## Featured Article

# PROPOSITION 71: HOW THE DEBATE IN CALIFORNIA OPENED UP A WIDER RANGE OF DISCUSSION ON THE FUTURE OF STEM CELL RESEARCH IN AMERICA

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**Proposition 71, an initiative that was passed by California voters in 2004, created a system of funding for stem cell research in the state of California. During that time, the use of federal money to fund such research was banned by executive order of former President George W. Bush. Proposition 71 created the California Institute of Regenerative Medicine (CIRM) to distribute funds to research institutions in California. To oversee this distribution, the Independent Citizens Oversight Committee (ICOC) was created. This paper examines the issues surrounding Prop 71 before its passage. Counter to the image largerly presented by the media, the opponents of Prop 71 were not solely religious conservatives. Many opponents focused on the large amounts of money involved and questioned the potential effectiveness of the ICOC. Additionally, there were concerns that supporters of Prop 71 exaggerated the benefits of stem cell research to the state of California. With the election of Barack Obama however, many foresee a change in the federal government's attitude towards stem cell research. A lifting of the previous ban on federal funding will provide a further argument against the infrastructure created by Prop 71. Many now question the need for the California program and want to do away with it unless major reforms are enacted.**

When people think of stem cells, they typically think of the debate between science and religion. On the one hand there are the supporters of stem cell research, who say it could cure many terrible diseases. On the other there is the opposition, who claim that stem cell research requires the indiscriminate taking of human life and is immoral. This classical debate was turned on its head in 2004: in November of that year, California voters took to the polls to decide whether to create a statewide program to fund stem cell research. The campaign leading up to that decision encompassed a range of arguments, both for and against. I shall examine how the issues surrounding the status of stem cell research in the US were played out in this experiment in California, and how they reflected at that time on stem cell research at a national level. Additionally, I shall look at the current state of California's program, now four years after its inception, as well as its future under the new president.

Stem cells are a class of unspecialized cells in the human body that have the ability, in varying degrees, to develop into diverse types of tissues. There are two main classes of stem cells: embryonic stem cells and adult stem cells. Embryonic stem cells arise from the very earliest stage of the human embryo and are prized in research because they are pluripotent, meaning they can develop into almost any type of cell in the human body. Adult stem cells are cells that have reached later stages of development, and can be obtained from fetuses through adults. Unlike embryonic stem cells, adult stem cells are only multipotent, meaning the tissue types they can differentiate into are limited. For example, hematopoietic adult stem cells can only develop into different blood tissues.[1]

The controversy over stem cell research surrounds the use of embryonic stem cells. Embryonic stem cells are typically obtained through two methods. The first method is in vitro fertilization (IFV). IFV is the fertilization of an egg with a sperm in a laboratory setting and is an infertility treatment. The process, however, usually creates more embryos than needed, and these are sometimes donated to research. The second method is somatic cell nuclear transfer (SCNT), wherein a somatic cell nucleus is implanted in an enucleated egg and allowed to develop. In both cases the embryo must be destroyed to harvest the stem cells. Individuals who believe that all stages of human development constitute a life view this as a serious problem. Additionally, SCNT is -in the technical sense- a cloning technique, and brings with it the controversial prospect of human cloning.[1]

In 2001, President Bush banned the future use of federal funds for stem cell research. Federal funds would only be available for research on stem cell lines (cells grown in culture and sustained in laboratory conditions) existing as of August 9th, 2001. Although research was not banned outright, several limitations were inherent within the policy. Researchers complained that the number of stem cell lines was insufficient, some contaminated, and that for successful research, new lines were needed to provide more genetic variation.[2]

The California program was thus a response to the freeze on federal research funding. The program was put forward via the 2004 ballot initiative, Proposition 71

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(Prop 71), which set aside $3 billion dollars in state funds over ten years for stem cell research in California (With interest, the total estimated cost to the state was $6 billion). Additionally, Prop 71 created the California Institute of Regenerative Medicine (CIRM) to handle the distribution of these funds to research institutions in California.[3] To govern the institute, the Independent Citizens Oversight committee (ICOC) was established. The ICOC was a 29-member committee consisting of "patient advocates, research institutes, and the business and general community of California."[4] Additionally, and possibly most contentiously, Prop 71 amended the state constitution of California to make stem cell research a protected right.[3]

