State of Vermont
Office of the Secretary of State

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To: House Health Care Committee
Representative Lippert, Chair
Representative Donahue, Vice Chair

From: S. Lauren Hibbert, Director, Office of Professional Regulation
Date: April 30, 2021
Re: S.22, an act relating to health care practitioners administering stem cell products not approved by the U.S. Food and Drug Administration

Dear Committee,

Thank you for the opportunity to testify on S.22 this week. The Office of Professional Regulation ("OPR") has regulatory authority over many of the professions that will be affected by the bill.

OPR supports the policy objectives of S.22 and appreciates the simple and effective way it approaches a complicated topic. The bill is notably modest and non-coercive. It does not restrict clinical practices, but instead ensures that patients know when they are being offered stem cell and stem cell-related therapies that have not been reviewed by the United States Food & Drug Administration (FDA) for safety and efficacy. Patients are not kept from any therapy, but only informed when a therapy has not been FDA approved. Patients expect to have this simple information, and requiring its disclosure is a small and commonsense step toward protecting the most important of any patient's rights: informed consent.

It is important that the bill's broad definition of "stem cell and stem cell-related products" be preserved. It creates the widest net for public protection. Experimental, valid, and/or effective treatments may be included in the definition. More importantly, it captures the "snake oil" sales vendors, as well.

The notice requirement is for non-FDA-approved stem cell products or treatments.

- The required notice is concise and recommends that the client consult their primary care provider. This is good advice replicated in many places in our common-day life, even for multivitamins. Notice requirements are not a new concept in Vermont law, we have notice requirements for other types of treatment in the health care system – for instance, mental health providers are required to provide mandatory disclosures that include their training and how to make a complaint with OPR. Massage therapists are required to provide more ominous disclosures related to sexual misconduct. The notice requirements in S.22 are far less prejudicial to the provider and are triggered only when a narrow range of therapies is recommended.

- Failure to provide notice to the patient and in advertisements results in a clear violation of unprofessional conduct standards. The simplicity and clarity of S.22's requirements will make complaints about stem cell scams easier to prosecute, reducing the need for an expert in stem-cell therapy can expedite cases- which is important for the providers that move state to state.

I would ask the Committee to consider other important characteristics of some of the activity around stem cells or other non-FDA-approved treatments:

- Not within the protections of an accredited healthcare institution or system;
- Appearance in pop-up clinics or stand-alone clinics with no regulatory oversight;
- Often not covered by third-party payers, meaning cash transactions from vulnerable patients' own funds, sometimes financed on credit;
- Exploits office-based compounding and administration to evade oversight by FDA as to safety and efficacy, as well as drug utilization review by an independent and objective pharmacist. These pillars of drug-product protection are so common that most patients assume adherence to the standard. Patients deserve to know when these protections are absent. This is a critical piece of public protection that is missing.

OPR has received a total of six stem cell-related complaints against practitioners including a dentist, a naturopathic physician, and an APRN. The policy objectives of S.22 would have been helpful in each instance. While I would like to share more with the Committee about these serious and ongoing concerns, I am constrained by 3 V.S.A. § 131 to avoid publicizing the facts of cases still under investigation.

S.22 would do no more and no less than ensure that patients have an opportunity to give informed consent to FDA-unapproved therapies related to stem cells. It is uncoercive and restricts no clinical practice and would aid OPR's efforts to enforce essential standards of acceptable and prevailing practice. If a provider does not want a patient to know a recommended therapy has never been reviewed nor approved by the FDA, or does not want a patient to consult a primary care provider before undertaking an unapproved therapy, one must ask why.