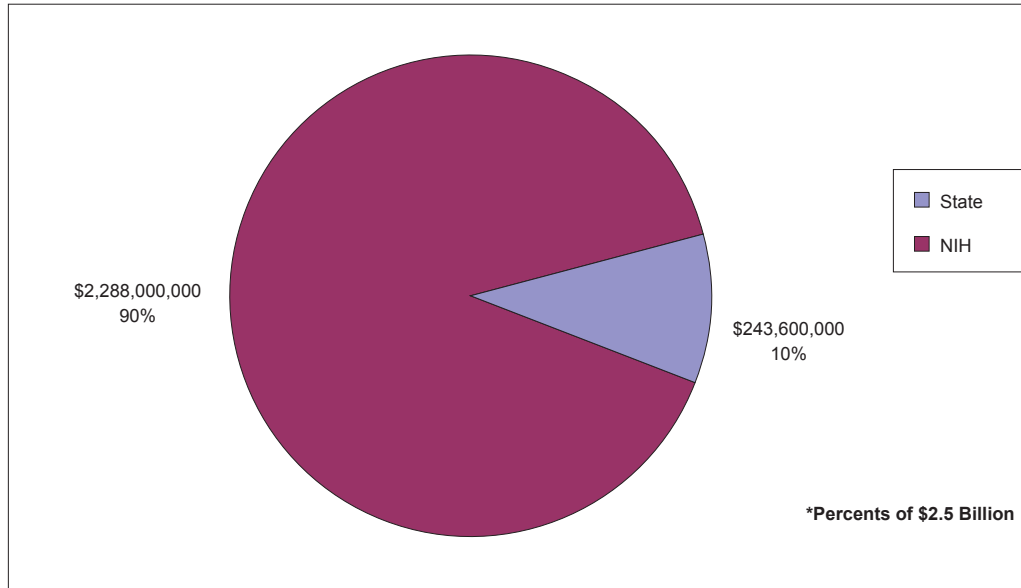


Of course, state funding will likely increase over time. Currently, state funding largely refers to California and Wisconsin, which provide 97% of promised state funds. As the federal government continues its restrictive policy and the research advances, however, more and more states are likely to begin funding stem cell research. These predictions for future state funding are therefore likely to be conservative, since they do not include any currently debated or suggested state stem cell initiatives, such as gubernatorial candidate Eliot Spitzer's \$1 billion stem cell proposal for New York. Of course, these estimates also assume that NIH funding will be held constant at the 2007 designation of \$608 million for the remaining nine years, which is unlikely as additional funding will probably be allocated as scientists further demonstrate the potential of this promising research.



Figure 3

Total spent on all stem cell research by the NIH and states (FY2003-FY2006)



Importance of Federal Funds for Stem Cell Research

Even with the likely increase in state funding for stem cell research, the increasing reliance on states to fund basic stem cell research is troubling because money is wasted building new facilities, regulation is less uniform, and basic research receives less funding. States are prohibited from using existing facilities or equipment that were built or purchased with federal money for research on federally ineligible stem cell lines.

Rather, they must recreate the research wheel, building new facilities, training researchers, purchasing new equipment, and creating new review boards and oversight committees. Moreover, the proliferation of different regulatory standards and competition between states, which often spurs new clinical applications, can have deleterious effects on basic research. And state funding by its very nature is not designed to be used for long-term, basic research – the very research necessary to compensate for the federal government’s restrictive funding policy.

The vast majority of allocated state spending on stem cell research goes to creating new infrastructure for research and attracting and training scientists. To date, the bulk of the Wisconsin, Ohio, and New Jersey funds have been spent on building new facilities and establishing research institutions. New Jersey, for instance, will spend 75% of its stem cell research funds on equipment and the construction of a stem cell research institute.²⁷

Further, all of the 2006 California funding went to “multi-year training grants to increase the number of young investigators (pre-doctoral, post-doctoral and clinical fellows) with the



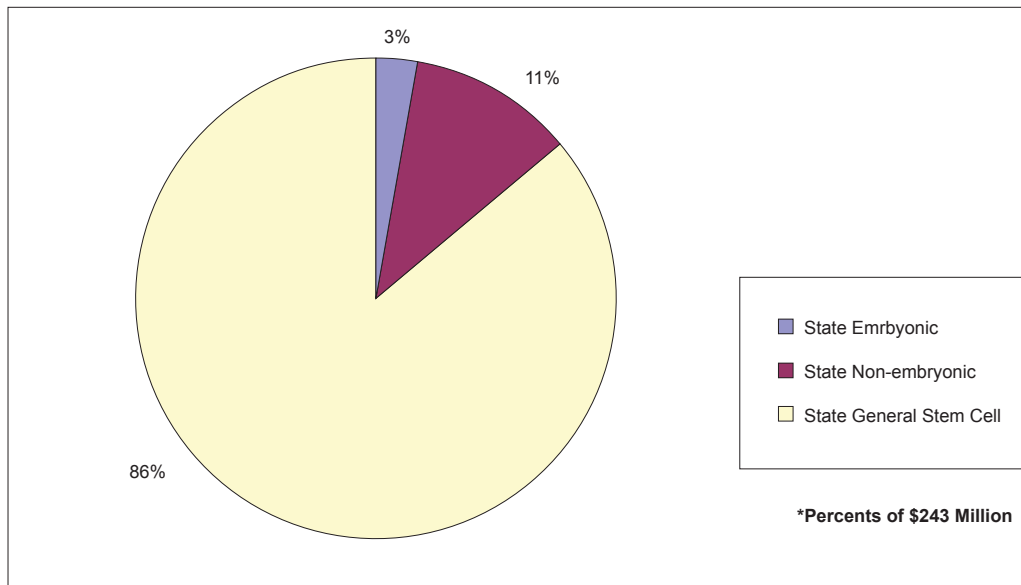
technical and academic skills necessary to conduct basic and applied stem cell research.”²⁸ In fact, 86% of allocated state funds have gone to building infrastructure, training scientists, and attracting researchers to the state (see Figure 4).

