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THE FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS

Affordability, Accessibility & Accountability in California Stem Cell Research

How to Ensure the Public Benefits from Proposition 71

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How to Ensure the Public Benefits from Proposition 71

Executive Summary

Proposition 71 was approved by California voters who were promised that a $3 billion bond issue would yield breakthrough medical therapies and cures while paying back the state's investment in stem cell research. Supporters said Proposition 71 would provide between $6.4 and $12.6 billion in revenue and health care cost savings to the state—more than offsetting the $6 billion in taxpayer funds and bond finance charges appropriated under the initiative.

Keeping Proposition 71's promises (See Appendix 2) means the organization it created, the California Institute for Regenerative Medicine (CIRM), and its oversight committee, must put the interests of taxpayers and patients ahead of private biotech companies who have a financial stake in the outcome. The stem cell oversight committee, known as the Independent Citizens' Oversight Committee (ICOC), has been broadly criticized for deep conflicts of interest between the overseers of public finds, drug companies and grant recipients. Concern has also been expressed about its exemption from good government laws.

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The ICOC is now drafting regulations governing who owns and controls the valuable medical discoveries that may result from $3 billion in taxpayer-funded research. These rules are known as intellectual property (IP) rights and spell out ownership and licensing policies. As the ICOC writes the rules, three principles are essential to ensure Proposition 71 benefits all Californians:

- Affordability—Cures and treatments must be priced so all Californians can afford and benefit from them, not just a wealthy few.
- Accessibility—Not only do all Californians deserve access to Proposition 71-funded therapies, but stem cell researchers need access to the results of other Proposition 71-funded research to develop the widest range of cures.
- Accountability—Policies must ensure that grantees and licensees fulfill their obligations when benefiting from public money.

Policymakers have the responsibility to adopt IP policies that implement the voters' will. After interviews with key intellectual property policy experts and a review of relevant studies (See references), the Foundation for Taxpayer and Consumer Rights (FTCR) has developed a framework for IP policy to govern Proposition 71-funded research:

1. Affordability

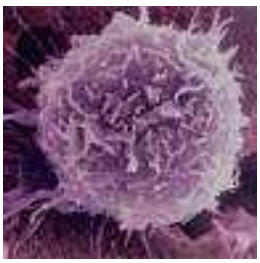
- Applicants for grants or loans must be required to explain how the rights to any discovery would be managed to benefit California.
- Research institutions that get CIRM funds should pay the state at least 25 percent of net royalties in excess of $100,000 received for any invention or discovery developed with Proposition 71 funds.
- Commercial entities that receive a grant or loan for research would pay royalties to the state on any drugs, therapies, products or inventions developed with Proposition 71 money at the same rate received by the University of California for similar types of research.
- The state's share of any royalties would be used to help fund access to Proposition 71 therapies for people who cannot afford them.
- The licensees of discoveries developed with Proposition 71 funds must sell any resulting drugs, therapies or products to the state at their lowest price.

• Licensees would be required to have plans to provide access to drugs and therapies for underserved populations.

2. Accessibility

• CIRM would create a patent pool that would include all patents resulting from research it funds. A three-person board including the California Attorney General would govern the pool.

• CIRM would be able to tell an applicant that no patent is possible for a particular project if



it determines that keeping the expected results in the public domain best promotes further research.

• CIRM could bar any discovery from being licensed exclusively when it determined nonexclusive licenses would best promote development of a treatment or therapy.

• Any California-based researcher would be able to use the results of CIRM-funded research for further research without paying a licensing fee.

• When granting an exclusive license to bring a particular drug or treatment to market, it would be issued on a disease specific basis.

3. Accountability

• The California Attorney General would have march-in rights—the ability to intervene—if a drug or therapy based on CIRM-funded research were priced unreasonably. A public hearing process overseen by the Attorney General would determine "unreasonable pricing."

• The Attorney General would have march-in rights if any other public benefit requirement is not met.

• CIRM would have march-in rights to take control of a CIRM-funded discovery if a grantee failed to develop it.

• CIRM would have march-in rights for public health and safety reasons, for instance meeting the public need of getting vaccines to market.

• All investors and shareholders in start-up companies resulting from Proposition 71-funded research would be required to file disclosure forms with CIRM. These would be public records.

