

1 H.23

2 Introduced by Representative Till of Jericho

3 Referred to Committee on

4 Date:

5 Subject: Health; health care providers; stem cell products

6 Statement of purpose of bill as introduced: This bill proposes to require health  
7 care practitioners who administer stem cell products that are not approved by  
8 the U.S. Food and Drug Administration (FDA) to provide notice of this fact to  
9 their patients and in their advertisements and to provide a disclosure form to  
10 each patient prior to administering any non-FDA-approved stem cell product.

11 An act relating to administering stem cell products not approved by the U.S.  
12 Food and Drug Administration

13 It is hereby enacted by the General Assembly of the State of Vermont:

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

15 CHAPTER 87. STEM CELL PRODUCTS

16 § 4501. DEFINITIONS

17 As used in this chapter:

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

1           (2) “Stem cell products” has the same meaning as “human cells, tissues,  
2           or cellular or tissue-based products” in 21 C.F.R. § 1271.3 as in effect on  
3           July 1, 2020.

4           § 4502. UNAPPROVED STEM CELL PRODUCTS; NOTICE;

5                   DISCLOSURE

6           (a) Notice.

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

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

16           (2) The written notice required by subdivision (1) of this subsection  
17           shall be at least 8.5 by 11 inches and printed in not less than 40-point type.  
18           The health care practitioner shall also prominently display the written notice at  
19           the entrance and in an area visible to patients in the health care practitioner’s  
20           office.

1        (b) Disclosure.

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

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

8            (A) the stem cell product's U.S. Food and Drug Administration  
9            approval status;

10           (B) the anticipated risks associated with administration of the  
11           unapproved stem cell product;

12           (C) the anticipated benefits associated with administration of the  
13           unapproved stem cell product; and

14           (D) the medically recognized alternative forms of treatment,  
15           including the risks and benefits of those treatments and of nontreatment.

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

18           (c) Advertisements. A health care practitioner shall include the notice set  
19           forth in subdivision (a)(1) of this section in any advertisement for stem cell  
20           products that are not approved by the U.S. Food and Drug Administration. In  
21           print advertisements, the notice shall be clearly legible and in a font size not

1 smaller than the largest font size used in the advertisement. For all other forms  
2 of advertisement, the notice shall either be clearly legible in a font size not  
3 smaller than the largest font size used in the advertisement or clearly spoken.

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

6 (1) a health care practitioner who has obtained approval for an  
7 investigational new drug or device from the U.S. Food and Drug  
8 Administration for the use of human cells, tissues, or cellular or tissue-based  
9 products; or

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

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

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

19 § 129a. UNPROFESSIONAL CONDUCT

20 (a) In addition to any other provision of law, the following conduct by a  
21 licensee constitutes unprofessional conduct. When that conduct is by an

1 applicant or person who later becomes an applicant, it may constitute grounds  
2 for denial of a license or other disciplinary action. Any one of the following  
3 items or any combination of items, whether the conduct at issue was  
4 committed within or outside the State, shall constitute unprofessional conduct:

5 \* \* \*

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

10 \* \* \*

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

12 § 1354. UNPROFESSIONAL CONDUCT

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

16 \* \* \*

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

18 (39) [Repealed.]

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

