



Warning About Unproven Stem Cell Therapies: Bacterial infections lead to investigation and warning

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SPRINGFIELD – The Illinois Department of Public Health (IDPH), along with the Centers for Disease Control and Prevention (CDC), is warning patients and health care providers about the risk of procedures involving unproven and non-Food and Drug Administration (FDA) approved stem cell therapies.

“While all medical treatments have benefits and risks, non-FDA approved stem cell therapies have the potential to expose patients to risks without a clear benefit,” said IDPH Director Dr. Ngozi O. Ezike. “If you are considering any stem cell treatment, first find out if the stem cell therapy is approved, and be sure to get all the facts.”

After an investigation of several bacterial infections in patients following the use of stem cell products from the ReGen Series® (distributed by Liveyon, LLC), an FDA investigation into the manufacturer, Genentech, found numerous deviations from established good practices and FDA guidelines, including screening stem cell donors for diseases such as HIV, hepatitis B, and hepatitis C infections.

Thus far, no bacterial infections occurring in Illinois residents following the use of these cells have been reported to IDPH. However, IDPH is advising patients who received these cells since 2017 to talk with their health care providers about the need to be tested for HIV, hepatitis B virus, hepatitis C virus, and possibly other blood-borne infections.

IDPH is providing information to clinics and health care providers, as well as notifying known clinics who may have received this product. IDPH requests that clinics notify patients who received these stem cells. It is also important for patients considering stem cell treatment to know the potential risks related to unproven stem cell treatments, which include:

- Injection site reaction
- Failure of the cells to work as expected
- Growth of tumors
- Infections
- Potential for contamination of the product

Currently, the only stem cell treatments approved by the FDA are products that treat certain cancers, blood disorders, and the immune system. Some clinics in the U.S. are marketing stem cell therapies with claims that the cells will treat many conditions, ranging from normal aging to chronic pain. The use of umbilical cord blood-derived stem cells to treat these types of conditions is not approved by the FDA, unless the stem cell product is part of a clinical trial and is being studied under an Investigational New Drug Application. Some clinics may advertise stem cell clinical trials that do not have FDA approval, while some may falsely advertise that it is not necessary for FDA to review and approve stem cell therapy.

If you are considering stem cell treatments, check to make sure the product you are considering is on the [FDA's approved list of stem cell treatments](#).