Supporters of Prop 71 encompassed an array of scientists, academics, and social liberals. The most frequently used argument in favor of the proposition was the potential of the research to cure multiple diseases. An oft-quoted figure by proponents was that 70 diseases had the potential to be cured by stem cell research in the future. This number was most strongly endorsed by "strategic participants, including many of its political and institutional supporters, patients and their families/friends, and patient advocacy groups."[5] Although outlining some of the most widespread arguments surrounding Prop 71, the summary offered by the attorney general to voters did not cite the 70 diseases figure, it mentions the potential to cure "cancer, heart disease, diabetes, Alzheimer's, Parkinson's, HIV/ AIDS, multiple sclerosis, lung diseases, and spinal injuries."[3]

A smaller scientific community sought to downplay the exaggerated claims of some supporters. However, it was not until after passage of Prop 71 that these voices were able to come to the forefront, as Lysaght et. al note:

"More cautious voices emerged in the discourse following the passage of Proposition 71 which expressed reservations about raising public expectations about short-term therapeutic outcomes and warned against 'overselling' the science... Dr. Stuart Newman, from the New York Medical College, stated that 'from the way that the campaign was conducted...[it is clear that] the people who were funding the ballot initiative often didn't have scruples in how... they were portraying the promise of the technology.' "[6]

Thus, from a scientific standpoint, California voters were lead to believe that Prop 71 would open the gateway to cures for many debilitating diseases diseases. Experts in the field, however, note that we are not close yet to being able to apply stem cell therapies to humans without many additional years of research.[6] The curative potential of stem cells was clearly overstated by Prop 71 supporters. Considering the controversy surrounding both stem cells and Prop 71, it is unsurprising that supporters would resort to exaggerated claims. Yet, it is detrimental or both society at large and the scientific community for these exaggerated claims to be disseminated. If the public does not see the results it was promised, the resulting backlash against stem cell research would limit future funding opportunities.

Supporters of Prop 71 also claimed it would benefit California economically. This line of argument was also marked by hyperbole,

"It was argued, particularly by proponents of the proposition...that the initiative would yield substantial economic benefits to the state of California, both in terms of direct taxation revenues and royalty income and directly 'building an enormous industry in California, creating countless new jobs and driving our economic engine.' " [6]

Supporters cited, "5,000 to 22,000 new jobs in California per year...spending would generate $240 million in income and sales tax revenue...$537 million to $1.1 billion from patents and royalties...reduced health care costs of $3.4 billion to $6.9 billion annually."[7] The health care savings were especially touted by supporters as being one of the greatest economic benefits of Prop 71. What should be apparent to the discerning observer, however, is that many of these economic benefits depend on assumptions that the program would produce new therapies both successfully and in a timely manner. Yet, as mentioned above, many of the therapeutic benefits of stem cells will not be realized for some time.

Thus, Prop 71 was sold to California voters as a being scientifically, medically, and economically beneficial. The opponents of Prop 71 were aware of this, and it is clear that they were not just from the religious right. They encompassed a broad range of people, including some groups who stem cell supporters may have believed to be their allies.

Religious and social conservatives still made up the core of the Prop 71 opposition. This group believes that destruction of a human embryo is the taking of a human life. Carol Hogan, of the California Catholic Conference in Sacramento was quoted saying that: "you can't take a stem cell out of an embryo without killing, and the embryo is the earliest form of human life."[6]

Although there is a scientific component in the "humanity" of an embryo debate, this argument divides mainly along ingrained religious beliefs. What are more important to the discussion of Prop 71 and to the future of stem cell research in this country are the other arguments of the opposition movement. First, there was the economic opposition. The costs of funding stem cell research had been little debated in the public arena. However, with a cost of $6 billion to the taxpayers, Prop 71 brought the economic component to the forefront. Much of the debate

surrounded the idea that public money was benefiting private companies at almost no cost, without assurance that taxpayers would see viable returns on their investments.[6] This concern grew out of the fact that the only program designed to govern the outlaying of the $3 billion in grants was the ICOC. There was the worry that the ICOC was not as independent as it was claimed to be, with business executives, university researchers, and disease group advocates making up much of its roster.[8] While it may be cynical to say that all the members of the committee would be self-serving, it is clear that there were conflicts of interest. Vested interests pose serious ethical concerns, especially when the individuals involved (i.e. scientists and industry executives) stand to benefit from the proposed spending. In California and across the nation, balancing interests of experts, private investors, and impartial parties, will be key in creating a successful stem cell research program.

