



SOMETHING BETTER THAN HOPE

Right now.

CIRM Presentation

Ideas for Enhancements to Proposition 71

May 23, 2019

CIRM
CALIFORNIA / STEM CELL AGENCY

Every Moment Counts. **Don't Stop Now.**

Background:

- Background: An initiative will be targeted for November 2020 that may invest \$5 billion or more in CIRM and its mission.
- Challenge: CIRM has a unique perspective to offer regarding possible enhancements to Proposition 71 that might further CIRM's mission more efficiently and improve its operations.
- ICOC/Subcommittees Discussion:
 - 1) Identify areas for improvement
 - 2) Discuss possible solutions

(the following ideas are intended to spark discussion and are not intended to limit discussion topics)

Governance:

- Background: CIRM adopted stringent conflict of interest laws, which are modeled on best practices established by the National Academy of Sciences and exceed the requirements of state law. The State Controller reviewed CIRM's conflict policies and practices and found no violations of conflicts of interest in the award of grants, nor has any conflict been documented. Nevertheless, certain groups, such as the Little Hoover Commission and IOM, have suggested that the structure of the ICOC creates the perception of a conflict. To address this perception, the Board created the Application Review Subcommittee of the Board to further address the issue of such perception.
- Challenge: How to harness value and expertise from academic and research institutions while eliminating the conflict of interest criticism that persists in some quarters.
- Ideas: Range of possibilities.....
 - 1) Continue with Application Review Subcommittee process
 - 2) Appoint former (retired) institutional officials to represent the sector
 - 3) Create advisory group to the ICOC consisting of such officials to advise on strategic issues and program concepts
 - 4) Restore full participation and make explicit finding in new law that voting does not pose a conflict

Equity Ownership:

- Background: CIRM's ATP partnering was complicated due to CIRM's inability as a state agency to accept stock. In addition, CIRM's loan program was also disadvantaged by this prohibition. In order for CIRM and the State of California to have the ability to maximize the return on investment, take a leadership role in commercializing and thus making accessible to patients new therapies, and to assist new biotech formation and success, CIRM needs to have a mechanism that allows it to act as "venture capital."
- Challenge: Given the State prohibition on holding stock, are there ways to create revenue for the General Fund and provide an ongoing funding stream for CIRM?
- Ideas:
 - Change State law to make an exception for CIRM
 - Create a separate entity/fund that can hold stocks and/or warrants and define destination of returns.
 - In the meantime, explore internally to identify possible mechanisms and approaches; outreach to Treasurer

HQ:

- Background: CIRM's unique mission and team composition narrow the geographical regions best suited for the agency's HQ. Acquiring sufficient office space to meet possibly greater strategic objectives and volumes in premium markets will take a significant toll on administrative resources.
- Challenge: How to ensure long-term HQ space efficiently?
- Idea:
 - Provide designated resources outside of the agency's limited overhead budget to acquire office space (lease or own)

Administrative Budget:

- Background: Prop 71 originally capped personnel to 50 and budget at six percent (6%). Legislative fix to personnel, but 6% remains. If CIRM's mission grows, is evergreened, and continues successful redeployment of recovered research funds, 6% cap is likely insufficient.
- Challenge: How to ensure administrative resources are adequate to meet demand brought about by mission demand and research recoupment?
- Ideas:
 - Allow additional 6% admin on redeployed/royalties/returned funds
 - Periodic large public meeting to examine portfolio and scientific direction

Scope – Science Funded:

- Background: Proposition 71 provides for stem cell research and “other vital research opportunities.” Establishes priority for pluripotent stem cell and progenitor cell research that is unlikely to receive adequate or timely NIH funding. Requires GWG to determine whether proposal is a VRO. In practice, the ICOC establishes eligibility requirements and technology focus. Moreover, CIRM looks to partner with the NIH and others to leverage CIRM resources. Ultimately, NIH funding is unpredictable.
- Challenge: How to ensure that CIRM can continue to fund new and innovative technologies?
- Ideas:
 - Eliminate reference to NIH funding
 - Ensure scope is defined at the ICOC level as opposed to GWG
 - Expand stem/progenitor cell research to “regenerative medicine,” with a specific definition consistent with NIH, FDA and others

Working Groups:

- Background: Prop 71 contains restraints around GWG composition and responsibilities. In practice, GWG panels are tailored to reviews and primary policy calls are made by ICOC in concept plans. Clinical stage programs have varied expertise requirements.
- Challenge: How to codify CIRM best practices and efficiencies?
- Ideas:
 - Allow # range of scientist members per panel/review:10-20, without diluting patient advocate participation
 - Simplify appointment from staggered terms to multiples of 6 years
 - Reexamine GWG role in recommending review criteria and award monitoring

Infrastructure and other initiatives:

- Background: While Prop 71 provides for separate science and facility review groups, CIRM's infrastructure programs have matured beyond such basic distinctions. Programs such as ATP3, Genomics, Stem Cell Accelerating Center or other infrastructure goals (manufacturing, etc) require more nuanced working group composition. Also, no clear mechanism to consider and provide policy input on accessibility to cell therapies.
- Challenge: How to ensure adequate and efficient reviews of infrastructure proposals and other important issues?
- Ideas:
 - Allow CIRM to create an ad-hoc working group to address infrastructure proposals (other than strict facilities)
 - Reconsider infrastructure initiatives
 - Expand SWG role to evaluate issues in re accessibility of cures and pricing (expand research funding to include research on these points)

RELENTLESS

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CHANGE

UNWAVERING

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