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Testimony Senate Health & Welfare Committee - February 19, 2021

Thank you for the opportunity to testify on S.22 regarding the administration of stem cell products that have not been approved by the US Food and Drug Administration. The Vermont Ethics Network (VEN) recognizes that legitimate research in the use of cellular based therapies remains a rapidly advancing and highly promising field for therapeutic products. However, the proliferation of clinics marketing unapproved stem cell products with claims of efficacy and safety that are not evidence-based is both concerning and ethically problematic. Particularly worrisome is the growing practice of promoting expensive "stem cell treatments" for myriad diseases (including COVID-19) that have unknown or unproven benefits and may pose significant risks to the health of sick and vulnerable patients.

History of Vermont Ethics Network Involvement

In October of 2018, the VEN Board had a presentation from a UVM pulmonologist on the topic of stem cell medical tourism. This, along with a series of ads appearing in the *Times Argus* in November of 2018, prompted the organization to send letters to the Attorney General, The Board of Medical Practice and the Office of Professional Regulation requesting investigation into the advertising practices of these clinics. Specifically that the ads may:

- Falsely imply that stem cell therapy is effective for all of the conditions listed in the ads;
- Falsely imply that the stem cell process is regulated by the FDA;
- Fail to give adequate informed consent of downside risks compared to lack of proven efficacy;
- Fail to disclose weak or non-existent scientific rationale for the treatment and the lack of knowledge of any known mechanism of "healing";
- Fail to disclose that the experimental nature of the treatment is not subject to standardized experimental protocols.

Also at that time, VEN expressed concern that the advertisement and practice may constitute unauthorized medical or naturopathic practice; may constitute false advertising; may be offering false hope to vulnerable persons desperate for any treatment, regardless of proven effectiveness; and may, as has been previously reported, cause serious harm.

In 2020, VEN testified in support of S.252, which was introduced in an effort to ensure that in Vermont, appropriate disclosures will be made to patients prior to the administration of any non-FDA approved stem cell product.

Ethical Issues Related to Current Advertising & Practice of Stem Cell Clinics

- ***Truth telling*** is a near absolute in medical ethics and underpins the very foundation of the clinician-patient relationship. Yet, research shows that the advertising strategies deployed by commercial stem cell providers exaggerate potential benefits, use misleading or ambiguous terminology to suggest scientific legitimacy, fail to disclose risks, and do not advertise what is actually being administered.[i] More recently, news that some clinics are marketing stem cell treatments to treat or prevent COVID-19 and COVID-19 related ARDS is particularly concerning.[ii] This practice of misrepresentation and misleading information about unproven stem cell products violates public trust, contributes to misunderstanding and confusion, promotes usage for an inappropriate range of applications and creates false hope.

- ***Challenges for Informed Consent:*** The core elements of informed consent include discussion about the risks, benefits and alternatives of any proposed treatment, including no treatment. Ethically, informed consent is the way clinicians demonstrate respect for patient autonomy. Legally,

it is the process that protects patients liberty interests—the right to noninterference without their permission. Practically, obtaining informed consent is what promotes patients in making informed, voluntary decisions based on accurate information through a shared decision-making process.

Unclear scientific evidence to suggest efficacy and insufficient data from animal and clinical studies regarding the safety profile to support use in patients means that there is inadequate information available to ensure a proper informed consent.

- ***Professional Standards & Scope of Practice:*** Professional standards require clinicians to know their scope of practice and to practice within that scope. Many stem cell clinics advertise "healing stem cell therapies" for a wide range of conditions. Yet, the clinicians administering the cellular preparations may have no formal training in the conditions they claim to treat. Clinicians providing unapproved stem cell interventions outside of their scope of training violate professional and ethical standards of practice and may increase risk of harm to patients.[iii]

- ***Commitment to the Advancement of Scientific Knowledge:*** The AMA Principles of Medical Ethics are the core elements that comprise the AMA Code of Ethics.[iv] One of those core principles is a "commitment to study, apply and advance scientific knowledge". Direct marketing to consumers by stem cell clinics and providers capitalizing on the "hype" that surrounds cell-based "therapies" puts the entire field of stem cell research at risk. Promoting unproven and expensive treatments as legitimate forms of therapy impedes scientific progress and makes the development of new and effective treatments harder to advance.

Recommended Terminology

According to recent literature, the phrase "stem cell therapy" as utilized in current commercial stem cell clinic advertising is scientifically inaccurate and misrepresents the minimally manipulated cellular preparations that are being administered as "stem cells". Moreover, the words "treatment" or "therapy" can be interpreted as a signal of a medical legitimacy or as having a positive therapeutic or curative effect. Vermont Ethics Network supports the terminology of "stem cell products" as we believe it avoids misinterpretation and accurately reflects the unproven and experimental nature of these preparations.

Section 4: Rule-Making by the Vermont Department of Health

The goal of S.22 is to ensure adequate notice and disclosure are provided to patients prior to the administration of unapproved stem cell products. We do not believe it is necessary for the Department of Health to engage in further rulemaking regarding consent for experimental treatment by health care agents at this time and recommend Section 4 be removed from the bill.

Respectfully submitted,

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[i] Murray IR, et.al. *Rogue Stem Cell Clinics.* Bone Joint J 2020; 102-B(2):148-154.

[ii] Turner, L. *Preying on Public Fears and Anxieties in an Pandemic: Businesses Selling Unproven and Unlicensed "Stem Cell Treatments" for COVID-19.* Cell Stem Cell 26, June 4, 2020.

[iii] Fu W, et.al. *Characteristics and Scope of Training of Clinicians Participating in US Direct-to-Consumer Marketplace for Unproven Stem Cell Preparations.* JAMA 2019; Volume 321, Number 24.

[iv] https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview