MEMORANDUM

TO: Members of the ICOC

FROM: C. Scott Tocher, Counsel to the Chair

RE: **Agenda Item 14:** Final Adoption of Amendments to Intellectual Property Regulations

DATE: January 13, 2012

Executive Summary

On September 30, 2010, Governor Schwarzenegger signed into law Senate Bill No. 1064, which was sponsored by Senator Alquist. The law became effective January 1, 2011, and made a number of amendments related to Proposition 71. The bill addressed numerous aspects of CIRM's operations. In addition, it codified, with four modifications, CIRM's revenue sharing and access plan regulations. Some of the bill's provisions required CIRM to amend it's IP regulations to harmonize the regulations with the bill.

To that end, the ICOC authorized staff in 2010 to begin the process of amending the relevant IP regulations based on the recommendations of the IP Subcommittee (formerly called the "Intellectual Property Taskforce"). The regulatory amendment process with the Office of Administrative Law ("OAL") began in March of 2011 and proposed amendments have been circulated for public comment. The Subcommittee met in December to consider the final amendments and it was the sense of the committee that the ICOC should adopt the amendments as proposed. That amendment process has concluded and **staff recommends the ICOC adopt the proposed amendments and finalize the rulemaking process with the OAL.** With the exception of two issues, noted below, the proposed amendments already have been reviewed and approved by the ICOC and Subcommittee and no further changes are proposed.

I. Regulatory Amendments

A. Section 100607 – Access Requirements

1. Californians with "no other means" to purchase a drug.

Prior to SB 1064, CIRM's IP regulations required CIRM Grantees, Collaborators and Exclusive Licensees to provide access to drugs resulting from CIRM research to "uninsured Californians" (section 100607, subdivision (a)). In codifying CIRM's regulation on this point, SB 1064 changed the scope of the access requirement from "uninsured" to Californians "who have no other means to purchase the drug." The legislation leaves the term "no other means" undefined. However, the bill's findings provide that "It is in the best interests of the state that therapies that are created in whole or in part by funding from the institute be made available to Californians who have no other means of purchasing those therapies for reasons that include, but are not limited to, low income or lack of available health care insurance." (S.B. 1064, § 1(g).)

Amended Language of Subdivision (a) of Section 100607: To conform section 100607 with the language of SB 1064, staff proposes the Subcommittee consider the language in subdivision (a) of section 100607, in Attachment "A." The proposed language defines Californians with "no other means" to include those Californians who satisfy both of the following conditions: 1) those who do not have prescription drug coverage that covers the particular drug; and 2) those with family incomes below 300 percent of the federal poverty level. The language is intended to cover Californians who may be insured but whose coverage does not reach the particular drug, and who are below the poverty level that the state uses as the qualifying threshold for the CalRx discount prescription drug program. The poverty level standard thus conforms CIRM's policy with that of the state in defining eligibility for this provision. In so doing, the proposed language ensures that companies are not required to provide access plans to Californians who are wealthy enough to purchase insurance or other coverage but who elect not to do so. Finally, the language in prior subsection (c) has been moved to the end of this subsection so that the contents of the access plan are addressed in one section.

2. Timeline for submission of access plan and to CIRM:

SB 1064 changed the deadline for submission of the proposed access plans from "no fewer than 90 calendar days prior to the time the Drug is commercialized in California" to "within 10 business days following approval of the drug by the federal Food and Drug Administration," unless an extension of no more than 30 days is requested and approved before the deadline.

Amended Language of Subdivision (b) of Section 100607: The proposed amendments to subsection (b) track the language of SB 1064. This language has already been approved by the predecessor of this Subcommittee and the Governing Board for circulation for public comment. No public comment was received regarding this amendment and the language proposed in the draft is unchanged from the version already approved by the Governing Board.

This text is unchanged from that which was approved by the Board at a prior meeting.

3. Waiver of access plan:

Senate Bill 1064 authorizes the Governing Board to waive the access plan requirement but requires the Governing Board to establish a public process to govern such waiver requests:

> "A process by which the ICOC may waive the requirement in subdivision (a) [access plan requirement] if the ICOC determines, after a public hearing, that in the absence of the waiver, development and broad delivery of the drug will be unreasonably hindered or that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to subdivision (a). The process shall include the requirement that a request for a waiver shall be posted on CIRM's Internet Web site for a minimum of 10 business days in advance of the public hearing and that CIRM shall notify the legislature if the ICOC grants a waiver request, including the reasons that justified the waiver request."

The purpose of this provision in SB 1064 is to preserve Proposition 71's delegation to the the Governing Board of the authority to develop IP standards governing CIRM grantees and loan recipients, and to preserve the flexibility to revisit these standards in circumstances where it is appropriate to do so.

Amended Language of Subdivision (f) of Section 100607: The proposed language describes the process by which the the Governing Board may grant a waiver of the requirement to provide an access plan as required in subdivision (a) of the regulation. The proposed language largely tracks SB 1064's language as described above. Specifically, the proposed language provides as follows:

> "(f) The Independent Citizens Oversight Committee ("ICOC") may waive the requirement in subdivision (a) of this section if the ICOC determines, after a public hearing, that in the absence of the waiver, development and broad delivery of the drug will be unreasonably hindered or that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to subdivision (a) of this section. To invoke this waiver provision, a Grantee, Collaborator or Exclusive Licensee must deliver a written request to the Chair of the ICOC within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless the Chair of the ICOC agrees to shortened time. The request must be accompanied by materials describing how development and broad delivery of the Drug will be unreasonably hindered by compliance with subdivision (a) of this section, and/or how the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to subdivision (a) of this section. The request shall be posted on CIRM's website no fewer than ten (10) business days prior to the ICOC's consideration. The ICOC may meet in closed session to review confidential or propriety material, or other material as allowed by Health and Safety Code section 125290.30, subdivision (d)."

The proposed language implements the statute's waiver authorization provided a public record is made of the request to do so and upon a showing by the applicant that the development and delivery of the drug will be unreasonably hindered by complying with the access plan requirement. The proposed language requires such a request be submitted in a timely manner, not less than 90 days prior to commercialization, so that the Governing Board may carefully consider the request and supportive documentation (although the Chair of the Governing Board may agree to shortened time). The subdivision alerts the requestor that the request will be made public by posting on the agency's website no fewer than 10 days before the meeting of the Governing Board. The regulation also reiterates the Governing Board's statutory ability to meet in closed session if necessary to review confidential or proprietary material in consideration of the request.

B. Section 100608 – Revenue Sharing

Senate Bill 1064 amended CIRM's revenue sharing regulation relating to the 1% royalty provision that applies to net commercial revenues in excess of $500 million in a calendar year when grantees receive in excess of $5 million in funding (section 100608, subdivision (b)(3)). Senate Bill 1064 limited the scope of this royalty provision to only those circumstances where a patented CIRM Funded Invention or patented CIRM Funded Technology contributed to the product generating the revenue. Under CIRM's existing regulation, the royalty applies more broadly to such inventions and technology *regardless* of whether they are patented.

The Governing Board authorized, upon recommendation by the IP Task Force, the proposed amendments to subdivision (b)(3) of section 100608 to implement SB 1064 for circulation for public comment. (See Attachment "B.") No public comment was received regarding this amendment and the language proposed in the draft is unchanged from the version already approved by the IP Task Force and the Governing Board.

This text is unchanged from that which was approved by the Board at a prior meeting.

Attachments:

A. Amended section 100607
B. Amended section 100608