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Stem Cell Recall and Legal Risks

Related Professionals

Hamilton B. Barber
803.253.8236
HBarber@nexsenpruet.com

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A recent nationwide recall of a series of non-Food and Drug Administration (FDA)-approved stem cell products that have infected at least 12 patients has raised serious questions concerning legal exposure to providers that use stem cell products to treat patients for arthritis, injury-related pain, chronic joint pain or other health issues.

A recent nationwide recall of a series of non-Food and Drug Administration (FDA)-approved stem cell products that have infected at least 12 patients has raised serious questions concerning legal exposure to providers that use stem cell products to treat patients for arthritis, injury-related pain, chronic joint pain or other health issues, excluding certain cancers and disorders of the blood and immune system.

(Although this article focuses only on the recall of one series of stem cell products, all providers that treat patients with stem cell products not listed by the FDA as an approved stem cell product or in a manner not approved by the FDA should seek out legal counsel to apprise themselves of their legal exposure associated with treating patients with such non-FDA-approved stem cell products.)

On September 28, 2018, Liveyon, LLC (Liveyon), a distributor of stem cell products manufactured by Genetech, Inc. (Genetech), a laboratory that was located in San Diego, California, voluntarily recalled all ReGen Series® products due to reported possible adverse reactions. Those products were not and are not legally marketed or FDA-approved.[1] The FDA has currently only approved stem cell products derived from umbilical cord blood for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system. Unless part of a study under an Investigational New Drug application, stem cell products are not approved for treatment of arthritis, injury-related pain, chronic joint pain, or other health issues.

As of December 14, 2018, the Centers for Disease Control and Prevention (CDC) has received reports of infections in 12 patients who received infusions or injections of Liveyon's products prior to the recall; the 12 known patients are from three states: Texas (seven), Florida (four) and Arizona (one). *Enterobacter cloacae*, *Citrobacter freundii*, *Escherichia coli*, *Enterococcus faecalis* or *Proteus mirabilis* infections were observed in the 12 patients.

In addition, the FDA has found that Genetech, the company that processed the ReGen Series® products, failed to appropriately screen umbilical cord blood donors for diseases such as human immunodeficiency virus (HIV), hepatitis B and hepatitis C. *Currently, the CDC is unaware of any HIV, hepatitis B or hepatitis C infections linked to ReGen Series® products.*

Providers that treated patients with ReGen Series® stem cell products processed prior to October 8, 2018 are at risk of being sued by patients whom the providers treated with ReGen Series® stem cell products. Since ReGen Series® stem cell products processed by Genetech have a one-year expiration date, providers who still have unexpired ReGen Series® stem cell products should ensure that they cease using those unexpired ReGen Series® stem cell products to treat patients and contact Liveyon for recall instructions. Bacterial infections have also occurred following injections with other non-FDA approved stem cell products. At least 17 people over the past year have been hospitalized following an injection from an umbilical cord blood stem cell product.

Some law firms are presently seeking out patients to file suit against not only Genetech and Liveyon, but also the providers that administered the infusions or injections to those patients. According to one such law firm, providers that administered stem cell infusions or injections to patients are the natural target of a medical malpractice or products liability suit since Genetech presently appears defunct, and Liveyon's $3 million insurance policy may be insufficient to adequately settle claims with patients who may have been infected by ReGen Series® stem cell products.

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[1] https://www.cdc.gov/mmwr/volumes/67/wr/mm6750a5.htm. *Liveyon marketed its ReGen Series® as umbilical cord stem cells and growth factors used to improve quality of life for those suffering from debilitating diseases/disorders, such as arthritis and orthopedic indications.* https://www.prlog.org/12697896-liveyon-stem-cells-regenerative-medicine.html

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Stephen Bittinger, Esq. is a Member of Nexsen Pruet based in Charleston, South Carolina. Stephen is admitted in North Carolina, Ohio and the District of Columbia. He is not licensed to practice law in South Carolina. Stephen has a unique, national practice in health care reimbursement defense and litigation.

Hamilton B. Barber, based in Charleston, South Carolina, is an Associate with the Health Care group. Hamilton is admitted in South Carolina. Prior to joining Nexsen Pruet, Hamilton served in the United States Air Force as an Imagery Analyst before working his way to Imagery Mission Supervisor.