ILLINOIS DEPARTMENT OF PUBLIC HEALTH
IDPH
PROTECTING HEALTH, IMPROVING LIVES

# HEALTH ALERT

**Division of Patient Safety and Quality** **February 27, 2019**

# Contaminated Stem Cell Products

## Summary and Action Items

1) The Centers for Disease Control and Prevention (CDC) are warning patients and providers about the risks of procedures involving unproven and unapproved stem cell therapies.
2) Currently, the only stem cell treatments approved by the Food and Drug Administration (FDA) are products that treat certain cancers and disorders of the blood and immune system. If the products are being used for arthritis, injury-related pain, chronic joint pain, anti-aging or other health issues, they are **NOT** approved by FDA unless they are part of a study under an Investigational New Drug Application (IND).
3) As a result of 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, Genetech, revealed inappropriate screening of stem cell donors for diseases such as human immunodeficiency virus (HIV), hepatitis B virus, and hepatitis C virus.
4) The Illinois Department of Public Health (IDPH) is unaware of bacterial infections occurring in Illinois residents following the use of cells from the ReGen Series®; however, **patients who received these cells since January 1, 2017 are advised to discuss evaluation for HIV, hepatitis B virus, hepatitis C virus, and possibly other blood-borne infections with their health care providers (see Diagnosis section below).**
5) IDPH and local health departments will be notifying clinics that used the ReGen Series® of these blood-borne pathogen screening recommendations. These clinics will be asked to notify patients that received these products.

## Background

In September 2018, the Texas and Florida Departments of Public Health were notified of bacterial infections in patients following the use of stem cell products from the ReGen Series® (manufactured by Genetech and distributed by Liveyon, LLC). Further investigation implicated bacterial contamination of the cells as the source of the infections. In response, on September 28, Liveyon issued a voluntary recall and immediately discontinued purchase of the Genetech-processed stem cell products. A more detailed account of this investigation was published in the MMWR in December 2018. **To date, IDPH has not received reports of bacterial infections in Illinois residents; however, IDPH has identified some Illinois clinics that received these cells for patient use.**

An FDA inspection of Genetech, the company that processed these products, found problems with the manufacturing process resulting in a warning letter to the company. The facility also did not adequately screen donors of the umbilical cord blood for diseases such as HIV, hepatitis B, and hepatitis C. **CDC is not currently aware of any HIV, hepatitis B, or hepatitis C infections linked to the ReGen Series® products, and transmission risk is very low. However, as a precaution, CDC recommends that patients talk to their health care provider about getting tested for HIV, hepatitis B virus, and hepatitis C virus.**

The FDA is sending letters to reiterate their compliance and enforcement policy to other manufacturers and health care providers who may be offering unapproved stem cell treatments. In addition, FDA and CDC are warning patients about the risks of accepting unproven and unapproved stem cell treatments. (see Prevention section)

## Potential Exposures

Patients and providers should be on alert for exposures to stem cell products from the ReGen Series® (manufactured by Genetech and distributed by Liveyon, LLC). Liveyon issued a recall of these products on September 28, 2018. Due to the recall and short shelf- life of these cells, it is unlikely that these cells are still in use by clinics. **However, IDPH requests that any present or past bacterial infections possibly associated with this stem cell series be reported via DPH.XDRORegistry@illinois.gov.**

**Any patient that received stem cell products from the ReGen Series® since 2017 should discuss HIV, hepatitis B, hepatitis C, and/or other blood-borne pathogens testing with their health care provider (see Diagnosis section).** Currently, post exposure prophylaxis for any blood borne pathogen is not recommended.

## Diagnosis

The diagnosis of bacterial infections following stem cell use requires obtaining the appropriate cultures based upon a patient's clinical presentation (e.g., blood cultures, joint cultures).

FDA recommends the screening of donors for the below blood-borne pathogens:

- Human immunodeficiency virus (HIV)
- Hepatitis B virus
- Hepatitis C virus
- Syphilis
- Cytomegalovirus
- Human T-lymphotropic virus I/II
- West Nile virus
- Zika virus

Testing guidance for the above pathogens can be found at the provided hyperlinks. **The screening of stem cell recipients for all of the above listed pathogens is likely unnecessary and should be tailored to the individual patient based upon known clinical characteristics such as pregnancy or immunosuppression and patient symptoms**. However, **IDPH is encouraging health care providers informed by their patients of receipt of stem cell products from the ReGen Series® since January 1, 2017 to discuss, at the minimum, the screening of HIV, hepatitis B virus, and hepatitis C virus with all recipients**. Although the risk of transmission is likely low from these cells, treatment options are available for anyone who does test positive.

## Prevention

Patients should be aware of potential risks related to unproven stem cell treatments:

- Injection site reaction
- Failure of the cells to work as expected
- Growth of tumors

- Infections
- Potential for contamination of the product
- The ability of cells to move from placement sites and multiply or change into inappropriate cell types

If patients are considering stem cell treatments, they should check to make sure the product is on the FDA's approved list of stem cell treatments. If the stem cell product is not on the approved list, providers should demonstrate that they have FDA permission to research a new drug, which requires an IND application number and acknowledgment communication issued by FDA. Patients should ask for this information *before* getting treatment—even if the stem cells are their own.

## IDPH and Local Health Department Response

Public health departments will be notifying known clinics that used the ReGen Series®. These clinics will be asked to provide verbal and written notification to patients that received these products from January 1, 2017 to the present regarding the need for blood borne pathogen screening. The clinics will be instructed to advise patients to speak with a health care provider regarding the need for testing for HIV, hepatitis B virus, and hepatitis C virus and, in some circumstances, other pathogens (see Diagnosis section). If patients do not have a health care provider or are unable to afford testing, they should contact their local health department for options.

## Contact

For questions regarding this health alert please contact the Health Care Associated Infections & Antimicrobial Resistance Prevention Program, Division of Patient Safety & Quality, at DPH.XDROregistry@illinois.gov

## Target Audience

Local Health Departments, Infectious Disease Physicians, Hospital Emergency Departments, Infection Control Preventionists, Health Care Providers, and Laboratories

## Date Issued

February 27, 2019