



Health Advisory: Stem Cell Product Contamination April 26, 2019

Summary

The Texas Department of State Health Services (DSHS) and the Centers for Disease Control and Prevention (CDC) are investigating bacterial infections that have occurred in individuals after receiving umbilical cord blood-derived stem cell product from the ReGen Series®, manufactured by Genetech, Inc. and distributed by Liveyon, LLC from mid-2017 through September 2018. Texas identified eight patients who developed bacterial infections soon after having a procedure involving the injection of a stem cell product. Types of infections include bloodstream infections, joint infections, and epidural abscesses. Symptoms of the infections include pain, fever, chills, and swelling at injection site.

In September 2018, the U.S. Food and Drug Administration (FDA) conducted an inspection at the manufacturing facility and identified that Genetech, Inc. was not appropriately testing and screening umbilical cord blood donors for communicable diseases, such as HIV, hepatitis B, and hepatitis C. The FDA warning letter outlining their findings can be located at <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm628019.htm>.

The transmission risk of HIV, hepatitis B, and hepatitis C through stem cell products is very low, and no reports of these diseases have been linked to the ReGen Series® product. Out of an abundance of caution, DSHS recommends that all patients who received ReGen Series® stem cell products from mid-2017 through September 2018 receive a full medical assessment to include testing for HIV, hepatitis B, and hepatitis C.

Recommendations for Clinicians

If your patient received ReGen Series® stem cell products from mid-2017 through September 2018, DSHS recommends conducting a full medical assessment and testing for HIV, hepatitis B, hepatitis C as well as any other infection of concern from the medical assessment.

Recommendations for the Public

If you received stem cell products from the ReGen Series® between mid-2017 through September 2018, talk to your healthcare provider about receiving a full medical assessment and testing for HIV, hepatitis B and

hepatitis C. Your provider may recommend additional testing as a result of your medical assessment.

For More Information

CDC Webpage for information on this investigation

<https://www.cdc.gov/hai/outbreaks/stem-cell-products.html>

MMWR publication describing the initial investigation

<https://www.cdc.gov/mmwr/volumes/67/wr/mm6750a5.htm>