These funds are directed toward creating the infrastructure and technical expertise for stem cell research because the restrictive federal policy prevents the use of existing infrastructure. State funding has been used to build research infrastructure and improve human capital, leaving little money to substantially support hES cell research that is ineligible for federal funding.

Even those state funds allocated for actual stem cell research do not substantively address federal funding shortcomings. States explicitly fund stem cell research with a goal to achieve not only medical benefits, but industrial and economic ones as well, and thus naturally gravitate toward the most promising areas of stem cell research. The result: rather than funding basic hES cell research, states have allocated most of their research funding to research using more readily and medically applicable adult stem cells.

In general, states have allocated almost four times more money to non-embryonic stem cell research as to embryonic stem cell research. State allocations for embryonic stem cell research – be they institutions or individual grants – represent only 3% of total state funding for stem cell research (see Figure 4).

Figure 4
State Funding For Stem Cell Research by Type²⁹





Besides the issue of cost, shifting the funding burden to states for stem cell research will have a deleterious effect on the regulation of the science. As bioethicist George Annas points out, the shift away from federal funding toward states, “indicates the erosion of the basic idea that the federal government should be the primary funding – and regulatory – source for very innovative research.”³⁰

Indeed, states cannot provide the uniform and rigorous regulation that allows research to proceed the most quickly, effectively, and ethically. Already there are concerns among advocates and scientists that single-state policies will give rise to a ‘patchwork quilt’³¹ of research and regulation, as well as research overlap due to the lack of federal coordination of research funding. Dr. Douglas Melton, co-director of the Stem Cell Institute and Harvard University, notes “In the long term, I don’t think it’s a good idea to have individual states trying to mount efforts which are going to be more piecemeal, less effective and take more time than a federal effort.”³²

States will be further slowed by the need to create new review boards and guidelines in each state before any funding can be used.³³ This process is not just time consuming, but troublesome: the lack of general oversight provided by the NIH could lead to divergent research guidelines and standards.

Primarily relying on state funding for stem cell research also causes problems due to competition between states. States naturally compete with each other for the top scientists and private research companies in order to use their money most efficiently. Funding reflects this reality; in 2006, Wisconsin Gov. Jim Doyle authorized \$5 million of state funds to be spent on recruiting stem cell research companies to the state.³⁴

While competition between states is valuable in quickly developing clinical applications for research in its later stages, the competitive jostling with one another could actually hinder advances in basic research.³⁵ States may engage in similar research projects in a “race” to successful completion, which engenders creativity but also leads to overlap and a less strategic overall use of state funds. The states will be increasingly tempted to focus on immediately applicable research in order to attract more scientists and build political support for the research, further hampering important, but less obviously successful, basic research.

To date, allocated state funding has not significantly improved the weaknesses of the current federal funding policy for hES cell research. On the whole, embryonic stem cell research receives little public funding from both the state and federal governments. Allocated state funding exclusively for embryonic research represents only 0.3% of all state and federal funding for stem cell research (see Figure 5).