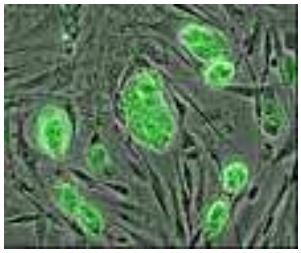
Section 1:
Who Owns Research Discoveries?

When scientific research leads to a new invention, technique or research tool, the discovery can be patented, giving the discoverer the exclusive right to develop it. In medical research the patented discovery almost always needs further development before it can be brought to market as a drug or treatment. The patent holder then licenses the right to develop a product and is paid royalties from the sale of the drug or therapy that is ultimately produced until the patent expires.

If the scientist were working in her own laboratory and had funded the investigation out of her own pocket, there would be little doubt as to who owns the discovery, or the so-called intellectual property (IP) rights. In this case the scientist would and could patent the invention.

But the real world is more complex. If the scientist is doing basic research, there may not be a patentable discovery. Instead the scientist would merely publish the results of the work and other scientists would build on it in their investigations. Usually the scientist is an employee of a university or commercial firm. Then, if there is a patentable discovery, the university or firm obtains the patent and controls the intellectual property rights. If the discovery were licensed, the scientist probably would get a share of the royalties based on an employment agreement with her employer.

Frequently, particularly in a university or not-for-profit research institution, the scientist's research is funded by the federal government with taxpayer dollars. Who should own the discovery and control its intellectual property rights in that case? Clearly the promise of Proposition 71 requires that the IP rights be managed to serve the public interest.



Proposition 71 created the California Institute of Regenerative Medicine (CIRM) to administer the $3 billion stem cell research program with the expectation that the research would lead to breakthrough cures and treatments. The Independent Citizens Oversight Committee (ICOC), which oversees CIRM, is formulating the regulations that determine who will patent the discoveries and control the IP rights resulting from research paid for by California taxpayers. It may be years before stem cell research yields breakthrough cures and treatments; significant results could come sooner. It is imperative that IP rules be written and implemented before any discoveries are made. What the ICOC decides is key to whether Proposition 71 fulfills its promise to all Californians or becomes a blank check providing corporate welfare to the biotech industry.

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Section 2:
An Intellectual Property Policy for California

The California Institute of Regenerative Medicine's intellectual property rules will need to fulfill two equally important policy objectives. First, they must serve the public interest, keeping Proposition 71's promise of direct benefits to the state. Second, they must promote research and the rapid development of therapies and treatments. CIRM's rules must be tailored to California's circumstances and go beyond federal guidelines.

The measures outlined here will ensure that the promises of Proposition 71 are kept. In most cases grantees will own and be able to patent discoveries; the proposed California requirements will assure a free exchange of knowledge so that therapies and treatments can be developed as rapidly as possible and so that all Californians will have access to them.

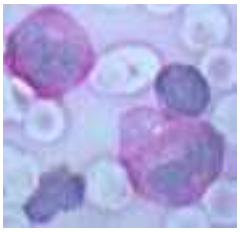
They will pose no unreasonable burden on universities and other research organizations accustomed to working within the federal framework. FTCR believes three principles should be the foundation for CIRM's IP policy: Affordability, Accessibility and Accountability.

Affordability

To ensure affordability, cures and treatments must be priced so all Californians can benefit from them, not just a wealthy few. These minimal licensing requirements are necessary to protect the public's interest and ensure there is a direct return to the state:

• Applicants for grants or loans must be required to explain how the rights to any discovery would be managed to benefit California.

• Research institutions that get CIRM funds would pay the state 25 percent of net royalties in excess of $100,000 for any invention or discovery developed with Proposition 71 funds.



• Commercial entities that receive a grant or loan for research would pay royalties to the state on any drugs, therapies, products or inventions developed with Proposition 71 money at the same rate received by the University of California for similar types of research.

• The state's share of any royalties would be used to help fund health care for people who cannot afford it, or to pay for further stem cell research.

• The licensees of discoveries developed with Proposition 71 funds must sell any resulting drugs, therapies or products to the state at their lowest price.

• Licensees would be required to have plans to provide access to therapies for underserved populations.

• The California Attorney General would have "march-in" rights to intervene if these minimal requirements were not met.

