VERMONT

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*Agency of Human Services*

February 25, 2021

To: Senate Committee on Health and Welfare
From: David Herlihy, Executive Director

David K. Herlihy

Digitally signed by David K. Herlihy
Date: 2021.02.25 09:03:02 -05'00'

Re: Testimony of February 19, 2021 on S.22 - An act relating to health care practitioners administering stem cell products not approved by the U.S. Food and Drug Administration

1. This is to summarize my testimony of last week. Thank you for allowing me to present input on behalf of the Vermont Board of Medical Practice. In short, with one small exception, the Board supports passage of the bill.

2. In recent years the Board became aware that certain Vermont businesses were offering individuals what were held out as stem cell therapies, but in fact were using stem cell products that were not approved by the U.S. Food and Drug Administration. Sales of these products is possible because of a loophole in the federal law, and to date the involved State of Vermont agencies have proceeded with the assumption that Vermont cannot pass laws banning these non-approved products, which are regulated by the FDA. No investigations by the Board have resulted when use of non-approved products came to the Board's attention because it was determined that no licensee of the Board was involved in any of the identified instances in which non-approved products were sold as stem cell treatments. The Board licenses and regulates medical doctors (MDs), physician assistants, podiatrists, anesthesiologist assistants, and radiologist assistants. Although no cases involving Board licensees have come up to date, MDs and PAs have been involved with such businesses in other states and it could happen here.

3. The Board supports this bill for two main reasons. First, it calls for individuals to have more information when making decisions about their health care. Allowing patients to be informed when making decisions about their medical care is recognized as desirable. The bill requires that information be provided in advertising about these products and before administering them to individuals, including a notice in writing and signed by the individual each time they are to receive an unapproved product. The average consumer probably assumes that products administered in the course of health care treatments are approved by the government. The disclosure requirements will help to ensure that people receiving these non-approved products understand that the products have not been approved as safe or effective by the FDA. That knowledge may help some Vermonters to avoid making an uninformed decision to accept the health and financial risks that come with buying these products; at a minimum it will avoid having them make that decision with the false belief that what they are buying is government approved.

4. The second reason the Board supports the approach taken in the bill is its simplicity. The obligations would be easily understood by any business needing to comply with the law. The clear and easily understood requirements would also make for more efficient enforcement. There are provisions in existing Vermont law that might apply to situations in which health care providers sell stem cell products that are not approved by the FDA. For example, any false or misleading statements about safety, efficacy, or approval status could be charged as unprofessional conduct. However, the investigation and prosecution of such an allegation would almost always present the need for expert testimony. It can be difficult, time consuming, and expensive to litigate a case involving experts, for both sides. Also, there can be more "grey area" when debating whether statements about safety or efficacy of products that have not been approved by the FDA are false or misleading. In contrast, the requirements of S.22 are clear and the violation of them could be investigated and litigated without experts. S.22 would serve the goal of empowering people to make better informed decisions about their health care without overburdening the businesses that would be required to make these simple disclosures about a critical fact regarding the product at issue.

5. As noted above, there is one part of the bill that the Board does not see as necessary Section 4 proposes to require VDH to revise the Rules for Advance Directives. Section 4 was carried forward from a draft of a bill introduced last session (S.252) that was not passed. Section 4 was added to the bill when the Committee considered dealing with this as a matter of informed consent. Because the approach has been changed to one of disclosure instead of informed consent, the topic of Advance Directives is not raised by S.22 and there is no need to look at revising the rules.