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AMERICAN SOCIETY of GENE & CELL THERAPY

January 29, 2020

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

Dear Senator Lyons,

The American Society of Gene & Cell Therapy (ASGCT) appreciates the opportunity to voice our support for policies that discourage the administration of cell and tissue products lacking strong scientific evidence of benefit to patients. ASGCT is a nonprofit professional membership organization comprised of more than 3,500 scientists, physicians, and other professionals working in gene and cell therapy in settings such as universities, hospitals, and biotechnology companies. The Society is dedicated to advancing the knowledge of gene and cell therapies to alleviate human disease.

The use of unproven stem cell products to treat diseases by providers operating in violation of current federal law is an increasing problem within and outside the United States. The Food and Drug Administration (FDA) has stated that they will begin to increase enforcement later this year. We support the Agency's efforts to crack down on bad actors while fostering clinical research and innovation. We also appreciate your efforts to advance legislation to better inform patients about the data and regulatory structures, or lack thereof, which govern such procedures and products. This action could help enhance the public perception of reputable cell and tissue therapy products and techniques.

ASGCT supports notifying patients who are consenting to the administration of unapproved human cell, tissue, and cellular or tissue-based products (HCT/Ps) that require FDA approval for use (which excludes procedures that rely on homologous use of minimally manipulated HCT/Ps, which are not required to submit an FDA application under Section 351 of the Public Health Service Act for approval, but rather are regulated under Section 361). To that end, we recommend the state ensures that S.252 will provide sufficient clarity that products not requiring an FDA application and approval for use are not considered to be "unapproved" for the purpose of this legislation. We also recommend that you consider making the notification agnostic to the site of the procedure or employment of the provider.

ASGCT would be pleased to provide any technical assistance or follow-up information the Committee may request. Thank you again for your attention to the use of unproven stem cell products, which may have a highly detrimental impact on vulnerable patients, their families, and responsible clinicians in the cell therapy field.

Sincerely,

Guangping Gao
President
American Society of Gene & Cell Therapy

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