

February 6, 2020

Senator Virginia Lyons, Chair Vermont Senate Committee on Health and Welfare Vermont State House 115 State Street Montpelier, VT 05633-5301

Dear Senator Lyons:

AABB (formerly the American Association of Blood Banks), an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies, is submitting this letter in support of the bills related to stem cell products (H. 626, S. 252) that are being considered by the Vermont legislature.

AABB is committed to "improving lives by making transfusion medicine and biotherapies safe, available, and effective worldwide." AABB works toward this vision by developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB's accreditation program started in 1958 and has been a key driver in the adoption of quality management systems by clinical laboratories and cell processing facilities. AABB has an Accreditation Program for Cellular Therapies that covers all aspects of collecting, manufacturing and administering hematopoietic stem cells and other cellular therapies and biotherapies.

AABB's accreditation program has an established history of ensuring quality and safety, which is recognized by the Federal government, states and international organizations. For example, AABB's Accreditation Program for Cellular Therapies is recognized by the Health Resources and Services Administration (HRSA) and the National Marrow Donor Program. AABB is the only accreditor in cellular therapies to have deemed status from the Centers for Medicare & Medicaid Services (CMS) to conduct CLIA inspections. CMS recognizes AABB for microbial testing of CT products, which is essential to product safety. In addition, AABB is the only accreditor in the United States, and one of 39accreditation programs worldwide, that is accredited by the International Society for Quality in Health Care External Evaluation Association (IEEA), the leading global health care external evaluation program.

We believe that the bills related to stem cell products being considered by the Vermont legislature are consistent with AABB's commitment to the quality and safety of cellular therapies and other biotherapies. As you recognize, the use of unregulated and unproven stem cell products is an increasing problem in the United States and worldwide and one that we as an organization are actively working against. We understand that Vermont's bill is similar to existing legislation in California and Washington State, and that other states are engaged in similar efforts to regulate these products.

If you have any questions or need additional information, please contact Leah Stone at $\underline{lmstone@aabb.org}$ or 301-215-6554.

Sincerely, Debra Berawam

Debra BenAvram

Chief Executive Officer

AABB