University of California
San Francisco

Brian R. Shy, MD, PhD
Assistant Professor, Dept. of Laboratory Medicine
Gladstone-UCSF Institute of Genomic Immunology
Director, Investigational Cell Therapy Program
University of California, San Francisco

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RE: Letter for the January 29th CIRM Board Meeting

Dear CIRM Board,

My name is Brian Shy. I'm a physician-scientist at UCSF and I direct our Investigational Cell Therapy Program which supports dozens of cell and gene therapy projects through pre-clinical stages, GMP manufacturing, and clinical trials. I'll add some comments as someone who sees the impact across many programs and sees many individual CIRM grants.

The implementation of the SAF puts a point system in place at the administrative level. If you don't get enough points, you do not receive scientific review. Some points are given for general criteria, and some are specific to a particular modality or indication: neurologic disease, in vivo therapy, pluripotent stem cell therapy, for example. Based on the threshold you have set, four points are needed to have confidence your grant will be reviewed. 90% of FIH projects that I see will get two points in the general criteria (California institution and prior CIRM award), meaning they also need to meet two specific criteria.

The result is that only certain combinations move forward to scientific review – predominantly either in vivo gene therapy for neurologic disease, or iPSC-derived therapy for neurologic disease. You can see that skewing very easily in your CLIN2 data or just by looking at the lists directly. These are important categories and we are all excited about their potential, but they are certainly not the only important areas for public health in California, nor are they underrepresented in your portfolio. In contrast, most of the projects I see across cancer, infectious disease, autoimmunity, rare disease, transplant, and many others are no longer eligible.

The current system is putting all of your eggs in a very narrow basket, reducing product diversity, and eliminating truly exciting areas of cellular engineering and synthetic biology. This and other areas of the SAF, such as eliminating funding for CIRMs California Manufacturing Network, is doing harm to the programs and ecosystem that you built, and alienating the community of public investigators that have supported CIRM for decades.

There are simple ways to fix this. For example, you could lower the number of points required for scientific review, eliminate overly specific criteria that are not underrepresented in your portfolio, and/or implement alternative triage systems that do not skew the application pool such as multi-stage scientific review. It is critical is that you do not wait a year to implement these changes, the damage is being done now.

Thank you all for your consideration of these important issues, and for your commitment to what has been a truly wonderful institution driving cell and gene therapy advancement and cures in California.

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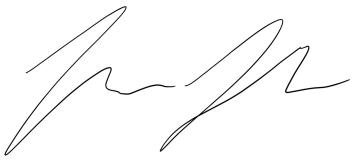
Sincerely,



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