VERMONT
DEPARTMENT OF HEALTH

Act 61 of 2021 – Stem Cell Products Not FDA Approved

July 2022

In 2021, Vermont enacted a law about stem cell products that are not approved by the U.S. Food and Drug Administration. The impetus for the law was concern about the safety and efficacy of treatments using such products. Fortunately, to date the Board of Medical Practice has not learned of any instances in which its licensees are believed to be offering or using such products to treat patients in Vermont. However, we are sharing information about the law to ensure that Vermont MDs and other licensees are aware of the requirements and can be ready to advise patients should they be asked about the unapproved treatments covered by the law.

V.S.A. Title18, Chapter 90: Stem Cells

The law does not ban the administration of unapproved stem cell products. The federal government, through the FDA, approves such products and the regulation of such products is considered a matter for the federal government.

The approach taken in the law is to ensure that patients understand that the products are not FDA approved by requiring notices in advertisements, posted notices in the offices of providers who offer such products, and signed, written disclosures obtained from patients prior to each administration of such treatments.

Written Notices

The written notices called for by the law mandate clear and specific language in large, easily readable type, as follows:

> "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."

Some licensees may already have received inquiries from patients who heeded the recommendation to consult with their primary care provider. We recommend that our licensees familiarize themselves with the law. A key to understanding the law and its scope is knowing how it defines “stem cell and stem-cell related products.”

Definition of “stem cell and stem-cell related products”

18 VSA § 4501:

> *(2)(A) "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 based on or in connection with a proven or purported attribute of stem cells:

(i) human cells, including cells from tissues such as bone marrow; 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;

(ii) intracellular or extracellular components or vesicles; or

(iii) amniotic fluid.

The law also includes some exceptions that apply to the definition of stem cell products and a list of practice situations that are exempt. Check the law itself if you have questions about whether it applies to you and your practice.

How you can help

In the absence of a ban on stem-cell products that are not approved by the FDA, the best alternative available is to work to inform patients of the unapproved status and what that means for them when making decisions about their health care. Please help us by:

- Being prepared to answer questions from your patients.
- Informing the Board or OPR regulators if you learn of practices that use unapproved stem cell or stem-cell related products and that are not in compliance with the law. The Board of Medical Practice can be reached at 802-657-4220, or by email to AHS.VDHMedicalBoard@vermont.gov. OPR is best reached via their website at https://sos.vermont.gov/opr/about-opr/contact-us/.And,
- Referring patients who may have complaints related to unapproved stem-cell products to the Board or appropriate OPR regulators using the contact information just above.