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CIRM: A Review of California's Political Experiment

Proposition 71 brought an unseen legislation before the California Congress. It proposed to set aside $3 billion over the next 10 years to further stem cell research. Scientific institution often faced problems of finding money to support research especially when the studies were controversial to religious groups or other organizations. Typically, research is funded through the National Institute for Health but the group can come under scrutiny if it gives money to political hot topics like stem cell research. California made legislative history by passing Proposition 71 in 2004 by taking research into the state's hands and deciding to spend the taxpayer's money towards stem cell studies and regenerative medicine. After seven years, the public can now look back on the California Institute of Regenerative Medicine (CIRM) and review its policies, success, and possible ways to improve.

The stem cell research institutions often have problems getting money because of the controversial nature of their studies. The federal government typically issues funds towards scientific research. For example, the Dickey Amendment prevented money from going to embryonic stem cell research. Studies have been done with only adult human stem cells but these cells is limited since they can only transform into a specific type of cell. However,

embryonic stem cells can turn into many types of cells in the body, so they have more potential for helping find treatment for diseases. Therefore, it was worthwhile for facilities to find a better way to getting funding for their projects without having to court the NIH and limit their studies to fit government standards. Before Prop 71, there was a similar statute that set aside money for research that was rejected in the state election. After this setback, Robert Klein saw the need for funding for stem cell research and became the driving force behind Prop 71. His son has type 1 diabetes motivated Klein to fight for stem cell research in thehopes to find a therapy for his son's illness and other diseases. The campaign for the passage of Prop 71 was financed by many prominent individuals like Bill Gates, Gordon Gund, and Williams Bowes Jr.. In total the campaign raised around $25 million to promote the Prop 71. The YES to 71 campaign was very successful and the statute was passed on a vote of 59.05 to 40.95 percent. This decisive victory put Prop 71 in action and the Constitution of California was amended to allow the state to fund stem cell and other biomedical research. The statute planned to give $3 billion over the next ten years to stem cell institutions and other facilities. It also created theThe CIRM to decide where that money should go and make sure the investments were being put to good use.

The CIRM is now the second largest funding of research in the United States other than the federal government. It is comprised of several governing committees, which represent the top experts in the biomedical research field. The IOCC has certain requirements and regulations of who can be on the

committees in order to maintain California research facilities' best interests. The CIRM is currently under the supervision of Klein who has thus far had a lot of success navigating an uncharted area of state funded research. The CIRM is currently funding 37 research facilities and having success to promoting new embryonic stem cell research. It strives to give researchers the ability to find new information about the potential of stem cells so that the studies will hopefully bring new treatments for damage caused by injuries or disease. thetheThethetheThetheWith theis ambitious mission, the organization created a new role for itself in the scientific community and has brought about many successful projects.

The potential gain of stem cell therapies far outweighs the initial cost of $300 million per year. For example, a theoretical therapy for type 1 diabetes has the ability to give back in many ways. The treatment would introduce cells that could sense glucose and release insulin. If the body did not reject the cellseo, then the patient would be essentially cured of diabetes. This therapy would eliminate the cost of medication and stress on the family, increase the patient's life, and improve the quality of life. From the individual patient perspective, the therapy is well worth the investment of the CIRM. Also from a larger perspective of the nation's economy, the cost of taking care of the sick would significantly reduced, the resources used for the sick would lessen, and the productivity of the workers would also increase. From all viewpoints, the theoretical therapy has a lot of payoffs. The journey to reach this level of treatment will take years. However, the CIRM "help[s] by shortening the time

that elapses before the treatment becomes available". (Proposition 71) By giving the facilities the funding to perform the research, the scientists can go at a much faster pace comparable to the rate at of other researchers in other countries. "CIRM plays a critical role by funding research from the basic discovery phase through the research to develop therapeutic candidates and the preclinical studies to help assure that the candidate approach is safe for patients in early phase clinical trials," said Jonathan Thomas, Chair of the CIRM governing board. (CIRM Approves..) Funding research for new therapies can not only be good for the patient but also for the state.

