To: Senate Committee on Health & Welfare
From: Jessa Barnard, Vermont Medical Society
Date: February 19, 2021
RE: S. 22 – Health Care Practitioners Administer Stem Cell Products

Thank you for the opportunity to testify in support of S. 22, An act relating to health care practitioners administering stem cell products not approved by the U.S. Food and Drug Administration. The Vermont Medical Society (VMS) is the largest physician membership organization in the state, representing over 2400 physicians and medical students across all specialties and geographic locations.

VMS became aware of the issue in 2019 and that fall our members adopted the following policy statement regarding non-FDA approved stem cell products:

RESOLVED, that the Vermont Medical Society disseminate evidence-based information to its members regarding stem cell clinics and therapies and encourage members to have evidence-based discussions with their patients when they inquire about such services; and be it further

RESOLVED, that VMS coordinate with appropriate professional licensing boards, the Attorney General's Office and other regulatory bodies to ensure that patients seeking stem cell therapies are provided safe and evidence-based information and services.

This position statement also led to VMS supporting the S. 252 last year and S. 22 this year. VMS supports S. 22 for the following reasons:

Why is S.22 needed?
Stem cell therapies are an emerging area of medicine, with FDA-approved research happening across the country as we speak. 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. These exaggerations are being promoted by unscrupulous "clinics," which regularly seek to capitalize on the hype around legitimate stem cell research by selling cell products 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 recent FDA and FTC enforcement actions against these clinics marketing unproven therapies to patients, S.22 is needed to adequately inform patients that these products have not received FDA approval.

What does S.22 do?
S.22 includes several requirements, including:

- A requirement that health care practitioners administering stem cell products not approved by the FDA provide each patient with a written notice before administering the product to the patient for the first time. The bill specifies the content and format of the notice and requires that it include information on methods for filing a complaint with the licensing authority and for making a consumer inquiry.
- A requirement that health care providers prominently display the written notice and consumer protection information at the entrance and in an area visible to patients in the practitioner's office.

- A requirement that health practitioners who administer stem cell products not approved by the FDA have the patient sign a disclosure form prior to each administration of an unapproved stem cell product and to keep a copy of each signed form in the patient's medical record.
- A requirement that health care practitioners include the notice in any advertisements relating to non-FDA-approved stem cell products and addresses both print and non-print forms of advertising.

S. 22 exempts health care practitioners with FDA approval or clearance for an investigational new drug or device for the use of stem cell products and practitioners who administer the products under a contract with an institution certified by certain national organizations. Additionally, this bill specifies that a violation of the section constitutes unprofessional conduct under the Board of Medical Practice and OPR statutes.

Background on the issue

There are different types of stem cells, and they can do different things that might be beneficial to patients. One particularly exciting action is in stimulating the body's own repair mechanisms to restore body tissues impacted by illness or injury. There is a wealth of research currently underway to study these and other possible uses of stem cells. However, we are still many years away from proven, FDA-approved clinical use.

With the exception of specific stem cell therapies for certain cancers, such as leukemias and lymphomas, current stem cell clinics in Vermont are not providing any FDA-approved research or treatments. In an effort to recruit customers at their information sessions, staff from stem cell clinics assert that FDA certification has not been granted for their therapies due to the heavy lobbying of pharmaceutical companies. In actuality, FDA approval has not been granted due to the lack of clinical trials with stem cell therapies; at the stem cell clinics that have opened in Vermont, patients are not receiving any stem cell treatments that have been FDA-approved.

Some patients with chronic or end-stage diseases turn to stem cell therapy, even if these treatments are still scientifically unproven, because they are motivated by the hope of a possible cure. These clinics unfortunately take advantage of these situations and charge very high prices; stem cell treatments can cost upwards of thousands of dollars out of pocket. Stem cell treatments are not covered by private insurance, Medicare, or Medicaid. Insurance companies currently view stem cell procedures as experimental. Further, these clinics offer misleading information about potential efficacy that is confusing to patients and to caregivers.

How is it legal?

Human cells and tissue-based products are considered drugs and need demonstration of safety and efficacy (e.g. through clinical trials). Exceptions to this rule include:

- Cell products that are minimally manipulated, intended for homologous use and not combined with other articles (section 361 of the PHS Act)
- Destined for use in the same individual within the same surgical procedure (surgical exemption)

Most stem cell businesses in the U.S. claim these two exemptions to avoid having their products/interventions considered as drugs.