

ICOC IP Task Force Meeting
November 22, 2010

Exhibit A

§ 100607. Access Requirements for Products Developed by Grantees.

(a) A Grantee, a Collaborator or an Exclusive Licensee that is commercializing a Drug, as defined in Title 17, California Code of Regulations, section 100601, subdivision (i), that resulted in whole or in part from CIRM-Funded Research must submit a plan to afford uninsured Californians access to such a Drug.

(b) A Grantee, a Collaborator or an Exclusive Licensee that commercializes a Drug must submit the access plan described in subdivision (a) of this regulation to CIRM, within 10 business days following final approval of the drug by the federal Food and Drug Administration unless within that timeframe, the Grantee, Collaborator or Exclusive Licensee seeks an extension from CIRM. If CIRM grants an extension, the access plan must be submitted no later than 30 business days following final approval of the drug by the federal Food and Drug Administration.

(d) The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the Grantee, the Collaborator or its Exclusive Licensee. Grantees, Collaborators and/or their Exclusive Licensees shall have the burden of establishing that the proposed access plan satisfies the requirements of this Section.

(e) The access plan shall be subject to the approval of CIRM after a public hearing conducted by CIRM that provides for receipt of public comment. CIRM may adopt appropriate procedures to protect proprietary information submitted by Grantees, Collaborators and Exclusive Licensees in connection with said public hearing. Approval shall not be unreasonably withheld. Overall, CIRM shall not require that proposed Access plans exceed industry standards for such plans at the time of commercialization in California.

(f) Access plans approved hereunder shall make Grantees, Collaborators and Exclusive Licensees that commercialize a Drug responsible only for providing the Drug itself. Nothing herein shall require the Grantee, Collaborator or Exclusive Licensee to be responsible for any costs of administering the Drug nor for any associate costs of medical procedures or protocols for the Drug therapy, nor for any costs for attendant care.

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(g) A Grantee, Collaborator, or an Exclusive Licensee that is commercializing the Drug must provide a Drug, that resulted in whole or in part from CIRM-Funded Research, at a price as provided in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) (or a successor statewide prescription drug discount program) to eligible Californians under said program.

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(h) A Grantee, Collaborator or its Exclusive Licensee that is commercializing the Drug must sell a Drug, that resulted in whole or in part from CIRM-Funded Research, and which is purchased in California with Public Funds (as defined in Title 17, California Code of Regulations, section 100601, subdivision (q)) at any benchmark price described in the California Discount Prescription Drug Program or a successor statewide prescription drug discount program.

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(i) This regulation is not intended, and this regulation shall not be construed, to preempt or prevent any other requirement under state or federal law or regulation, or agreement or contract, that would result in selling a Drug at a lower price than provided hereunder.

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§ 100608. Revenue Sharing.

(a) A Grantee and Collaborator must share with the State of California a fraction of Licensing Revenue received under a License Agreement for a CIRM-Funded Invention, CIRM-Funded Technology, or results of CIRM-Funded Research, as follows:

(1) Subject to subdivision (a)(2) of this regulation and to adjustments made in accordance with the provisions hereof, the amount owed is 25 percent of Licensing Revenue received in excess of \$500,000 to the State of California for deposit into the State's General Fund (such payments to be used by the State of California in a manner consistent with Title 35 United States Code, Section 202, subdivision (c)(7)). The threshold amount of \$500,000 (in the aggregate) shall be adjusted annually by a multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of October 2009, and the numerator of which is such Index published for the month in which the Grantee accepts the Grant.

(2) If any funding sources other than CIRM (including those of the Grantee or Collaborator, as the case may be) directly contributed to the development of said CIRM-Funded Invention or CIRM-Funded Technology, then the return to the State of California on Licensing Revenue in excess of the threshold amount described in subdivision (a)(1) of this regulation shall be proportionate to the support provided by CIRM, as follows: The amount of CIRM funding of the CIRM-Funded Invention or CIRM-Funded Technology shall be divided by the total of funding provided by all sources, and that

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Item 3 Exhibit

fraction shall be multiplied by 25. That numeral is the percentage due to the State of California of Licensing Revenue.

(b) A Grantee and Collaborator must share with the State of California a fraction of any Net Commercial Revenue it receives from a self-commercialized product it commercializes itself and which resulted from its CIRM-Funded Research (regardless of whether a CIRM-Funded Invention or CIRM-Funded Technology is involved) as follows:

(1) Grantees and Collaborators must pay royalties to the State of California for deposit into the State’s General Fund on Net Commercial Revenue exceeding the threshold amount described in subdivision (a)(1) of this regulation. Total payments under this subdivision (b)(1) shall equal and not exceed three times the total amount of the CIRM Grant or Grants that led to the product. The rate of payback of the royalty shall be at a rate of three (3) percent of the annual Net Commercial Revenue from the product.

(2) In addition, if Net Commercial Revenue from a product commercialized by the Grantee, or Collaborators and which resulted from its CIRM-Funded Research exceeds the milestone of \$250 million in any calendar year, a one-time payment of three times the total amount of the Grant(s) awarded shall be paid to the State of California. In addition, if Net Commercial Revenue exceeds the milestone of \$500 million in any calendar year, an additional one-time payment of three times the total amount of the Grant(s) awarded shall be paid to the State of California.

(3) In addition to any amounts due under any other provision of this regulation, where a patented CIRM-Funded Invention(s) or patented CIRM-Funded Technology is involved in the achievement of Net Commercial Revenue realized by a Grantee or Collaborator equivalent to or greater than \$500 million in any year, and where a CIRM Grant or Grants amounting to more than \$5 million (in the aggregate) were made in support of CIRM-Funded Research that contributed to the creation of Net Commercial Revenue, the Grantee or Collaborator will pay the State of California one percent annually of Net Commercial Revenue in excess of \$500 million for the life of any patent covering such patented CIRM-Funded Invention or patened CIRM-Funded Technology.

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Deleted: or CIRM-Funded Technology, or 20 years after the close of the . Grant if the CIRM-Funded Invention or CIRM-Funded Technology is not patented.

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