

VERMONT REGENERATIVE MEDICINE

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Board Certified in:
Physical Medicine and Rehabilitation
Neuromusculoskeletal Medicine
Orthopaedic Medicine
Musculoskeletal Ultrasound

Practice limited to:
Osteopathic Physical Medicine
Image Guided Injections
Interventional Regenerative Orthopedic Medicine

October 1, 2019

The Honorable Christina E Nolan
US Attorney for Vermont
United States Courthouse and Federal Building
Post Office Box 570
11 Elmwood Avenue, 3rd Floor
Burlington, VT 05402-0570

Re: Vermont stem cell clinic

Dear Ms. Nolan:

It has recently come to our attention that a new "regenerative" clinic, Vermont Center For Regenerative Medicine, in Williston, VT, has opened and are actively deceiving patients in several ways. Apart from adding the word "Center," their business name is identical to ours, and their website name is even closer (vermontregenmed.com). Unfortunately, due to a legislative change in 2015, this one-word difference in a DBA is allowed by Vermont statute, even if it can lead to consumer confusion and fraud.

It has been about a month since their name has appeared online and in media, and already we have received many calls and e-mails from confused people. This clinic is NOT affiliated with us, nor with Regenexx. Their ads and seminars, which have taken place both in the US and Canada, are not affiliated with us. Their ads and seminars also violate the rules set forth by the FDA and FTC and are thus illegal.

More importantly, this clinic is perpetuating medical fraud by stating in person, during promotional seminars, on their website, and in their ads that there are live mesenchymal stem cells in the amniotic, placental, and umbilical cord products they use. To sell these products in the US they must be sold as dead tissue products, as per FDA rules. The studies they list on their website claiming live cells do not apply to these products but to fresh culture expanded cells available at a Panama clinic only.

The amniotic and cord products they use (Signature Biologics) are collagen, hyaluronic acid and growth factor grafts, NOT stem cells. If they had live cells they would be subject to drug approval by the FDA, not merely a simple online registration process.

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Placental and umbilical products that claim to be stem cells are listed as fraudulent and illegal by both the FDA and FTC. There have been actions by both organizations against these clinics, as well as by the NY State Attorney General. Unfortunately, there are limited resources for enforcement by these agencies considering the hundreds of clinics across the USA that often open for a year or less and then close, only to open in another state or location shortly after. The prior clinic in Williston did so and is now making the same fraudulent claims in New Hampshire. There are many such clinics in New Hampshire and Maine.

Links to these actions are listed below. Attached are additional supporting documents.

<https://www.fda.gov/news-events/press-announcements/fda-sends-warning-company-selling-unapproved-umbilical-cord-blood-and-umbilical-cord-products-may>

<https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies>

<https://www.fda.gov/news-events/press-announcements/fda-puts-company-notice-marketing-unapproved-stem-cell-products-treating-serious-conditions>

https://www.washingtonpost.com/national/health-science/fda-sends-letters-to-20-companies-in-attempt-to-rein-in-stem-cell-industry/2019/04/03/7e01556e-564e-11e9-8ef3-fbd41a2ce4d5_story.html

<https://www.ftc.gov/news-events/press-releases/2019/04/ftc-returns-almost-515000-consumers-who-bought-deceptively>

<https://www.ftc.gov/news-events/press-releases/2018/10/ftc-stops-deceptive-health-claims-stem-cell-therapy-clinic>

We are asking for enforcement from your office while also working at the state and local level to protect consumers from what is essentially geriatric financial fraud. Our clinic meets all the strict criteria from the FDA, FTC, state medical boards, and professional societies regarding our practices.

Thank you for your attention to this matter.

Sincerely,

Jonathan E. Fenton, DO, FAAPM&R

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