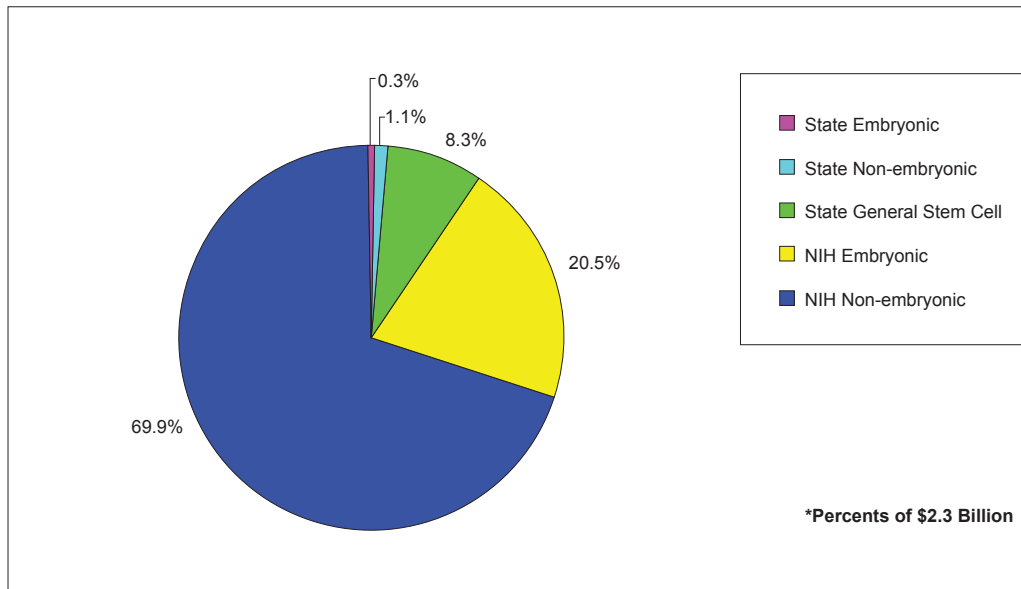
Furthermore, total public embryonic stem cell research funding, when federal funding for research on the older, possibly contaminated lines is included, accounts for only 20.8% of total stem cell research funding. It is important to note that these figures do not include promised funds



that have yet to be spent. Depending on the quality of research proposals, large amounts of this promised money could go to human embryonic stem cell research that is ineligible for federal funding. So far, however, the general pattern of state grants awarded to specific research projects has been directed to non-embryonic stem cell research.³⁶

Figure 5

Total Funding For Stem Cell Research by the NIH and States (FY2003-FY2006)



Conclusions and Recommendations

States recognize the importance of federal funding to drive basic research, provide regulatory frameworks, and standardize research practices. When Congress was considering the Stem Cell Research Enhancement Act this July, Gov. Doyle of Wisconsin was joined by the governors from Oregon, Iowa, Illinois, New Jersey, New Mexico, Michigan, and Delaware in urging the passage of legislation to help the science move forward.³⁷

Lack of federal funding hinders research at every level: discouraging future scientists from entering the field; forcing states to spend additional money on new equipment, new facilities and training scientists; causing preventable overlap in state research projects; and forcing federally funded researchers to use inferior tools in the race towards life-saving cures. State funding cannot solve these problems alone.

State efforts have been admirable, but it is unfair and unwise to expect them to fund basic research, create uniform regulations, or pursue risky and time-consuming, but promising, research areas. Restrictive federal policy has forced states to spend the majority of their money on duplicate research infrastructure and training instead of actual meaningful research. Competition between states and less available funds also means the states are unable to focus on basic embryonic stem cell research for which federal funding would generally be used.



Despite significant efforts by the states to secure funding and support stem cell research, allocated state funds for embryonic stem cell research are only three-tenths of a percent of total public funding for stem cell research. The need for a federal funding policy that is more supportive of both stem cell research and state efforts to fund that research is clear.

We recommend several actions at both the state and federal level:

- As federal action appears unlikely in the near term, states should seek to adopt similar guidelines to standardize policies and practices in the field. States have already begun this by adopting provisions similar to those proposed in the National Academies Guidelines for Human Embryonic Stem Cell Research.
- States should continue to provide funding to encourage interest in hES cell research and provide training for young scientists.
- States should pay greater attention to the allocation of funding, working to ensure that hES cell research is adequately funded.
- The federal government should allow federal funding for research using additional stem cell lines. It can start by passing the Stem Cell Research Enhancement Act.
- The federal government should create research guidelines and standards similar to those outlined by the National Academies.
- The federal government should ensure that funding is more equally divided between hES cell and adult stem cell research, and provide more funding for basic stem cell research.
- The federal government should show greater support for hES cell research in order to encourage scientists to enter the field.

Funding for embryonic stem cell research cannot come solely from the states. The NIH will be needed to fulfill its role of funding long term basic research and creating unified oversight and regulatory systems. We cannot only rely on limited and targeted state funding. States will need to continue to fund the research, but a more permissive federal-funding policy will allow the states to focus on more immediately realizable areas of stem cell research. The most effective science is a product of cooperation and collaboration, not simply between those in the scientific community, but also between those funding this research at both the state and federal level.



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- ³³ For example, Maryland passed a law in April 2006 for \$15 million to be awarded in stem cell grants. The target date for awarding grants was planned for July 1, 2006. However, the Maryland Stem Cell Research Commission members were not announced until July 6th 2006. These members must then vote to appoint a separate scientific peer review committee to evaluate and rank research proposals, before proposals can even begin to be considered. California also spent months debating and creating ethical guidelines and policies to oversee the grant selection process.
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- ³⁵ Owen-Smith, J and J. McCormick "An internal gap in human stem cell research". *Nature Biotechnology*. 24: 4. (April 2006). 392
- ³⁶ Only 10 out of the 27 research grants in New Jersey and Illinois involve embryonic stem cells.
- ³⁷ "Eight Governors Urge Passage of Critical Stem Cell Legislation." *Office of the Governor. Jim Doyle* 18 July 2006. <http://www.wisgov.state.wi.us/journal_media_detail.asp?locid=19&prid=2145> 22 July, 2006.>