



**LAC DPH Health Advisory:
Infections Associated with Unapproved
Stem Cell Injections**



January 22, 2019

This message is intended for orthopedic surgeons; pain management, infectious disease, primary care, emergency medicine, and urgent care providers; and health care personnel who provide injections using stem cell products.

Please distribute as appropriate.

Key Messages

- The Los Angeles County Department of Public Health (LAC DPH) has identified 2 cases of *Enterobacter cloacae* bloodstream infections in persons who received non-FDA approved stem cell injections.
- 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.
- Any suspect infections should be reported to LAC DPH immediately. In addition, providers are encouraged to report any previous cases associated with stem cell injections.
- Providers and patients who are considering the use of stem cell treatments need to be aware of the unapproved therapies that are being marketed and the associated risks, including infection.

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, the 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. LAC DPH has recently received reports of 2 cases of *Enterobacter cloacae* bloodstream infections in persons who received non-FDA approved stem cell injections in August 2018 (not from 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 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. See [FDA Warns About Stem Cell Therapies](#) for more details.

Actions Requested of Providers

- **Be vigilant for possible infections in patients who have 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 stem cell product for further testing, if available.
- **Immediately report all suspect infections to LAC DPH.** In addition, providers are encouraged to report any previous cases if associated with stem cell injections (see reporting below).
- **Report adverse events associated with stem cell therapies to FDA's [MedWatch Safety Information and Adverse Event Reporting Program](#).**
- **Counsel patients on the risks of unapproved stem cell therapies.** Warnings and advice for consumers who are considering obtaining stem cell therapy in the US and overseas, is available from the [FDA](#). Information on how to spot a scam is available at the DPH health care consumer protection [website](#).

Reporting

Los Angeles County DPH Acute Communicable Disease Control:

- Weekdays 8:30am – 5pm: call 888-397-3993.
- After-hours: call 213-974-1234 and ask for the physician on call.

Pasadena Public Health Department:

- Weekdays 8am – 5pm (closed every other Friday): call 626-744-6089.
- After-hours: call 626-744-6043.

Long Beach Health and Human Services:

- Weekdays 8am – 5pm: call 562-570-4302.
- After-hours: call the Duty Officer at 562-500-5537.

This Health Advisory was sent by Dr. Sharon Balter, Director, Division of Communicable Disease Control and Prevention, Los Angeles County Department of Public Health.

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