STANDARDS COORDINATING BODY
REGENERATIVE MEDICINE

Food and Drug Administration

10903 New Hampshire Ave WO71-3128

Silver Spring, MD 20993-0002

[RE: Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies: Docket No. FDA-2022-D-0745]

To Whom it May Concern,

This response represents the shared perspective of the Standards Coordinating Body (SCB)'s stakeholder community, which includes standards development organizations, regenerative medicine therapies (RMT) stakeholders, and RMT subject matter experts working within academia, industry, and patient advocacy.

We strongly support the Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies: Docket No. FDA-2022-D-0745 as written in the draft guidance. We appreciate FDA's acknowledgment of the importance of Voluntary Consensus Standards (VCS) as demonstrated in the creation of this standards recognition program, as well as their continued input and feedback within the consensus standards development and review processes. By continuing to support the drafting of, and by formally recognizing VCS, FDA is strengthening the RMT standards community and spurring the involvement of additional subject matter experts. We're in agreement with FDA that this dedication paired with added regulatory predictability will "facilitate the overall development of safe and effective RMT products"[1].

[1] Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies: Docket No. FDA-2022-D-0745

However, RMT products are inherently variable and complex as a consequence of the inherent variability and complexity of the biological systems from which they are produced. In contrast to the standards within the S-CAP program for medical devices that was used as the template for the VCS Recognition Program, standards most useful to the RMT community emphasize processes, methods, and quality systems, and acknowledge clinical implications of the RMT products. We believe the acknowledgment of these differences within the guidance will encourage the success of the program.

On August 24, 2022, SCB held an educational webinar on the Consensus Standards Recognition Program Draft Guidance. A recording and slides from the meeting can be found on SCB's webpage. In this webinar, SCB explained the draft guidance document, answered participant questions, and collected and coordinated participant comments on the proposed VCS Recognition Program. The majority of the comments were on the basics of VCS, determination of VCS relevancy, and the VCS Recognition Program submission process.

Summary stakeholder comments, concerns, and questions heard expressed in the webinar:

- What constitutes a VCS; the principals of the voluntary consensus standard development are listed within the guidance document, but are is there a requirement that the standard comes from an ANSI accredited organization?
- Will the FDA be providing funds to support the education of stakeholders on the VCS Recognition Program and on the use of consensus standards within RMT?
- What criteria will be used to determine if a particular VCS is relevant?
- What specific types of therapies will be included within the program?

- Will relevant lexicon VCS be included in the program?
- Are VCS being recognized only if they can impact the regulatory process or on their general benefit to the field? For example, would an equipment VCS that does not directly impact regulatory issues be recognized?
- There is a concern about the recognition of part of a VCS that is meant to be used as a wholistic document. How does the FDA intent to manage this concern?
- Will VCS recognition precedence, or lack thereof, be part of the submission process or recognition decision?
- What is the best avenue for engaging with FDA on pending VCS submissions?

Finally, we are grateful for the creation of the VCS recognition program and the Standards Coordinating Body and its stakeholders within the RMT community are looking forward to collaborative activities on future RMT VCS with the FDA and other stakeholders.

Signed,

Justin Barch, CAE

Executive Director

Standards Coordinating Body