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Ensuring All Californians Benefit from Prop. 71 Grants to Businesses: State Should Hold Patents; Attorney General Must Be Enforcer

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Introduction:

The Independent Citizens' Oversight Committee now faces one of its most important tasks: drawing up the rules governing who controls and owns any discoveries made by for-profit businesses doing stem cell research funded with California taxpayer dollars. To fulfill Proposition 71's promise of a public benefit research, products developed with taxpayer money must be priced affordably for all Californians. To meet this standard the California Attorney General must be able to intervene to ensure that products of taxpayer-funded research are priced based on the true cost of development and to reflect the taxpayers' investment.

Grants and loans of taxpayer money to for-profit businesses open greater possibilities for abuse than grants to universities and non-profit institutions. Certainly the public will have questions and concerns about funding given directly to researchers who are primarily interested in making a profit. So it is essential that the policy controlling ownership of any valuable medical discoveries that result from Proposition 71-funded research by businesses must be crafted so that all Californians -- not just a few biotech firms -- benefit from the research paid for by taxpayers.

There was a clear promise of public benefit in Proposition 71, with more than 70 diseases and disorders cited as potentially curable through stem cell research. About half of all California's families were estimated to have a child or adult who suffers from, or

will suffer from, diseases that potentially could be cured with stem cell therapies. More than just the hope of cures through stem cell research, Proposition 71 also promised the voters who overwhelmingly supported it that the $6 billion investment was built on a sound economic base. It is the intellectual property rules -- in other words, who will control the ownership of Proposition 71 discoveries -- that will ultimately determine whether the bold initiative's promises are kept.

Section 1: Disbursing Prop 71 Money: Grants, Loans And Contracts

Because intellectual property (IP) rules are the way to keep Proposition 71's promises, there may be a tendency to approach the issue with unnecessary complexity. In thinking about applying IP rules to businesses receiving taxpayer money, don't first focus on patents, licenses, royalties and commissions. Instead, consider straightforward business models. In doling out Proposition 71 money to businesses there are really only four different basic situations that arise.

Scenario 1: The first grant situation is like building a house. If you pay a company to build a house, you own the house when it's finished. You might live in it or sell it. The company that received your money makes a profit and has an incentive to build more houses. Similarly, if the taxpayers pay a company to do stem cell research, the taxpayers should own and thus directly benefit from any discoveries that result from the research for which they paid. The state should own the patent.

Scenario 2: The second scenario is a partnership. Say the builder owns some land. He comes to you and asks for money from you so he can build a house on his land. When it's finished and sold, you as an investor get a share of the profits. The analogy in the world of biotech and Proposition 71 would be that the company already owns or has a license to a stem cell-derived treatment or therapy. The company needs Prop 71 money to bring the cure or therapy to market. If taxpayer money goes to the company, the public deserves a return on its investment when the product generates revenue, as a commission on the sales.

Scenario 3: The third situation is like a banking relationship. Prop 71 money would be lent to a business. Such transactions would be treated just like a loan from a bank, with the company paying back the loan within an agreed time frame at an appropriate interest rate. Usually the state would not have a claim on any discoveries that might be developed, but just as a mortgage lender has requirements to qualify for a loan, meeting appropriate public benefit requirements would be necessary to receive funds.

Scenario 4: The final model would be like contracting with someone to perform a task, say cleaning your house. For instance, Prop 71 money might be used to contract with a company to provide a particular service, perhaps maintaining a stem cell bank or providing an assay that many Prop 71-funded researchers would require. Again, the state likely would not have direct IP claims to assert, but contracts should be awarded with conditions to maximize public benefit.

The California Institute of Regenerative Medicine's (CIRM) intellectual property (IP) rules are the best -- if not the only -- vehicle to ensure that Proposition 71's promises of public benefit are fulfilled when outright grants and loans are made. Just as with the non-profit policies, IP rules for businesses must be grounded in three basic principles. They are:

- **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 also need access to the results of other Proposition 71-funded research to develop the widest range of cures.
- **Accountability** -- Polices must ensure that grantees and licensees fulfill their obligations when benefiting from public money.

Section 2: Biotech Lining Up for "Free Money"

The biotech industry is lining up to take Proposition 71 money and wants as few public benefit requirements attached as possible. Private venture capitalists have already described the stem cell research funding being provided by taxpayers in California as "almost like free money" compared to commercial venture capital, which inevitably comes with the expectation of payback for the investors. It's a tip-off to the lack of any sense of obligation to the public's investment.

The right IP rules, governing such things as price and accessibility for underserved populations, will ensure that businesses meet fair obligations to the public when they take the public's "free money."

Certainly drug firms are entitled to fair profits; they just aren't entitled to charge exorbitant rates when taxpayers directly funded the research that made a drug or treatment possible in the first place. Californians overwhelmingly approved Proposition 71 because they believed the promises of public benefit from stem cell research. They did not intend a blank check for biotech.

Section 3: Non-profit Rules Need Improvement, But Are Starting Point

CIRM's IP rules for non-profits need improvement before they are fully implemented through the Office of Administrative Law process. Among the ways they must be strengthened are the following:

- The California Attorney General must be able to "march-in" and intervene in cases of "unreasonable pricing" of a Prop 71-funded drug or therapy by a licensee. Reasonable pricing reflects the true cost of development and the public's investment, no matter if it provided all or part of the money.

- There should be a patent pool to foster sharing of publicly funded research and to promote commercialization of discoveries.

