Consumer Alert on Regenerative Medicine Products Including Stem Cells and Exosomes

Date: July 22, 2020

If you were hurt or had a bad side effect following treatment with anything that was supposed to be a regenerative medicine product, including, for example, stem cell products and exosome products, we encourage you to report it to the FDA's MedWatch Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program). Additional information for patients on reporting adverse events for these products can be found here (/vaccines-blood-biologics/consumers-biologics/reporting-adverse-events-related-stem-cells-exosomes-or-other-products-marketed-regenerative).

The US Food and Drug Administration (FDA) has authority to regulate regenerative medicine products, including stem cell products and exosome products. There is a lot of misleading information on the internet about these products, including statements about the conditions they can be used to treat. FDA is concerned that many patients seeking cures and remedies may be misled by information about products that are illegally marketed, have not been shown to be safe or effective, and, in some cases, may have significant safety issues that put patients at risk. FDA wants to help consumers be informed about how these products are regulated, and what to look for when considering treatment with one of these products.

Stem cell products are regulated by FDA, and, generally, all stem cell products require FDA approval. Currently, the only stem cell products that are FDA-approved for use in the United States consist of blood-forming stem cells (also known as hematopoietic progenitor cells) that

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are derived from umbilical cord blood. These products are approved for use in patients with disorders that affect the production of blood (i.e., the "hematopoietic" system) but they are not approved for other uses.

Exosome products are also regulated by FDA. As a general matter, exosome products intended to treat diseases or conditions in humans require FDA approval. There are currently no FDA-approved exosome products.

Anyone considering the use of anything purported to be a regenerative medicine product, including stem cell products, exosome products, or other widely promoted products such as products derived from adipose tissue (this product is also known as stromal vascular fraction), human umbilical cord blood, Wharton's Jelly, or amniotic fluid should know:

- None of these products have been approved for the treatment or prevention of COVID-19, acute respiratory distress syndrome (ARDS), or any other complication related to COVID-19.
- None of these products have been approved for the treatment of any orthopedic condition, such as osteoarthritis, tendonitis, disc disease, tennis elbow, back pain, hip pain, knee pain, neck pain, or shoulder pain.
- None of these products have been approved to treat any neurological disorder, such as multiple sclerosis, amyotrophic lateral sclerosis (ALS; Lou Gehrig's disease), Alzheimer's disease, Parkinson's disease, epilepsy, or stroke.
- None of these products have been approved for the treatment of any cardiovascular or pulmonary (lung) diseases, such as heart disease, emphysema, or chronic obstructive pulmonary disease (COPD).
- None of these products have been approved to treat autism, macular degeneration, blindness, chronic pain, or fatigue.

FDA has posted information for consumers and patients (/consumers/consumer-updates/fda-warns-about-stem-cell-therapies) that discusses the potential risks, and provides advice for people considering the use of these products. Consumers should be cautious of any clinics, including regenerative medicine clinics, or health care providers, including physicians, chiropractors, or nurses, that advertise or offer any of these products. FDA also issued a public safety notification (/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products) on exosome products on December 6, 2019.

Resources for Consumers

- FDA Video – Watch Out for Unapproved Stem Cell Therapies! (https://youtu.be/onnlZeQlaio) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

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- For information on the different types of actions FDA can take when products are found to be in violation of the law, visit this page (/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/regulatory-actions-issued-cber)
- FDA Consumer Update - FDA Warns About Stem Cell Therapies (/consumers/consumer-updates/fda-warns-about-stem-cell-therapies)

Contacting FDA

If you are considering a regenerative medicine product and have questions about how it is regulated (including whether FDA approval is required), whether it is FDA-approved, or what to consider before participating in a clinical trial, we urge you to call (800-835-4709) or email (ocod@fda.hhs.gov) (mailto:ocod@fda.hhs.gov) for information.

Healthcare professionals and consumers should report any adverse events related to the use of stem cells, exosomes, or other products purported to be regenerative medicine products to the FDA's MedWatch Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program). To report an adverse event online, click here: Report a Problem (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm). Additional information for patients on reporting adverse events associated with stem cells, exosomes, or other products purporting to be regenerative medicine products can be found here (/vaccines-blood-biologics/consumers-biologics/reporting-adverse-events-related-stem-cells-exosomes-or-other-products-marketed-regenerative). The FDA monitors these reports and takes appropriate action to help ensure the safety of medical products in the U.S. marketplace.

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