FDA Files Complaints in Federal Court Against Two Stem Cell Clinics

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FDA historically has limited its enforcement actions against stem cell clinics to warning letters. On May 9, 2018, FDA went a step further and filed two complaints in federal court seeking permanent injunctions that would prevent two stem cell clinics from marketing stem cell products prior to receiving FDA approval. This action signifies FDA's willingness to take legal action against stem cell clinics that do not heed FDA's warning. As noted on its website, "FDA is increasing its oversight and enforcement to protect people from dishonest and unscrupulous stem cell clinics, while continuing to encourage innovation so that the medical industry can properly harness the potential of stem cell products."[1]

Background

Stem cell treatments are required to be approved by FDA or be studied under an Investigational New Drug (IND) application which FDA reviews and has discretion to allow to proceed based on how the product is manufactured to ensure appropriate steps are being taken to assure the product's safety, purity, and strength. In spite of these requirements, according to FDA, some clinics still inappropriately advertise stem cell clinical trials without submitting an IND application, or falsely advertise that FDA review or approval is not necessary.[2] If a stem cell product is used in an unapproved way, the FDA has discretion to take legal action.

The Complaints

The first complaint was filed against a stem cell clinic located in Sunrise, Florida, its Chief Scientific Officer, and its co-owner and managing officer, seeking a permanent injunction alleging that the stem cell products were marketed without FDA approval and violated current good manufacturing practice requirements. According to an FDA news release, FDA filed the complaint because the clinic did not address the violations outlined in an August 2017 Warning Letter (OBPO 1 17-02).[3] FDA issued the Warning Letter upon finding that the clinic was marketing stem cell products without FDA approval and deviated significantly from current good manufacturing practice requirements, including some that FDA found could affect the sterility of the products. The Warning Letter also cited an FDA inspection which uncovered that the clinic was processing adipose tissue into stromal vascular fraction (a cellular product derived from body fat) and administering the product both intravenously or directly into the spinal cord of patients to treat certain diseases or conditions, including Parkinson's disease, chronic obstructive pulmonary disease (COPD), and heart disease, among others. FDA, however, had not approved any biological products manufactured by the clinic for any use. The permanent injunction would require the defendants to cease marketing stem cell products until the required FDA approvals are obtained and correct their violations of current good manufacturing practice requirements.

The second complaint was filed against a stem cell treatment center operating stem cell clinics in Rancho Mirage and Beverly Hills, California and two of the company's proprietors. The complaint

1 U.S. Food & Drug Administration, FDA Warns About Stem Cell Therapies, available at https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm286155.htm (last accessed May 15, 2018).
2 Id.
3 FDA, Warning Letter to U.S. Stem Cell Clinics, LLC, (Aug. 24, 2017), available at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm573187.htm (last accessed May 21, 2018).

seeks a permanent injunction based on allegations that the clinic marketed stem cell products to patients without FDA approval. The complaint follows the FDA's action in August 2017 to prevent the use of a potentially dangerous treatment administered through intravenous injections directly into the tumors of cancer patients.[4] According to FDA's news release, the treatment center products are also being used for experimental treatments for individuals who have a number of serious diseases or conditions, including amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS), among others. FDA, however, has not approved any biological products manufactured by the treatment center for any use. FDA investigations of the facilities in July 2017 also uncovered other violations, including evidence of significant deviations from current good manufacturing practice requirements. The permanent injunction would require the defendants to cease marketing stem cell products until the necessary FDA approvals are obtained and defendants correct their violations of current good manufacturing practice requirements.

According to FDA Commissioner Scott Gottlieb, M.D, "[i]n the two cases filed …, the clinics and their leadership have continued to disregard the law and more importantly, patient safety."[5] Prior to these complaints, in August 2017, FDA announced increased enforcement of regulations and oversight of stem cell clinics, and published a perspective article in the New England Journal of Medicine in March 2017 to further clarify the risks and benefits of stem cell therapy.

AGG Takeaways

- Stem cell clinics and providers of stem cell therapies can expect to see increased regulatory scrutiny and oversight of stem cell therapies, including enforcement actions above and beyond a traditional Warning Letter.
- FDA's focus will likely include ensuring that stem cell therapies are marketed and advertised only for FDA-approved use, and clinics are not advertising stem cell clinical trials without submitting an IND or falsely advertising that FDA review or approval is not necessary.

4 On August 25, 2017, the U.S. Marshals Service seized five vials, each containing 100 doses of a vaccine that is reserved for people at high risk for smallpox and not commercially available. FDA News Release, FDA Acts To Remove Unproven, Potentially Harmful Treatment Used In 'Stem Cell' Centers Targeting Vulnerable Patients (August 28, 2017), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm573427.htm (last accessed May 21, 2018).

5 FDA News Release, FDA Seeks Permanent Injunctions Against Two Stem Cell Clinics (May 9, 2018), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607257.htm (last accessed May 21, 2018).

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