Accessibility

Affordable prices for medical therapies will ensure that all Californians receive access to Proposition 71-funded therapies. Another form of access is also crucial: California's stem cell researchers need access to the results of other Proposition 71-funded research to develop the widest range of cures.

First, CIRM should create a patent pool that would include all patents resulting from research it funds. The pool should be expanded to include as many additional stem cell related patents as possible. A serious concern not only about stem cell patents, but biotechnology patents in general, is that many different patentees hold complimentary and blocking patents. This means that a company must negotiate with a number of organizations to obtain rights to market a particular drug or therapy even if it owns a final implementing patent. This can prove a costly disincentive to innovation. [1]

"FTCR believes three principles should be the foundation for CIRM's IP policy: Affordability, Accessibility and Accountability."

A study of the problem released by the United States Patent and Trademark Office concludes that patent pools in the biotech industry would "serve the interests of both the public and private industry, a win-win situation." The envisioned pool would offer "affordable prepackaged patent 'stacks' that could easily be licensed." The study concludes a patent pool "can provide greater innovation, parallel research and development, removal of patent bottlenecks, and faster product development."[2] A proposal for a stem cell patent pool envisions the possibility of a "one-stop license." "This would certainly benefit the companies bringing stem cell therapies to the market as well as the patentees themselves." [3] A three-person board comprising two members selected by the ICOC and the California Attorney General would govern the patent pool.

Second, CIRM must be able to deny patents in the public interest. Well-founded worries about "patent thickets" and the negative impact on "upstream" basic research mandate a departure from some federal assumptions. Under federal rules the fund-granting agency can categorize research results as ineligible for a patent only in "exceptional circumstances." Instead, CIRM must be able to tell an applicant that no patent is possible in a particular research project whenever it deems keeping

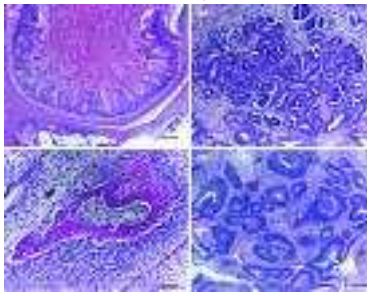
> **"CIRM must be able to tell an applicant that no patent is possible in a particular research project whenever it deems keeping the discovery in the public domain would better serve the public interest."**

the discovery in the public domain would better serve the public interest.

Third, CIRM would be able to bar any discovery from being licensed exclusively when it determined nonexclusive licenses would best promote development of a treatment or therapy. This is most likely in so-called "upstream" research where the results tend to be techniques rather than specific therapies and drugs.

Fourth, there must be a research exemption. The results of all CIRM-funded research should be available to all researchers in California—and any other researchers designated by CIRM—for further research without a licensing fee. Once California taxpayers have paid to develop a technology, researchers in the state ought not be required to pay to access it for further research that benefits the public.

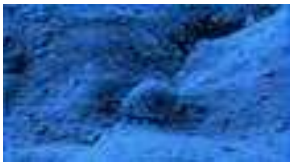
Finally, when granting an exclusive license to bring a particular drug or treatment to market, it would be issued on a disease-specific basis. This would prevent one company from obtaining a license that could apply to several therapies, but only developing one drug at a time, thus blocking others from pursuing cures for different diseases that relied on the same discovery.



Accountability

First, the public's business must be conducted in public. All aspects of good government laws including those requiring opening meetings, public records and conflicts of interest should apply to the ICOC and CIRM, just as they apply to other state agencies.

Second, there must be recourse if grantees or licensees fail to meet their obligations to the public. Potential problems could include a grantee failing to develop a CIRM-funded discovery or a licensee abusing its market position and charging unreasonable prices for a drug or therapy. If this happened "march-in" rights could be exercised and the exclusive license that had been granted could be revoked and granted to someone else. March-in rights would work like this:



• The Attorney General would have march-in rights if a drug or therapy based on CIRM-funded research were priced unreasonably. A public hearing process administered by the Attorney General would determine "unreasonable pricing."

• CIRM would have march-in rights to take control of a CIRM-funded discovery if a grantee failed to develop it. The Attorney General would have the power to enforce this provision if CIRM fails to protect the public interest.

