Public Safety Notification on Exosome Products

December 6, 2019

The Food and Drug Administration (FDA) is informing the public, especially patients, health care practitioners, and clinics, of multiple recent reports of serious adverse events experienced by patients in Nebraska who were treated with unapproved products marketed as containing exosomes. These reports were brought to the agency's attention by the Centers for Disease Control and Prevention, among others, and the agencies worked with the Nebraska Department of Health and Human Services. FDA is carefully assessing this situation along with our federal and state partners.

There are currently no FDA-approved exosome products. Certain clinics across the country, including some that manufacture or market violative "stem cell" products, are now also offering exosome products to patients. They deceive patients with unsubstantiated claims about the potential for these products to prevent, treat or cure various diseases or conditions. They may claim that they these products do not fall under the regulatory provisions for drugs and biological products – that is simply untrue. As a general matter, exosomes used to treat diseases and conditions in humans are regulated as drugs and biological products under the Public Health Service Act and the Federal Food Drug and Cosmetic Act and are subject to premarket review and approval requirements.

The clinics currently offering these products outside of FDA's review process are taking advantage of patients and flouting federal statutes and FDA regulations. This ultimately puts at risk the very patients that these clinics claim to want to help, by either delaying treatment with legitimate and scientifically sound treatment options, or worse, posing harm to patients, as evidenced by these recent reports of adverse events.

Health care professionals and consumers should report any adverse events related to exosome products or any other unapproved product to the FDA's MedWatch (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) Adverse Event Reporting program. To file a report, use the MedWatch Online Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home). The completed form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) can be submitted online or via fax to 1-800-FDA-0178. FDA monitors these reports and takes appropriate action necessary to ensure the safety of medical products in the marketplace.

Patients considering treatment with exosome products in the United States should:

- Ask if the FDA has reviewed the treatment. You also can ask the clinical investigator to give you the FDA-issued Investigational New Drug Application (IND) number and the chance to review the FDA communication acknowledging the IND. Ask for this information

before getting treatment and follow up with your personal health care provider to confirm this information.

- Request the facts and ask questions if you don't understand. To participate in a clinical trial that requires an IND application, you must sign a consent form that explains the experimental procedure. The consent form also identifies the Institutional Review Board (IRB) that assures the protection of the rights and welfare of human subjects. Make sure you understand the entire process and known risks before you sign. You also can ask the study sponsor for the clinical investigator's brochure, which includes a short description of the product and information about its safety and effectiveness.

Patients considering treatment using an exosome product in another country should:

- Learn about regulations that cover products in that country.
- Know that FDA does not have oversight of treatments done in other countries. FDA typically has little information about foreign establishments or their products.
- Be cautious. If you're considering an exosome product in a country that may not require regulatory review of clinical studies, it may be hard to know if the experimental treatment is reasonably safe.

FDA remains committed to protecting patients. Our work to ensure compliance with the law does not take away from our firm commitment to advance an efficient path for the safe and effective development of novel regenerative medicine therapies and to help foster beneficial new innovations. We'll continue to work closely with investigators and firms legitimately working in this field and will do so in the most effective manner possible, while meeting the FDA's standards for safety and efficacy. We look forward to working with those who share our goal of bringing safe and effective products to market to benefit individuals in need.