

1 Adopt 17 Cal. Code of Regs. section 100410 to read:

2 **§ 100410. March-In Rights.**

3 (a) CIRM may request that a Grantee or its exclusive licensee to enter into a  
4 nonexclusive, partially exclusive, or exclusive License Agreement with respect to a CIRM-  
5 funded Patented Invention and/or data generated in CIRM-funded Research, in any field of use  
6 with a responsible applicant or applicants, upon terms that are reasonable under the  
7 circumstances.

8 (b) If a Grantee or its exclusive licensee refuses CIRM's request to enter into a License  
9 Agreement to a CIRM-funded Patented Invention as provided by this regulation, CIRM shall  
10 have the right to enter into such a license with an applicant on behalf of the Grantee or its  
11 exclusive licensee (march in) if :

12 (1) the Grantee or its exclusive licensee has not made commercially reasonable efforts to  
13 achieve practical application of a CIRM-funded Patented Invention and/or CIRM-funded  
14 Research data, as applicable;

15 (2) the Grantee or its exclusive licensee has failed to provide or comply with a plan for  
16 access to a Drug in accordance with Title 17, California Code of Regulations, section 100407;

17 (3) the Grantee or its exclusive licensee has failed to satisfy requirements for public use,  
18 including broad availability in California (for reasons other than price) in accordance with Title  
19 17, California Code of Regulations, section 100407;

20 (4) the Grantee or its exclusive licensee has unreasonably failed to use a CIRM-funded  
21 Patented Invention or CIRM-funded Research data to alleviate public health and safety needs  
22 that constitute a public health emergency as declared by the Governor.

1 (c) CIRM will promptly notify a Grantee or its exclusive licensee of any adverse  
2 determination under this provision and the basis therefore, as well as its intention to exercise  
3 march-in rights.

4 (d) CIRM will not exercise its march-in rights if the Grantee or its exclusive licensee  
5 promptly takes action to cure the deficiency and such deficiency is cured sooner than one year  
6 from the date of notice (or longer period by mutual agreement). With respect to a deficiency  
7 described in subdivision (b)(4) of this regulation, however, CIRM may exercise such right at any  
8 time in the event of a public health or safety emergency declared by the Governor and where  
9 CIRM finds that exercise of march-in rights is likely to alleviate the circumstances or conditions  
10 that give rise to the emergency declaration.

11 (e) At any time within one year of the date CIRM issues a notice of determination and  
12 intent to exercise march-in rights, a Grantee may appeal CIRM's decision to the ICOC by  
13 notifying the President of CIRM in writing within 30 days of the next regularly scheduled  
14 meeting of the ICOC of its intent to appeal CIRM's decision. The ICOC may reverse the  
15 decision of the CIRM to exercise march-in rights under this regulation for any reason.

16 (f) Any applicant to receive a license pursuant to this regulation will be bound by this  
17 Chapter as if it were an original Grantee recipient of the funding that resulted in the applicable  
18 CIRM-funded Patented Invention.

19 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and  
20 Safety Code. Reference: Section 125290.30, Health and Safety Code.