To: CAHAN San Diego Participants
Date: January 25, 2019
From: Epidemiology Program, Public Health Services

Infections Associated with Unapproved Stem Cell Injections

This health advisory informs providers about reports of serious infections after the use of stem cell injections that have not been approved by the U.S. Food and Drug Administration (FDA). Recommendations for local healthcare professionals and resource links are provided.

Key Points:

- Serious infections associated with non-FDA approved stem cell injections have been reported nationally and in Southern California.
- FDA has warned members of the public who are considering obtaining stem cell therapy in the United States and overseas to be aware of the unapproved therapies that are being marketed and the associated risks, including infection.
- Clinicians should inquire about stem cell therapy in patients presenting with bacterial infections and be vigilant for possible infections in patients known to have had unapproved therapies.
- Infections related to stem cell products should be reported to the County Epidemiology Program within one working day. In addition, providers are encouraged to report any previous cases associated with stem cell injections.

Situation

In September 2018, a nationwide recall of a stem cell product distributed by Liveyon, LLC and processed by Genetech, Inc. was announced. As of December 14, 2018, the Centers for Disease Control and Prevention (CDC) has received reports of infections in 12 patients from Texas, Florida, and Arizona, all associated with non-FDA approved infusions or injections from this product. The Los Angeles County Department of Public Health recently reported two cases of *Enterobacter cloacae* bloodstream infections in persons who received non-FDA approved stem cell injections that were not distributed by Liveyon. These two separate situations highlight the serious potential risks to patients of stem cell therapies administered for unapproved uses.

The CDC investigation of the 12 cases related to the Liveyon products identified *Enterobacter, Citrobacter, E. coli,* and *Enterococcus* infections. Sites of infection included knee, bloodstream, lumbosacral abscess, discitis, vertebral osteomyelitis, shoulder, and cellulitis at the injection site. Patients had received stem cell injections in a variety of clinical settings including orthopedic clinics, an

ambulatory surgery center, pain clinics, a chiropractic clinic, and a spine treatment clinic. Among 11 patients for whom conditions prompting product administration were known, all had nonhematopoietic conditions such as pain or orthopedic conditions, for which stem cell treatment is not FDA approved.

Background

The only FDA–approved stem cell products are derived from umbilical cord blood, and their only approved use is hematopoietic and immunologic reconstitution. Stem cell treatments are also used under Investigational New Drug Applications (INDs), which are reviewed by the FDA.

Some companies, clinics, and clinicians market unapproved products from various sources directly to consumers. They may claim to treat a wide range of diseases including orthopedic, neurologic, and rheumatologic conditions. Some clinics may advertise stem cell clinical trials without submitting an IND and others may falsely advertise that FDA review and approval of the stem cell therapy is unnecessary.

Stem cell therapy is offered at medical clinics outside the United States, including clinics in Mexico. The FDA has no oversight of these clinics and little information is available about the products administered at these locations. See FDA Warns About Stem Cell Therapies for more details.

Recommendations for Providers

- Be vigilant for the possibility of infections occurring in patients who had unapproved stem cell therapies.
- Inquire about recent stem cell therapy in patients presenting with infections such as acute discitis, joint, bone, or bloodstream infections as well as cellulitis and abscesses. If stem cell therapy is reported, ask your laboratory to save clinical isolates and any available stem cell product for further testing.
- Report cases of any infections in patients who have recently undergone stem cell therapy. Call the County Epidemiology Program during normal business hours at 619-692-8499 (Mon-Fri 8 AM to 5 PM) or fax a Confidential Morbidity Report to 858-715-6458. In addition, providers are encouraged to report any previous cases of infections that were temporally related to stem cell injections.
- Report adverse events associated with stem cell therapies to the FDA MedWatch Safety Information and Adverse Event Reporting Program. Subscribe to FDA MedWatch Safety Alerts here.
- Counsel patients on the risks of unapproved stem cell therapies. FDA has published advice for consumers who are considering obtaining stem cell therapy in the United States and overseas.

Thank you for your participation.

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