• CIRM would have march-in rights for public health and safety reasons. For example, if an exclusive licensee could not manufacture a particular drug rapidly enough to combat a sudden pandemic, CIRM could award the license to others as well. The Attorney General could enforce this if CIRM failed to act.

Finally, investors and shareholders in start-up companies that result from Proposition 71-funded research would be required to disclose their involvement in the firm to CIRM. These disclosures would be public records. The potential for conflicts of interest in start-ups is great. Transparency is necessary.

> **"Once California taxpayers have paid to develop a technology, researchers in the state ought not be required to pay to access it for further research that benefits the public."**

Californians voted to spend taxpayers' money under Proposition 71 because they recognized an opportunity to make the state a world leader in stem cell research. They understood the potential for breakthrough cures and therapies and endorsed a $6 billion investment in the quest. They did not intend a blank check for

> **"There must be recourse if grantees or licensees fail to meet their obligations to the public."**

the biotech industry. The correct intellectual property rules governing stem cell research discoveries are essential for public oversight and control and to keep Proposition 71's promises to the voters.

Section 3: How Federal IP Policies Have Failed to Protect the Public Interest

For the past 25 years federal IP policy has followed the federal Bayh-Dole Act, which gives ownership of any discovery to the research institution where it is made even though taxpayers paid for the research. Under its provisions private drug companies have reaped huge profits while benefiting from taxpayer-funded research. Experts also worry that Bayh-Dole has commercialized universities, prompted over-patenting of basic research, and created obstacles to the free flow of information hindering further research. The ICOC must learn from the flawed federal policy as it implements IP rules for CIRM.

Before 1980 the IP rights to discoveries made with federally funded research would have remained with the federal government. Since the passage of the Bayh-Dole Act, the IP rights at least with respect to federally funded research belong to the grantee institution, which is expected to patent the discovery and license it for commercial exploitation.

Giving IP rights to an institution was meant to increase the competitiveness of U.S. industry, giving it greater access to technological innovation. The recipients of the federal Research and Development money were expected to develop inventions or license others to put them to commercial use.[4] Supporters of the Bayh-Dole Act claim it regenerated American innovation. "More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance," enthused *The Economist*.[5]

From the outset there were critics of Bayh-Dole. Admiral Hyman Rickover, the "father" of the U.S. nuclear fleet, was responsible for overseeing a significant amount of federally funded research. Rickover testified at Congressional hearings on the legislation and warned that giving private companies exclusive rights to taxpayer-funded inventions was forcing the public to pay twice: once for the research and once for higher prices made possible by the monopoly granted under a patent.[6]

And, indeed, Bayh-Dole has provided opportunities for drug companies to reap huge profits when benefiting from taxpayer-funded research. Take the case of Xalatan, a blockbuster drug to fight glaucoma. Key research for the drug was done with a $4 million federal grant by a little-known science professor, Laszlo Z. Bito at Columbia University. His discovery was patented and licensed exclusively to Pharmacia Corp. (now Pfizer) for less than $150,000. Pharmacia made $507 million on Xalatan in 1999 alone, charging U.S. patients $50 a bottle for ingredients that cost only pennies to produce. The university received $20 million in royalties. Prof. Bito's share was one fifth of that. U.S. taxpayers got nothing for their investment except a price for the drug that's twice as high as what Europeans pay.[7]

The Boston Globe examined the 50 top-selling drugs approved by the Food and Drug Administration over a five-year period. Forty-five of them received federal taxpayer money to help in the discovery, development or testing of the drugs with virtually no payback.[8] Some examples:

- Chiron Corp. of Emeryville, CA, charged cancer patients up to $20,000 for a treatment with Proleukin. It was approved after nearly $46 million in funds from the National Institutes of Health.
- Cambridge, MA- based Biogen developed and tested Avonex, a drug to treat multiple sclerosis, with $4.6 million in federal aid and was charging $11,000 for a year's supply.
- Teva Pharmaceutical Industries of Israel sold about $50 million worth of Copaxone, its multiple sclerosis drug, in the United

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States in 1997. It received $5 million from the U.S. government to help test it.