If stem cell therapy were to be successful, the payoffs would be tremendous to the state's economy. Reviews of the CIRM's possible impact on the state's healthcare and economy have been very favorable. The Analysis Group did an extrapolation to see just how much the program could benefit California. In a state of limited therapeutic success for CIRM funded facilities, the government still comes out ahead and profits from its initial investment. The assessment calculated the lowest possible outcome for the program. It accounted only 1 percent reduction in healthcare costs, 2.5 percent growth in the

Table 2.1
Total Program Costs and Benefits – Case 1: Limited Therapeutic Success
($ Millions)

	Phase 1 Years 1-5	Phase 2 Years 6-14	Phase 3 Years 15-35	Total
Economic Costs to State Budget	$56	$1,289	$4,010	$5,355
Economic Benefits to State Budget				
1) Tax revenues from Proposition 71 direct spending	73	167	-	240
2) Tax revenues from 2.5% increase in life sciences activity	54	355	1,796	2,206
3) Cost savings from 1% reduction in State spending on 6 conditions	-	382	3,062	3,444
4) Royalty revenues using 2% royalty rate	-	10	527	537
Total	**127**	**914**	**5,385**	**6,426**
Percent of Total Costs	***227%***	***71%***	***134%***	***120%***
Additional Benefits to Californians Not Included in State Budget*				
Health care cost savings from 1% cost reductions	-	**1,136**	**8,043**	**9,180**
Percent of Total Costs	*0%*	*88%*	*201%*	*171%*
Estimated Jobs Created (One job for one year = one job year)				
Job years from Proposition 71 direct spending	14,272	33,209		47,480
Job years from Increase in life sciences activity	11,967	67,732	233,148	312,847
Total	26,239	100,940	233,148	360,328

** These are savings from the reduction in direct spending and lost work time on the 6 conditions that are not included in the State budget but benefit*

baseline life sciences industry, and a 2 percent royalty rate. The program would still generate 120 percent profit from the initial investment. the(Economic Impact) CIRM helps the economy by reducing the amount of costs for extensive long term treatment, increasing the amounts of jobs in the biotechnology and life sciences industries, and increases the number of treatment patents.In this economy, it is difficult for many people to find jobs. However, tThe CIRM helps the biomedical field expand and adds an average of 5,200 to 11,000 jobs per year. At maximum level of therapeutic success, the payoff from the cost of the program to the benefits is 750 percent. (Economic Impact) With such a lucrative business plan and profitable outlook, it is likely that other states will look into adding funding for scientific research. The CIRM has numerous benefits that outweigh the initial investments into the program, and it makes it worthwhile for California to continue supporting the organization.

Even though the CIRM had contributed greatly to the scientific community, some critics point out flaws in the organization's policies and promises. When Prop 71 was instated and the CIRM was founded, many promises were made to the Californian people like cures for Alzheimer's, Parkinson's, diabetes, and spinal paralysis. However research is slow in those areas and sometimes the facilities doing the work cannot afford to continue the stem cell research. This was the case for Geron, a well-known research company in California. In November, the company announced that it would not pursue anymore stem cell research to look for spinal paralysis treatment due to financial reasons. Even though CIRM provided them a $6.4 million award for the

studies, Geron found that the stem cell therapy was not profitable in the long term. Some critics point out disappoint of the patients who were hopeful that they make walk again. The study already got permission for the FDA to inject patients with stem cells that would repair the injured spinal tissue; however, the company still halted any more progress. Over the years, Geron had been criticized for many large promises. For the failure of the company to continue the research, CIRM was criticized for not upholding standards for its loans. Geron's trials had only scored a 66 out 100 on CIRM's evaluation due to missing information of the possible results but CIRM still gave the facility a significant loan. (California Stem Cell Agency)

There are more critics of the CIRM for not making any funding available for larger companies who also are interested in pursuing stem cell and other biomedical research. Currently, more than seven percent of CIRM's money goes to companies. (Science 10) However, it's a small amount compared to the funding for university facilities. "Several California biotech leaders say they have been frustrated by their interactions with CIRM." (CIRM the Good...) A difficult application and selection process can discourage other companies from trying to apply for grants from the CIRM. Chris Arriess, the chief operating officer of California Stem Cell Inc. blames it on "a lack of recognition that it takes a company to actually take a treatment forward from the bench top into the clinic". (CIRM the Good..) According to critics, more companies should be receiving funding to make the newfound therapies available to he public. The more money the company has to spend on trials and testing, the quicker the

treatment can be used. Companies also “have been discouraged from applying for CIRM funds by terms that require paying CIRM back with equity in the company or with cash equivalent to several times the original loan if a project bears commercially viable fruit.” (CIRM the Good..)This makes testing stem cell and other biomedical therapies much less profitable and companies are even more unwilling to do the research. Fortunately, CIRM representatives have assessed their reviewing process and are looking to become more industry friendly over the next few years..

Proposition 71 began an unparalleled program that made California one of the main centers of biomedical research in the world. The CIRM has helped stem cell research get off its feet and made other states consider allocating funding for research. The legislation set up a new way for facilities to procure funding and it is helping hasten new treatment that could change the way healthcare works. As it grows and changes, CIRM will be able to fully meet facilities’ and companies’ need for funding. Hopefully, it will help science progress, as it no longer has to bend to political controversies and requirements.

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