

Dear Healthcare Provider:

Your patient has received one or more umbilical cord blood-derived stem cell products from the ReGen Series® (distributed by Liveyon, LLC). These products were recalled on September 28, 2018, and your patient has been notified of a potential risk of bacterial infection and a very low risk of transmission of other communicable diseases.

An inspection of the processing facility by the U.S. Food and Drug Administration (FDA) identified deviations in the requirements for testing and screening of the umbilical cord blood donors for these products and in the processing of these products. An FDA warning letter issued to that manufacturer outlines these deviations:

<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm628019.htm>.

Additionally, the FDA and Centers for Disease Control and Prevention (CDC) have received reports of patients developing bacterial infections of the joints, bloodstream, and/or spine, among other sites, after receiving the ReGen® series products. Most of these patients developed signs and symptoms of infection like, pain, swelling, and chills, within a few days of receiving these products. However, diagnosis can be difficult due to nonspecific presentation of illness, so not all bacterial infections may have been recognized. Therefore, healthcare providers should consider assessing patients who have received these products for bacterial infections.

The FDA identified deviations in the testing and screening of the umbilical cord blood donors for the following communicable diseases:

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

Although the risk of transmission of the above communicable diseases is very low, healthcare providers are advised to discuss testing for HIV, hepatitis B, and hepatitis C, with their patients. Testing for the other communicable diseases listed is not likely to be necessary, but could be considered on a case-by-case basis after considering patient symptoms and concerns.

For further information on testing for hepatitis B, hepatitis C, and HIV, please visit <https://www.cdc.gov/hepatitis/outbreaks/toolkit.htm>.

If you believe you have a patient who has had an infection related to the administration of this product, please notify your state health department.