In another case, researchers at the University of Utah backed by $4.6 million in U.S. taxpayers' funds discovered an important human gene responsible for hereditary breast cancer. What did taxpayers get for their money? The university patented the discovery and then licensed it exclusively to Myriad Genetics, a startup biotech company founded by a University of Utah professor. Myriad actively sought to block others from using the gene in their research, even threatening legal action against Haig Kazazian, chairman of the genetics department at the University of Pennsylvania.[9]

In 1991 Baylor College of Medicine patented the p53 or knockout mouse that has a tumor-suppressing gene missing. Although taxpayers funded the research that led to the mouse's creation, Baylor didn't make the mouse generally available to academic researchers. Instead it opted to license the creature exclusively to GenPharm. Earlier, Harvard had followed a similar course with the so-called oncomouse. MIT went on to develop its own version of the p53 mouse, but Baylor compelled the university and its distributor to pay royalties. The mouse controversy prompted the National Institutes of Health (NIH) to call on universities to refrain from imposing overly restrictive licenses on basic research tools financed by the taxpayer. But there is no real enforcement mechanism associated with the advisory and most university licensing data is confidential making it difficult to know whether it is being followed. [10]

More troubling to Proposition 71 is the emerging patent thicket in stem cell research. The University of Wisconsin's James Thompson was able to derive stem cells from rhesus monkeys and macaques. The university's technology arm, the Wisconsin Alumni Research Foundation (WARF), was able to obtain a patent covering all lines of embryonic stem cells for primates—including humans—and licensed six types to Genron. [11] Jeanne Loring, an embryologist at Burnham Institute in La Jolla, said her start-up firm failed when it couldn't get access to embryonic stem cells at a reasonable price. Commercial firms were charged $100,000. Academic researchers had been paying $5,000. [12]

Already there are more than 1,400 U.S. patents issued in connection with stem cells. Lawyers with Smith, Kessler, Goldstein & Fox, a Washington Law firm specializing in IP rights, put it this way: "The patent landscape

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is littered with issued patents that may affect the ability to practice stem cell based therapies." [13]

Increasingly, scholars express concern about Bayh-Dole's effect on universities and on accessibility to basic research. Clearly Bayh-Dole had an impact on the way universities do business. From 1979 to 1984 the number of patents issued to universities more than doubled, more than doubled again from 1984 to 1989, and doubled again over the 1990s. University technology transfer offices increased from 25 in 1980 to 200 by 1990. Now virtually every American research university has such an office. [14] By 1997 the number of patents issued annually to universities had reached 2,436. Many of these don't cover commercial products, but rather research discoveries and research tools. [15]

Under the terms of the Bayh-Dole Act, grant-making agencies such as NIH can restrict patenting in "exceptional circumstances" when that would better promote the goals of the act—technology transfer. But that has apparently happened only once. And if the university or licensee fails to take steps to implement the invention, or if it is necessary for health or safety reasons, the agency can exercise "march-in" rights and compel the invention be licensed to others. In the quarter of a century since Bayh-Dole was enacted, "march-in" rights have never been exercised. [16]

The Bayh-Dole regime has commercialized

universities, allowed private companies to reap monopoly benefits from taxpayer-funded research and created obstacles to the free flow of knowledge that has hindered further research.

Conclusion

Supporters of Proposition 71 promised medical breakthroughs and a substantial return to the state for a $6 billion investment in stem cell research and bond financing costs. The breakthrough cures may be years away; they may come much sooner. Clearly, however, the policies governing research results must be in place before the discoveries are made.

The backers of the initiative now dominate the committee overseeing the stem cell institute and the initiative's implementation. They have a legal and moral responsibility to keep the promises they made during the Proposition 71 campaign.

A key element in meeting that obligation is determining who will own, control and benefit from the discoveries made with Proposition 71-funded research. The oversight committee is currently drawing up the intellectual property rules that will determine this. FTCR has outlined specific IP policy provisions based on three principles: affordability, accessibility and accountability.

In voting for Proposition 71 Californians did not intend to write a blank check for the biotech industry. Instead of blindly adhering to a flawed federal system under the Bayh-Dole Act, the ICOC must craft an IP policy that fulfills Proposition 71's promise to California's voters and taxpayers.