Yet another line of argument was the ethics surrounding egg donation, since, as noted above, SCNT requires eggs. A group known as the Pro-Choice Alliance Against Prop 71 spearheaded this issue. The group, "includes university professors, women's health activists and feminists and is backed by the California Nurses Association in Oakland, the National Women's Health Network in Washington D.C and Our Bodies Ourselves, the Boston-based women's health advocacy group that produces the popular health-book series."[9] While the group supports stem cell research itself, it did not support Prop 71 because of fears about the exploitation of egg donors,

"Opponents of Prop 71 say the ethical guidelines are hazy. For instance, California law currently calls for 'reasonable' reimbursement of expenses to egg donors while Prop 71 calls for 'permitting reimbursement of expenses.' Beeson [a medical sociologist at California State University at Hayward and Prop 71 opponent] says it is critical to retain the terminology 'reasonable' so women aren't driven by large cash payments to give up their eggs, or otherwise be exploited."[9]

The concerns about exploitation may be overstated, but it remains a point of contention for some. Nationally, there is currently much debate about egg donation. In 2005, the National Academy of Sciences issued a new set of ethical guidelines, one of which limited compensation of egg donors to just the costs of the harvesting procedure. But many now question why there is not greater compensation for egg donation, since donation of other tissue, such as corneas, is compensated.[10] Egg harvesting is a particularly invasive and stressful procedure for donors. However, raising compensation also creates concerns about the selling of organs for profit. The potential compensation can be quite substantial, and may be an inducement to impoverished women, who would be risking their health so that they may provide for themselves. With the imminent release of federal funds for stem cell research, egg donation may become a much more publicized issue and the issue of compensation will become more contentious.

Despite the opposition, voters passed Proposition 71 in November 2004. A little over a year after the passage, in January 2006, the Center for Genetics and Society issued a "progress report" on the California stem cell program. Among the numerous criticisms levied on the program, one was that conflicts of interest within the ICOC remained: "The relationship between the ICOC and the institutions it funds can be seen in the first round of training grants announced on September 9, 2005. Of the 16 institutions that were awarded almost $40 million, 14 are represented on the ICOC. Viewed another way, all but two of the 17 ICOC members affiliated with an institution eligible for this round of funding saw their institutions receive grants."[11] Additionally, there was concern on the return on investment for California voters,

"...some ICOC members have argued against policies that would provide a share of revenues to the state...In its deliberations to date on the kind of IP [intellectual property] agreements it will adopt, the leadership of the CIRM has consulted only a narrow range of stakeholders...Experts in public health, consumer and public interest groups, and critics of current policies have not been invited into the discussion in any meaningful way."[11]

It may seem unfair, however, to criticize the program after only one year. But four years have since passed, and new assessments of Prop 71 are emerging. As recently as November 2008, Jesse Reynolds, Director of the Project on Biotechnology in the Public Interest at the Center for Genetics and Society, gave testimony before the Little Hoover Commission on California State Government, a commission which evaluates the effectiveness of California's governmental programs. Among his concerns were that the ICOC was still rife with conflicts of interest. Additionally, CIRM was still funded by essentially unquestioned handouts of money from the government. Furthermore, the language on financial returns to the state of California via intellectual property rights remained vague.[12]

To its credit, CIRM has issued several reports assessing its own activities, including annual reports for 2006 and 2007. However, in September 2008, CIRM also issued a report assessing its economic impact, both current and future. Despite some lawsuits early on, which prevented CIRM from using federal monies in its grants, they claim to have now issued "over $614 million to 27 institutions."[13] In its report, CIRM concedes that many of its potential benefits will not be realized for some time, including tax and intellectual property revenue. There have been some concrete developments as well. A good ex-

ample is University of California, Davis, where, "the Stem Cell Program... has developed significantly, receiving over $100 million in grant approvals...allowing the program to develop new NIH free facilities, explore novel cell lines, and conduct high risk/ high impact studies and train new scientists."[13] Additionally, "faculty have expanded from 35 to over 100."[13]

Thus, after four years, the program's results have been mixed. Research infrastructure in California has clearly benefited, as can be seen by the developments at UC Davis. However, flaws in CIRM's infrastructure and oversight still exist. California must find a way to restructure the program, such as by addressing the conflict of interest issues at the IOC. Additionally, financial returns on the program continue to be slow in coming, as was expected. The program clearly requires more time, but it does not appear that the costs of the program, as it is currently structured, will be outweighed by the far off benefits.

