

1 TO THE HONORABLE SENATE:

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

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

9 CHAPTER 87. STEM CELL PRODUCTS

10 § 4501. DEFINITIONS

11 As used in this chapter:

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

15 (2)(A) “Stem cell and stem cell-related products” means any articles that
16 contain or consist, or purport to contain or consist, of one or more of the
17 following, when intended for implantation, transplantation, infusion, or
18 transfer into a human recipient and when intended for use in the diagnosis,
19 cure, mitigation, treatment, or prevention of any disease or condition **based on**
20 **or in connection with a proven or purported attribute of stem cells:**

1 (i) human cells, including cells from tissues such as **bone**
2 **marrow**; adipose tissue; amniotic membrane; umbilical cord blood, when not
3 autologous or in a first- or second-degree relative; placenta; and other tissue or
4 cell sources;

5 (ii) intracellular or extracellular components or vesicles; or

6 (iii) amniotic fluid.

7 **(B) For purposes of this chapter, “stem cell and stem cell-related**
8 **products” does not include the use of whole blood or blood products for**
9 **routine transfusions or use of hematopoietic stem cells for reconstitution**
10 **of bone marrow after treatment of blood-related cancers or diseases such**
11 **as leukemias or lymphomas.**

12 § 4502. UNAPPROVED STEM CELL AND STEM CELL-RELATED
13 PRODUCTS; NOTICE; DISCLOSURE

14 (a) Notice.

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

19 “THIS NOTICE MUST BE PROVIDED TO YOU UNDER VERMONT
20 LAW. This health care practitioner administers one or more stem cell or stem
21 cell-related products that have not been approved by the U.S. Food and Drug

1 Administration. You are encouraged to consult with your primary care
2 provider prior to having an unapproved stem cell or stem cell-related product
3 administered to you.”

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

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

8 (ii) include information on methods for filing a complaint with the
9 applicable licensing authority and for making a consumer inquiry, **including to**
10 **the Attorney General’s Consumer Assistance Program.**

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

16 (b) Disclosure.

17 (1) A health care practitioner who administers stem cell or stem cell-
18 related products that are not approved by the U.S. Food and Drug
19 Administration shall provide a disclosure form to a patient for the patient’s
20 signature prior to each administration of an unapproved stem cell or stem cell-
21 related product.

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

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

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

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

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

20 (2) a health care practitioner who administers a stem cell or stem cell-
21 related product pursuant to an employment or other contract to administer stem

1 cell or stem cell-related products on behalf of or under the auspices of an
2 institution certified by the Foundation for the Accreditation of Cellular
3 Therapy, the National Institutes of Health Blood and Marrow Transplant
4 Clinical Trials Network, or AABB, formerly known as the American
5 Association of Blood Banks; or

6 (3) a health care practitioner who has **documentation personally**
7 **received a formal or informal determination** from the U.S. Food and Drug
8 Administration **certifying stating** that approval is not necessary for the
9 practitioner’s specific usage of the stem cell or stem cell-related products.

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

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

13 § 129a. UNPROFESSIONAL CONDUCT

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

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