Appendices and Notes

Promises of Proposition 71	Foundation for Taxpayer and Consumer Rights (FTCR) Recommendations to Achieve Prop 71 Promises	Federal Guidelines Under Bayh-Dole Act ("BDA")	CA Stem Cell Institute ("CIRM")
Affordability • Prop 71 promised that new medical breakthroughs would directly help a substantial portion of Californians. "About half of California's families have a child or an adult who has suffered or will suffer from a serious, often critical or terminal, medical condition that could potentially be treated or cured with stem cell therapies."	Prop 71 grants must benefit Californians in the form of affordable treatments and royalties.	No enforceable provisions requiring that the taxpayers that fund research should be the primary benefactors. FTCR recommendation does not conflict with BDA.	TBA
	The state's share of any royalties shall be used to pay for stem cell therapies for patients who cannot afford them.	No such provisions. FTCR recommendation does not conflict with BDA.	TBA
• Prop 71 was intended to "benefit the California economy by creating projects, jobs, and therapies that will generate millions of dollars in new tax revenues in our state."	Discoveries (drugs, therapies or products) developed with Prop 71 funds must be sold to public health programs run by the state at their lowest price.	No such requirements under BDA. Federal law requires public health programs like Medicare & Medicaid to receive prescription drugs at "best price."	TBA
• "If Proposition 71 leads to cures that reduce our health care costs by only 1 percent, it will pay for itself -- and could cut health care costs by tens of billions of dollars in future decades."	Grantees must provide access to drugs and therapies for underserved populations.	No such provisions. FTCR recommendation does not conflict with BDA.	TBA

Promises of Proposition 71	Foundation for Taxpayer and Consumer Rights (FTCR) Recommendations to Achieve Prop 71 Promises	Federal Guidelines Under Bayh-Dole Act ("BDA")	CA Stem Cell Institute ("CIRM")
Accessibility Californians overwhelmingly voted for Proposition 71 authorizing $3 billion in bonds to fund stem cell research because they believed its sponsors and the language in the initiative itself. Stem cell research was described as way to discover breakthrough cures for more than 70 diseases and disorders ranging from cancer, diabetes, Alzheimer's, and Parkinson's to spinal cord injuries and blindness.	All patents resulting from research shall be placed in a patent pool allowing easy access to Prop 71 discoveries.	BDA allows for the creation of patent pools but does not require them. Federal research has been hindered by "patent thickets" that could have been prevented by a patent pool. FTCR recommendation does not conflict with BDA.	TBA
	Patents will not be granted if it is determined that keeping the expected results in the public domain best promotes further research.	BDA provides this authority in "exceptional circumstances" but has virtually never been used. FTCR recommendation does not conflict with BDA.	TBA
	An exclusive license may not be granted if it is determined that nonexclusive licenses would best promote development of a treatment or therapy.	Under BDA, the grantee determines the nature of the license agreement. FTCR recommendation does not conflict with BDA.	TBA
	Any California-based researcher would be able to use the results of funded research for further research without paying a licensing fee.	BDA contains no such requirements. Under federal law researchers pay thousands of dollars to access research tools, inhibiting further discoveries. FTCR recommendation does not conflict with BDA.	TBA
	When granting an exclusive license to bring a particular drug or treatment to market, the license would be issued to treat a specific disease.	BDA contains no such provisions. FTCR recommendation does not conflict with BDA.	TBA

Promises of Proposition 71	Foundation for Taxpayer and Consumer Rights (FTCR) Recommendations to Achieve Prop 71 Promises	Federal Guidelines Under Bayh-Dole Act ("BDA")	CA Stem Cell Institute ("CIRM")
Accountability Robert Klein, now chairman of the 29-member committee overseeing the implementation of Prop 71, was the initiative's primary sponsor. As he and the members of the Independent Citizens Oversight Committee implement Prop 71, the policies they develop must keep the promises of new therapies, lower medical costs, additional tax revenue and royalties for the state.	• The CA Attorney General would have the ability to intervene ("march-in") if a drug or therapy were priced unreasonably or if any other public benefit requirement is not met. • CIRM must take control of a funded discovery if a grantee failed to develop it or for public health and safety reasons.	BDA provides "march-in" rights to protect the public interest however, they have never been effectively exercised. FTCR recommendation does not conflict with BDA.	TBA
	All investors and shareholders in start-up companies resulting from Prop 71-funded research would be required to file disclosure forms open to public review.	BDA contains no such provisions. Some university researchers must abide by similar rules under the terms of university employment contracts but there need not be public disclosure. FTCR recommendation does not conflict with BDA.	TBA

Californians overwhelmingly voted for Proposition 71 authorizing $3 billion in bonds to fund stem cell research because they believed its sponsors and the language in the initiative itself. Stem cell research was described as way to discover breakthrough cures for more than 70 diseases and disorders ranging from cancer, diabetes, Alzheimer's, and Parkinson's to spinal cord injuries and blindness.

