State of California—Health and Human Services Agency
California Department of Public Health

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A NOTICE TO PATIENTS ABOUT UMBILICAL CORD BLOOD STEM CELL PRODUCTS

The California Department of Public Health (CDPH), California local health departments (LHD) and the Centers for Disease Control and Prevention (CDC) are working together to investigate bacterial infections following injections of ReGen Series® stem cell products produced by Genetech and distributed by Liveyon, LLC.

Use of stem cell products to treat conditions such as normal aging or chronic pain is not approved by the Food and Drug Administration (FDA). FDA inspected Genetech and found deficiencies with the manufacturing process for this product and methods used to screen donors of the umbilical cord blood for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C. Liveyon, LLC, recalled the ReGen Series® products on September 28, 2018. CDC provides additional information about the investigation at: https://www.cdc.gov/hai/outbreaks/stem-cell-products.html.

Infections have also been reported in persons who received other non-FDA approved stem cell products distributed by companies besides Liveyon. **If you were diagnosed with an infection potentially associated with the ReGen Series® or other stem cell product, please contact [local health department] at [phone number].** Most patients developed symptoms such as pain, swelling, and chills, within a few days of receiving these products.

CDC is not currently aware of any HIV, hepatitis B, or hepatitis C infections linked to the ReGen Series® products, and transmission risk via stem cell products for these is very low. However, as a precaution, **CDPH and LHD recommend that patients talk to their healthcare provider about getting tested for HIV, hepatitis B virus, hepatitis C virus, or other communicable diseases.** We encourage you to take this letter with you to your healthcare provider. Information for your healthcare provider on testing for HIV, hepatitis B, and hepatitis C is available at: https://www.cdc.gov/hepatitis/outbreaks/toolkit.htm. There are treatment options for these infections. Your healthcare provider should report any positive results to your local public health department.

All of us in public health are concerned by this development, and we are available to assist you in any way that we can. If you have additional questions or concerns, please call your LHD, [name of LHD], at [NUMBER].