A new challenge in the future of Prop 71, however, is that the new administration under Barack Obama may change the relationship between the federal government and stem cell research. "[Obama] has pledged to lift the Bush administration's restrictions on federal funding for stem cell research that uses embryos created but not used for reproductive purposes, and aides have suggested that he'll do this by executive order immediately after taking office."[14]

What does this mean for the California program? It is mostly speculation now, but many are pessimistic. The San Fransisco Chronicle notes that, "Now that a federal policy shift seems imminent, however, watchdog groups are questioning whether California taxpayers should be laying out millions of dollars for stem cell research every year while the state's budget deficit ... is forcing painful spending cutbacks." The financial crisis may further prevent the allocation of federal funding towards stem cell researchers even if the current federal policy is changed.[15] Thus, the California program's future is uncertain, but not doomed. It will depend on the state of the nation's economy, the state of California's budget, and whether or not the numerous flaws in the program's structure are ever addressed. Nonetheless, when federal money is opened up to stem cell research, the program will be forced to present tangible results to merit continuation.

The most important lesson to be learned from Prop 71 is that the stem cell debate can potentially encompass more than just scientists versus the religious right. The Prop 71 debate showed that there are also other substantive ethical and economic issues to be addressed when dealing with the financing of stem cell research, whether on a state or federal level. Unfortunately these issues are usually under-publicized. The California experience may offer important insights into how issues of scientific progress, finances, and ethics may play out on a national scale as President Obama brings the issue of stem cells back into the spotlight.

**Editors Update:** On March 9, 2009 President Obama signed an Executive Order lifting the ban of federal funding for human embryonic stem cell line research. See the news brief in this issue for more information.

## References


1. Hayes, R. (2006). Stem cells and public policy. New York: The Century Foundation.
2. Cohen, C. B. (2004).Stem cell research in the U.S. after the president's speech of august 2001. Kennedy Institute of Ethics Journal. 97-114.
3. California Office of the Attorney General. (2004). Proposition 71:Stem cell research. funding. bonds. initiative constitutional amendment and statute (68-73).
4. Trounson, A., Klein, R., & Murphy, R. (2008). Stem cell research in California: The game is on. Cell. 132, 522-524.
5. Hall, S.S. (2006).Stem cells: A status report. Hastings Center Report. 16-22.
6. Lysaght, T., Ankeny, R. A., & Kerridge, I (2006). The scope of public dis course surrounding proposition 71: Looking beyond the moral status of the embryo. Bioethical Inquiry. 3, 109-119.
7. Mecoy, L. (2004, September 15). Stem cell backers cite savings - Study released by Prop. 71 supporters says it will bring economic, health benefits. The Sacramento Bee, Retrieved November 30, 2008, from http://docs.newsbank.com/openurl?ctx_ver=z39.88-2004&rft_id=info:sid/iw.newsbank.com:AWNB:SCBB&rft_val_format=info:ofi/fmt:kev:mtx:ctx&rft_dat=10524507B08D150F&svc_dat=InfoWeb:aggregated5&req_dat=0D0CB57AB53DF815
8. Winickoff, D. (2004, October 17). Prop. 71 a risky experiment in squan deringpublic monies. San Francisco Chronicle, Retrieved November 30, 2008, from http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2004/10/17/ING9T995C41.DTL&hw=prop+71+risky+experiment&sn=001&sc=1000
9. Vesely, R. (2004, October 26). [Weblog] California's prop 71. divides de bate on stem cells. Women's eNews. Retrieved November 29, 2008, from http://www.womensenews.org/article.cfm/dyn/aid/2042
10. Barnum, A. (2005). Stem cell scientists debate finer points of research ethics: Should egg donors be paid? When are animal studies ok?. San Francisco Chronicle, Retrieved December 3, 2008, from http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2005/06/26/MNG1VDF5D91.DTL
11. Reynolds, J., & Darnovsky, M. (2006). The california stem cell program at one year: A progress report. Oakland: The Center for Genetics and Society.
12. Reynolds, J. (2008, November 20). Submitted testimony concerning the California stem cell research program. Retrieved November 29, 2008, from Center for Genetics and Society Web site: http://www.geneticsandsociety.org/article.php?id=4386
13. Baker, L., & Deal, B. (2008). CIRM - Interim economic impact review. Menlo Park: Analysis Group.
14. Center for Genetics and Society (2008, November 12). Obama and the new biopolitical challenge. Retrieved November 30, 2008, from Center for Genetics and Society Web site: http://www.geneticsandsociety.org/article.php?id=4372
15. Tansey, B. (2008, November 29). Obama policy a lift for stem cell re searchers. San Francisco Chronicle, Retrieved November 30, 2008, from http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2008/11/29/MN76147PBR.DTL&hw=Obama+policy+lift+for+stem+cell+researchers&sn=001&sc=1000