The proposition promised the bond issue would yield discoveries that would directly help a substantial portion of Californians. "About half of California's families have a child or an adult who has suffered or will suffer from a serious, often critical or terminal, medical condition that could potentially be treated or cured with stem cell therapies." [17]

The federal government was not providing adequate funding for stem cell research and $6 billion, including the bond financing, of taxpayers' money was requested from taxpayers to close the gap, which "currently prevents the rapid advancement of research that could benefit millions of Californians." [18]

More than the hope of cures, the initiative promised a sound economic basis for investing in Proposition 71's bond issue. The publicly funded research would "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." [19] There would be "an opportunity for the state to benefit from royalties, patents and licensing fees that result from the research." [20] Proposition 71 was intended to "benefit the California economy by creating projects, jobs, and therapies that will generate millions of dollars in new tax revenues in our state." [21]

Supporters of the proposition were even more specific about the economic benefits in the argument in favor of the proposition mailed to voters. Noting that California has the nation's highest health care costs at $110 billion a year, they wrote, "if Proposition 71 leads to cures that reduce our health care costs by only 1 percent, it will pay for itself—and could cut health care costs by tens of billions of dollars in future decades." [22]

An economic analysis paid for by supporters of the initiative and conducted by the Analysis Group was widely cited in advertisements for the proposition. "In even the modest scenarios examined," it said, "Proposition 71 provides total state revenues and health care cost savings of between $6.4 billion and $12.6 billion during the payback period, generating a 120 percent to 236 percent return on investment made in the research." [23]

Robert Klein, now chairman of the 29-member committee overseeing the implementation of Proposition 71, was the initiative's primary sponsor. As he and the members of the Independent Citizens Oversight Committee implement Proposition 71, the policies they develop must keep the promises of new therapies, lower medical costs, new jobs, additional tax revenue and royalties for the state.

[1] Ebersole, T., Esmond, R. & Schwartzman, R. (June 2005). Stem Cells—Patent Pools to the Rescue? Washington: Sterne, Kessler, Goldstein & Fox P.L.L.C. p. 1.

[2] Clark, J., Piccolo, J., Stanton, B. & Tyson, K. (December 2000). Patent Pools: A Solution To The Problem Of Access In Biotechnology Patents? United States Patent and Trademark Office. p. 11.

[3] Ebersole et al. pgs 3-4.

[4] Arno, P. & Davis, M. "Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Price Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research." Tulane Law Review, Vol. 75, p. 646.

[5] The Economist. (December 2002) Technology Quarterly.

[6] Washburn, J. (2005). University Inc.: The Corporate Corruption of Higher Education. New York: Basic Books, p. 61.

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Interviews

Intellectual property policy issues were discussed with the following people. However, the positions in the paper are FTCR's and do not necessarily reflect the opinions of the interviewees. We appreciate their time and consideration.

Rebecca Eisenberg, Robert & Barbara Luciano Professor, University of Michigan Law School.

Merrill Goozner, Director, Integrity in Science Project, Center for Science in the Public Interest.

Kathy Ku, Director of Technology Transfer, Stanford University.

Jeffrey Labovitz, Vice President, Technology Transfer, Buck Institute for Age Research.

Jeanne F. Loring, Adjunct Associate Professor, Burnham Institute for Medical Research.

Lita Nelsen, Director of Technology Transfer, Massachusetts Institute of Technology.

Daniel Ravicher, Executive Director, Public Patent Foundation.

Arti Rai, Professor, Duke University Law School.

Bhavan Sampat, Assistant Professor, Mailman School of Public Health and School of International and Public Affairs, Columbia University.

Joshua Trojak, Assistant Director of the New Jersey Council on Science and Technology.

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