- There should be a lower threshold for when the state begins to recoup some of its investment. As the rules are now written, payback begins when net revenue to a grantee tops $500,000. Because it's net revenue rather than gross, the threshold should be $100,000.

Even without the necessary improvements, the non-profit IP rules do establish important principles that serve as a minimum starting point for writing the IP policies for business. These principles must be included in the commercial IP policy. First is the principle that the state should receive payment if a revenue stream results from publicly funded research. Second is the principle that underserved populations should have affordable access to therapies. The non-profit IP rules accomplish this by requiring licensees to sell drugs or therapies to publicly funded health plans at the Medicaid price. They are also required to have a plan to provide a drug or therapy to uninsured people. Finally, the IP rules provide for broad sharing of research results with other California researchers.

Again, it must be stressed, these rules most be improved to ensure all Californians affordable access to the benefits of taxpayer-funded research based on reasonable prices. Reasonable prices reflect the public's investment and the true cost of the drug or treatment's development. This fundamental principle must be incorporated in the IP rules for both non-profit and for-profit organizations.

Section 4: Federal Bayh-Dole Act Does Not Apply

Though CIRM did not adopt all aspects of the flawed federal model -- the Bayh-Dole Act -- in its IP policies, the non-profit rules are compatible with the federal act. So, in keeping with Bayh-Dole, grantee universities and institutions are expected to patent and license any discoveries that result from their Prop 71-funded research. Much of this university research is likely to yield "upstream discoveries," in other words, significant and sometimes patentable discoveries, but results still far removed from drugs and therapies that can be sold. Grants to commercial firms are much more likely to involve "downstream research" efforts that are closer to the bedside than the lab bench -- actual treatments and cures nearly ready for general use.

Bayh-Dole provides that discoveries funded with federal money must by provided on "reasonable terms." Many hold this provision gives the government the right to act against unreasonable pricing, however, this has never been enforced. There is absolutely no reason to invoke the Bayh-Dole Act in developing IP polices for Prop 71 grants to businesses. If the public pays for an invention, it should own it. Here's how it would work with Prop 71-funded research.

Section 5: State Should Hold the Patent

If a Prop 71 grant to a business results in a patentable discovery, the state would hold the patent. Generally the patent would go into a patent pool making it available to

as many researchers and companies as possible. Or, it could be licensed on an exclusive basis if it was necessary to commercialize a drug in the public interest. The grantee company would have the first option on such a license. The royalty rate to the state would be comparable to that received by the University of California when it licenses an invention. The Attorney General could intervene if the license were abused.

Licensing requirements would essentially the be same as those required in the non-profit regulations when a university grantee licenses an invention to a commercial firm. The company would have to have a plan to provide access for uninsured populations. Drugs and therapies would be provided to publicly funded health plans at its lowest price. And, still to be added, the attorney general could intervene in cases of unreasonable pricing. If the company already owns the patent or has a license, CIRM should share in any revenues generated on a commission basis.

Section 6: Specific IP Provisions

Here are specific rules that should be incorporated in the IP policy based on the principles of affordability, accessibility and accountability:

Affordability

- A business receiving Proposition 71 funding must be required to sell any therapies and diagnostics at a reasonable price. A reasonable price reflects the true cost of development and the public's investment, whether taxpayers provided all or part of the funding.
- Businesses must pay the state 25 percent of any net royalties they receive for any invention or discovery developed with Proposition 71 funds.
- Businesses receiving grants must pay a commission on gross sales of any Proposition 71-funded drug or cure at least as great as the royalty paid to the University of California for similar research.
- Businesses receiving grants or loans must be required to explain how any discovery would be managed to benefit all Californians.
- A business receiving Proposition 71 funding must agree to sell all its therapies and diagnostics to publicly funded health plans in California at its lowest price.

Accessibility

- A business receiving Proposition 71 funding must be required to have a plan to provide access to resultant therapies and diagnostics for uninsured patients.
- CIRM should create a patent pool that would include all patents resulting from research it funds, including businesses. A three-person board including the California Attorney General would govern the pool.
- CIRM could bar any discovery from being licensed exclusively to one company when it determined nonexclusive licenses would best promote development of a treatment or therapy.

- Any California-based researcher must 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 should be issued on a disease specific basis, so that later discoveries of usefulness for other diseases could be separately licensed.

Accountability

- The California Attorney General must 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." Reasonable pricing reflects the true cost of development and the public's investment.
- The Attorney General should have march-in rights if any other public benefit requirement were not met.
- CIRM should have march-in rights to take control of a CIRM-funded discovery if a business failed to reasonably develop it.
- CIRM should 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 must be required to file disclosure forms with CIRM. These would be public records.

Conclusion

Already some biotech executives have said the industry will decline CIRM money if the companies must share the rewards of Proposition 71 stem cell research grants with California taxpayers who put up $6 billion to finance the research. Too many biotech companies act like committed socialists when it comes to taxpayers and the government bearing the risk of drug development. But they are greedy capitalists when it's time to parcel out the profits

Ignore the bluff and blustering threats of picking up the Petri dishes and going home if they don't get their way. Any attempt to grab "free money" without equitable public benefit requirements for biotech won't work. First-class companies understand that with the acceptance of taxpayer dollars comes the responsibility of public benefit. And with $3 billion on the table, there will be plenty of top-flight firms and researchers ready to play by fair rules like those outlined here to search for cures.

-- John M. Simpson
Stem Cell Project director