VERMONT

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*Agency of Human Services*

April 6, 2021

To: House Committee on Health Care
From: David Herlihy, Executive Director

David K. Herlihy Digitally signed by David K. Herlihy
Date: 2021.04.06 13:35:36 -04'00'

Re: Written Testimony 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 memorialize my anticipated testimony. Thank you for allowing me to present input on behalf of the Vermont Board of Medical Practice. In short, the Board supports passage of the bill.

2. In recent years the Board has learned of instances in which certain Vermont businesses were offering individuals what were held out as stem cell therapies, but in fact were using products not approved by the U.S. Food and Drug Administration (FDA). Sales of these products are 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. The federal government, through the FDA, regulates drugs, devices, and biological products used in healthcare.

3. The Board licenses and regulates medical doctors (MDs), physician assistants, podiatrists, anesthesiologist assistants, and radiologist assistants. No investigations resulted when the Board learned of concern about use of those non-approved products because it was determined that no licensee of the Board was involved in any of the identified instances. Although to date none of these cases have featured Board licensees, MDs and PAs have been involved with such businesses in other states and it could happen here.

4. The Board supports S.22 for three reasons. First, something should be done about this situation. The sale of unapproved treatments that are being marketed as stem cell therapies presents both financial and health risks. There are financial risks to individuals because the products and services are not covered by private insurance or government programs, and charges are significant. It is not unusual for individuals to spend many thousands of dollars. Why do people spend so much on treatments that are not approved by the FDA? One contributor certainly is the large volume of positive news about successful treatment using FDA-approved stem-cell treatments and the promise of treatments that are in experimental stages and in the process of seeking FDA approval. Another likely factor is that people may assume that medical products and services cannot be offered unless they've been found safe and effective by government regulators, similar to prescription drugs, but that is not the case here because of the above-mentioned loophole. In addition to the risk that people may be financially victimized by spending significant sums of money without an understanding that treatments they are

buying are not approved as safe and effective by the federal government, there are also health risks. Often these products involve some kind of injection or intravenous infusion, such as reinfusing a patient's own blood after it has been run through a centrifuge. These processes are not without risk, such as risk of infection. While many approved treatments may present some level of risk, the difference is that approved products and treatments have been found to be effective through rigorous testing and approval processes. People should understand all this before spending money and accepting the health risks. While the State of Vermont may not be in a position to ban the sale of these treatments, something must be done to promote a better understanding among those who buy these products and services.

6. The second reason the Board supports S.22 is that it takes a reasonable, balanced approach to the situation, simply requiring that individuals have more information when making decisions about their health and healthcare spending. It would be hard to identify a downside to a requirement for people to have more information when making decisions about their medical care. 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 one of the covered products that has not been approved by the FDA. 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.

7. The third reason the Board supports the approach taken in the bill is its simplicity. The obligations are straightforward and should be easily understood by any business that would be subject to 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 could 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 simple, 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.

8. The Board recommends support for S.22 and its requirement to better inform health care consumers.