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FDA Barred From Shutting Down Tissue Therapy Co.

By **Jeff Overley**

Law360, New York (August 19, 2016, 5:55 PM ET) -- A Texas federal judge on Friday barred the U.S. Food and Drug Administration from shuttering a tissue therapy maker over perceived sanitary problems, a move that came just hours after the company filed a lawsuit alleging "outrageous" regulatory overreach.

U.S. District Judge Ed Kinkeade granted an emergency motion for a temporary restraining order requested on Friday by Dallas-based Amniotic Therapies LLC, which makes wound-healing products from donated placenta tissue. The company filed suit earlier Friday to block an FDA order that would have required it to temporarily halt manufacturing, recall certain products and destroy all batches of those products, effective Tuesday.

In an order, Judge Kinkeade said that Amniotic Therapies doesn't have to stop manufacturing or issue a recall, but that it must stop distribution of some products for the time being. The judge scheduled arguments on Aug. 31 to further explore the merits of the case.

"The facts in [the company's] emergency motion demonstrate that the FDA order likely falls short of the necessary requirements to require [the company] to cease manufacturing, recall products and destroy inventory," Judge Kinkeade wrote.

According to the judge's order, federal law only authorizes the FDA's proposed action if tissue products are "found to be so infected or contaminated as to be sources of dangerous infection to human beings."

The FDA, however, only said that it had "reasonable grounds to believe" there was a danger to public health, and so its enforcement likely wasn't justified, the judge wrote.

Judge Kinkeade also found that Amniotic Therapies would be irreparably harmed if required to destroy inventory valued at $359,000.

In its complaint, Amniotic Therapies said that there haven't been any defects found in the products that the FDA wanted recalled and destroyed. In addition, manufacturing problems that the FDA discovered during an inspection several months ago have since been corrected, according to the company.

Although the FDA identified four infections linked to the company's products, Amniotic Therapies said that the infections all occurred because one physician at an Ohio hospital repeatedly failed to follow package instructions meant to ensure sterility.

Judge Kinkeade said that no other infections have been reported and that the company recalled the products associated with the four infections. "So, there is not a risk to the

public," the judge wrote.

In its emergency motion, Amniotic Therapies said that the FDA's enforcement action would have "devastating consequences," including probable layoffs for three of its five employees.

"The company's very existence is in peril," Amniotic Therapies wrote.

A spokeswoman for the FDA declined to comment.

Exhibits filed with the case show that Amniotic Therapies received a warning letter after an inspection that lasted from late March to early May. The letter described "significant deviations from current good manufacturing practice," including an alleged failure to follow procedures designed to prevent microbial contamination of purportedly sterile products.

The warning letter said that the FDA tested unopened vials of an Amniotic Therapies product and found bacterial contamination. However, the company accuses FDA officials of stonewalling its requests for more information about how the vials were handled prior to testing and how the testing was performed.

"It would be a fundamental injustice to condemn Amniotic Therapies based on evidence that it hasn't been allowed to see or to question," the company wrote.

Amniotic Therapies is represented by Joe Kendall, Jody Rudman and Jamie McKey of Kendall Law Group PC and Douglas B. Farquhar of Hyman Phelps & McNamara PC.

The FDA is represented by Thomas Edward Ross of the U.S. Department of Justice.

The case is Amniotic Therapies LLC v. U.S. Food and Drug Administration, case number 3:16-cv-02412, in the U.S. District Court for the Northern District of Texas.

--Editing by Ben Guilfoy and Katherine Rautenberg.
