

1 TO THE HONORABLE SENATE:

2 The Committee on Health and Welfare to which was referred Senate Bill  
3 No. 252 entitled “An act relating to stem cell therapies not approved by the  
4 U.S. Food and Drug Administration” respectfully reports that it has considered  
5 the same and recommends that the bill be amended by striking out all after the  
6 enacting clause and inserting in lieu thereof the following:

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

8 CHAPTER 87. STEM CELL PRODUCTS

9 § 4501. DEFINITIONS

10 As used in this chapter:

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

14 (2) “Stem cell products” has the same meaning as “human cells, tissues,  
15 or cellular or tissue-based products” in 21 C.F.R. § 1271.3 as in effect on July  
16 January 1, 2020, and applies to both homologous and nonhomologous use.  
17 The term also includes homologous use of minimally manipulated cell or tissue  
18 products and whole blood, blood derivatives, and blood components, as  
19 those terms are defined in 21 C.F.R. § 1271.3 as in effect on July January 1,  
20 2020, when used or proposed for use in one or more applications not approved  
21 by the U.S. Food and Drug Administration.

1     § 4502. UNAPPROVED STEM CELL PRODUCTS; NOTICE;

2             DISCLOSURE

3             (a) Notice.

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

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

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

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

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

19            (B) The health care practitioner shall also prominently display the  
20            written notice required by subdivision (1) of this subsection, along with the  
21            information required **to be included** by subdivision (A)(ii) of this subdivision

1 (2), at the entrance and in an area visible to patients in the health care  
2 practitioner’s office.

3 (b) Disclosure.

4 (1) A health care practitioner who administers stem cell products that  
5 are not approved by the U.S. Food and Drug Administration shall provide a  
6 disclosure form to a patient for the patient’s signature prior to each  
7 administration of an unapproved stem cell product.

8 (2) The disclosure form shall state, in language that the patient could  
9 reasonably be expected to understand:

10 (A), the stem cell product’s U.S. Food and Drug Administration  
11 approval status;

12 (3) The health care practitioner shall retain in the patient’s medical  
13 record a copy of each disclosure form signed and dated by the patient.

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

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

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

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

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

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

15        § 129a. UNPROFESSIONAL CONDUCT

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

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(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 products not approved by the U.S. Food and Drug Administration.

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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:

\* \* \*

(39) use of the services of a physician assistant by a physician in a manner that is inconsistent with the provisions of chapter 31 of this title; ~~or~~

(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 products not approved by the U.S. Food and Drug Administration.

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1       Sec. 4. DEPARTMENT OF HEALTH; ADVANCE DIRECTIVES;  
2                   RULEMAKING

3               The Department of Health shall amend its rules on advance directives to  
4               further clarify the scope of experimental treatments to which an agent may and  
5               may not provide consent on behalf of a principal. The Department’s amended  
6               rules shall take effect not later than January 1, 2021.

7       Sec. 5. EFFECTIVE DATE

8               This act shall take effect on July 1, 2020.

9               and that after passage the title of the bill be amended to read: “An act  
10              relating to administering stem cell products not approved by the U.S. Food and  
11              Drug Administration”

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(Committee vote: \_\_\_\_\_)

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Senator \_\_\_\_\_  
FOR THE COMMITTEE