DRAFT amendment for committee discussion

TO THE HONORABLE SENATE:

The Committee on Health and Welfare to which was referred Senate Bill No. 22 entitled "An act relating to health care practitioners administering stem cell products not approved by the U.S. Food and Drug Administration" respectfully reports that it has considered the same and recommends that the bill be amended by striking out all after the enacting clause and inserting in lieu thereof the following:

Sec. 1. 18 V.S.A. chapter 87 is added to read:

CHAPTER 87. STEM CELL PRODUCTS

§ 4501. DEFINITIONS

As used in this chapter:

(1) "Health care practitioner" means an individual licensed by the Board of Medical Practice or ~~by a board attached to~~ the Office of Professional Regulation to provide professional health care services in this State.

~~(2) "Stem cell products" has the same meaning as "human cells, tissues, or cellular or tissue-based products" in 21 C.F.R. § 1271.3, as in effect on January 1, 2020, and applies to both homologous and nonhomologous use. The term also includes homologous use of minimally manipulated cell or tissue products, as those terms are defined in 21 C.F.R. § 1271.3, as in effect on January 1, 2020, when used or proposed~~

~~**for use in one or more applications not approved by the U.S. Food and Drug Administration.**~~

(2) "Stem cell and stem cell-related products" means any articles that contain or consist, or purport to contain or consist, of one or more of the following, when intended for implantation, transplantation, infusion, or transfer into a human recipient and when intended for use in the diagnosis, cure, mitigation, treatment, or prevention of any disease or condition:

(A) human cells, including cells from tissues such as adipose tissue; amniotic membrane; umbilical cord blood, when not autologous or in a first- or second-degree relative; placenta; and other tissue or cell sources;

(B) intracellular or extracellular components or vesicles; or

(C) amniotic fluid.

§ 4502. UNAPPROVED STEM CELL **AND STEM CELL-RELATED** PRODUCTS; NOTICE; DISCLOSURE

(a) Notice.

(1) A health care practitioner who administers one or more stem cell **or stem cell-related** products that are not approved by the U.S. Food and Drug Administration shall provide each patient with the following written notice prior to administering any such product to the patient for the first time:

"THIS NOTICE MUST BE PROVIDED TO YOU UNDER VERMONT LAW. This health care practitioner administers one or more stem cell **or stem cell-related** products that have not been approved by the U.S. Food and Drug Administration. You are encouraged to consult with your primary care provider prior to having an unapproved stem cell **or stem cell-related** product administered to you."

(2)(A) The written notice required by subdivision (1) of this subsection shall:

(i) be at least 8.5 by 11 inches and printed in not less than 40-point type; and

(ii) include information on methods for filing a complaint with the applicable licensing authority and for making a consumer inquiry.

(B) The health care practitioner shall also prominently display the written notice required by subdivision (1) of this subsection, along with the information required to be included by subdivision (A)(ii) of this subdivision (2), at the entrance and in an area visible to patients in the health care practitioner's office.

(b) Disclosure.

(1) A health care practitioner who administers stem cell **or stem cell-related** products that are not approved by the U.S. Food and Drug Administration shall provide a disclosure form to a patient for the patient's

signature prior to each administration of an unapproved stem cell **or stem cell-related** product.

(2) The disclosure form shall state, in language that the patient could reasonably be expected to understand, the stem cell **or stem cell-related** product's U.S. Food and Drug Administration approval status.

(3) The health care practitioner shall retain in the patient's medical record a copy of each disclosure form signed and dated by the patient **and shall provide a copy of the disclosure form for the patient to take home**.

(c) Advertisements. A health care practitioner shall include the notice set forth in subdivision (a)(1) of this section in any advertisements relating to the use of stem cell **or stem cell-related** products that are not approved by the U.S. Food and Drug Administration. In print advertisements, the notice shall be clearly legible and in a font size not smaller than the largest font size used in the advertisement. For all other forms of advertisements, the notice shall either be clearly legible in a font size not smaller than the largest font size used in the advertisement or clearly spoken.

(d) Nonapplicability. The provisions of this section shall not apply to the following:

(1) a health care practitioner who has obtained approval or clearance for an investigational new drug or device from the U.S. Food and Drug Administration for the use of stem cell **or stem cell-related** products; ~~**or**~~

(2) a health care practitioner who administers a stem cell **or stem cell-related** product pursuant to an employment or other contract to administer stem cell **or stem cell-related** products on behalf of or under the auspices of an institution certified by the Foundation for the Accreditation of Cellular Therapy, the National Institutes of Health Blood and Marrow Transplant Clinical Trials Network, or AABB, formerly known as the American Association of Blood Banks**; or**

(3) a health care practitioner who has documentation from the U.S. Food and Drug Administration certifying that approval is not necessary for the practitioner's specific usage of the stem cell or stem cell-related products.

(e) Violations. A violation of this section constitutes unprofessional conduct under 3 V.S.A. § 129a and 26 V.S.A. § 1354.

Sec. 2. 3 V.S.A. § 129a is amended to read:

§ 129a. UNPROFESSIONAL CONDUCT

(a) In addition to any other provision of law, the following conduct by a licensee constitutes unprofessional conduct. When that conduct is by an applicant or person who later becomes an applicant, it may constitute grounds for denial of a license or other disciplinary action. Any one of the following items or any combination of items, whether the conduct at issue was committed within or outside the State, shall constitute unprofessional conduct:

* * *

(27) For a health care practitioner, failing to comply with one or more of the notice, disclosure, or advertising requirements in 18 V.S.A. § 4502 for administering stem cell **or stem cell-related** products not approved by the U.S. Food and Drug Administration.

* * *

Sec. 3. 26 V.S.A. § 1354 is amended to read:

§ 1354. UNPROFESSIONAL CONDUCT

(a) The Board shall find that any one of the following, or any combination of the following, whether the conduct at issue was committed within or outside the State, constitutes unprofessional conduct:

* * *

(38) signing a blank or undated prescription form; ~~or~~

(39) [Repealed.]

(40) use of conversion therapy as defined in 18 V.S.A. § 8351 on a client younger than 18 years of age; or

(41) failure to comply with one or more of the notice, disclosure, or advertising requirements in 18 V.S.A. § 4502 for administering stem cell **or stem cell-related** products not approved by the U.S. Food and Drug Administration.

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~~**Sec. 4. DEPARTMENT OF HEALTH; ADVANCE DIRECTIVES; RULEMAKING**~~

~~**The Department of Health shall amend its rules on advance directives to further clarify the scope of experimental treatments to which an agent may and may not provide consent on behalf of a principal. The Department's amended rules shall take effect not later than January 1, 2022.**~~

Sec. 4. EFFECTIVE DATE

This act shall take effect on July 1, 2021.

(Committee vote: _____)

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Senator _____

FOR THE COMMITTEE