FDA Steps Up Enforcement Against Stem Cell Clinics

With the rapid growth of the regenerative medicine field, the U.S. Food and Drug Administration (FDA) is trying to strike the right balance between preventing harm to the public and fostering innovation of new treatments. This happens of course right when the public view and confidence in regenerative medicine services like stem cells, PRP and exosomes is rising steadily, leaving many orthopedic practices no alternative but to offer them.

In an effort to prevent potential harm, the FDA recently stepped up enforcement. In two complaints filed by the U.S. Department of Justice (DOJ) on behalf of the FDA, the FDA has sought permanent injunctions against a California and Florida stem cell clinic along with their owners and officers to prevent the marketing of stem cell products without FDA approval and for failure to correct deviations from manufacturing practice requirements. This is causing many regenerative medicine providers, including orthopedic practices, to shy away from venturing into stem cell services.

The recent injunctions are aimed at U.S. Stem Cell Clinic, LLC of Sunrise, Florida and California Stem Cell Treatment Center, Inc. with multiple locations in California. Both companies previously received warning letters from the FDA for administering processed adipose tissue (stromal vascular fraction) to patients to treat a variety of conditions ranging from mascular degeneration to Parkinson's disease. The letters also addressed the results of inspections and the need to resolve significant deviations from manufacturing practice requirements.

A complaint has been filed for an injunction…now what? Once a complaint for injunction is filed, an injunction may be entered at any time either following a hearing or as a result of a negotiated settlement. If a hearing is held, the burden will be on the government to prove each element required to obtain an injunction by a preponderance of the evidence. As the word "permanent" infers, an injunction will remain in place until removed by an order from the court.

On April 16th, Iowa Senator Chuck Grassley sent a letter to the leadership of the FDA pressing for answers on the results of their investigation into U.S. Stem Cell Clinic, LLC and asked whether the company or any of its employees were referred

for potential prosecution. Given the timing of these complaints in relation to Grassley's letter, are these isolated events in response to the letter or a sign of more enforcement action to come?

There's a saying in law: bad facts make bad law. The developments above arise out of some very contentious and controversial circumstances. If the FDA fires back in like kind, there is a real possibility that they will overshoot the issue of patient protection and impact the legitimate use of such therapies on many patients receiving them in medical practices.