Biocom California

September 14, 2022

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies (FDA-2022-D-0745)

Submitted electronically

Dear Sir/Madam:

Biocom California appreciates the opportunity to offer comments on the Food & Drug Administration (FDA) draft guidance document, *Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies*[1].

Biocom California is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,600 members dedicated to improving health and quality of life, Biocom California drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates over $400 billion in annual economic activity, supports almost 1.4 million jobs, and increases labor income by $131 billion per year[2].

We commend the agency on its ongoing efforts to provide guidance to the regenerative therapy research and development community. With over 100 members in the cell and gene therapy sector and a cell and gene working group, Biocom California is committed to engaging with the agency to provide feedback and support, as appropriate, on this and future draft guidances.

In the medical device community, the Standards and Conformity Assessment Program (S-CAP) has promoted patient safety and advanced regulatory science while maintaining FDA's least burdensome principles[3]. Through conformance to FDA-recognized consensus standards, the S-CAP has facilitated a more efficient and consistent regulatory review for all stakeholders. In the FDA draft guidance *Voluntary*

[1] Federal Register, 87 FR 36327, pp. 36327-36329, June 16, 2022.
[2] Biocom California 2021 Economic Impact Report Databook. https://www.biocom.org/eir/
[3] Standards and Conformity Assessment Program. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/standards-and-conformity-assessment-program

Consensus Standards Recognition Program for Regenerative Medicine Therapies, the FDA describes a standards recognition program for regenerative medicine therapies (SRP-RMT) which is modeled after the S-CAP for medical devices. **In general, Biocom California agrees with the FDA's efforts to create a SRP-RMT as it will facilitate a more efficient review of RMTs and FDA-recognized voluntary consensus standards (VCS) will enhance regulatory predictability for these products.**

Section V of the draft guidance outlines procedures for evaluating VCS for recognition in the SRP-RMT. In this section, the FDA's Center for Biologics Evaluation and Research (CBER) explains how it intends to consider multiple factors when assessing a standard, including that the standard be "scientifically sound." Based on this information, it is unclear what specific, objective criteria a standard should meet in order to be considered for inclusion into the SRP-RMT. **Biocom California suggests that the agency provide specific, objective criteria and clarifying examples in the guidance document. Furthermore, we ask the FDA to please include additional language explaining how these criteria will be utilized during CBER's VCS evaluation process**.

Additionally, the draft guidance states that "RMTs are defined in section 506(g)(8) of the [Food, Drug, and Cosmetic] FD&C Act and include cell therapies (allogeneic and autologous), therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products except those regulated solely under section 361 of the PHS Act (42 U.S.C. 264) and 21 CFR Part 1271." RMTs may encompass a variety of product types with diverse technological characteristics, and we are pleased that the agency acknowledges that "the scientific and manufacturing novelty of many RMT products present unique challenges for meeting regulatory requirements." **However, Biocom California is concerned that a uniform approach to applying a VCS for these products may be challenging for stakeholders. We encourage the agency to consider the applicability of a standard for a particular RMT when evaluating how manufacturers utilize VCSs, especially in the case where deviations from the standard are made and supported by a scientific rationale and data**.

We appreciate the opportunity to provide feedback on behalf of our members and thank you for your time and diligence in examining our comments. Please contact Biocom California's Associate Manager of Regulatory Policy, Zoe Bilis, at zbilis@biocom.org for additional information or questions. We look forward to continuing to work with you on this critical matter.

Sincerely,

Joe Panetta
President and CEO
Biocom California