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13 February 2020

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

Dear Senator Lyons,

On behalf of the International Society for Stem Cell Research (ISSCR), I write to express our support for S. 252, "An act relating to stem cell therapies not approved by the U.S. Food and Drug Administration." The ISSCR is the leading professional organization of stem cell scientists and represents more than 4,000 members in the United States and around the world. Our members are scientists, clinicians, ethicists, and educators dedicated to the responsible advancement of stem cell research and its translation to the clinic. We support S. 252 because we believe it will help warn patients about the risks of unapproved therapies whose safety and efficacy have not been proven in well-regulated clinical trials.

While stem cell-based interventions may someday have the potential to treat serious diseases, the current capacity to use stem cells effectively as treatments is often exaggerated by those who do not fully understand the science and present limitations. Unscrupulous "clinics" regularly seek to capitalize on the hype by selling cell therapies that have not been proven safe or effective. Unproven treatments marketed by these clinics have resulted in patients being [blinded](#), [paralyzed](#), and [infected](#) with dangerous pathogens. Despite the recent [FDA](#) and [FTC](#) enforcement actions against unscrupulous clinics illicitly marketing unproven therapies to patients, we believe S. 252 is needed to adequately inform patients about the risks of unproven treatments.

For many years, the ISSCR has cautioned against the premature marketing and commercialization of stem cell-based interventions. The society's [Guidelines for Stem Cell Research and Clinical Translation](#) condemned the administration of unproven stem cell-based interventions outside of clinical research, and they urged governments to strictly enforce regulations to ensure the safety and efficacy of new therapies. Last year, the ISSCR released an [Informed Consent Standard for Stem Cell-Based Interventions Offered Outside of Formal Clinical Trials](#) to set a professional standard for the

Promoting excellence in stem cell science and applications to human health.

information that patients need to be provided to prepare them to make an informed decision regarding treatments. We believe S. 252 will complement these efforts and help ensure patients in Vermont are warned about the potential risks of unproven stem cell therapies.

Thank you for your leadership on this issue. If the ISSCR can clarify any of these views or be of assistance, please contact Eric Anthony, ISSCR's Director of Policy at eanthony@isscr.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Srivastava', with a stylized flourish at the end.

Deepak Srivastava, MD
President, ISSCR
President, Gladstone Institutes