

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

Case No.: 0:18-cv-61047-UU

UNITED STATES OF AMERICA.,

Plaintiff,

v.

US STEM CELL CLINIC, *et al.*,

Defendants.

OMNIBUS ORDER

THIS CAUSE is before the Court upon the following Motions:

- (1) Motion to Intervene and for Stay of Destruction of Applicants for Intervention's Property and Clarification of Order of Permanent Injunction, D.E. 215;
- (2) Amended Motion to Intervene and for Stay of Destruction of Applicants for Intervention's Property and Clarification of Order of Permanent Injunction, D.E. 220;
- (3) Motion to Intervene and for Stay of Destruction of Applicants for Intervention's Property and Clarification of Order of Permanent Injunction, D.E. 228;
- (4) Motion to Intervene and to Stay the Requirement that Patient Cells Currently Stored in an FDA-Registered Tissue Bank be Destroyed under the Intervenor's Opportunity to be Heard, D.E. 236, (collectively, the "Motions").

The Court has reviewed the Motions, the pertinent portions of the record and is otherwise fully advised in the premises.

I. Background

On June 3, 2019, the Court granted summary judgment in favor of Plaintiff, the United States of America. D.E. 73. In that order, the Court agreed with the FDA that Defendant's stromal vascular fraction ("SVF") product was an adulterated and misbranded drug under the Food Drug

and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 et seq. *see* D.E. 73 at 28-30. Consequently, on June 25, 2019, the Court entered an injunction, which *inter alia*, enjoined Defendant from manufacturing and/or providing any services relating to its SVF product and requiring Defendant to destroy all SVF product currently in Defendant’s possession, custody, or control. D.E. 83 at 9 ¶ 10.

On July 12, 2019, Defendants filed a Motion requesting that the Court modify the portion of the injunction that required the Defendants to destroy the SVF Product by June 25, 2019. D.E. 207. The United States agreed to a modification of the destruction provision pending appeal of the Injunction, which Defendants further agreed to in their reply memoranda. D.E. 231. As a result, the Court granted Defendants’ Motion, and modified the injunction to provide that the SVF Product was only to be destroyed within 30 days after the deadline for a timely appeal of the injunction or if Defendants timely appealed, within 30 days after the Eleventh Circuit Court of Appeals’ mandate as to such an appeal. *See* D.E. 233 at 3-5.

II. Analysis

In the instant Motions, the moving parties all seek to intervene for the purposes of staying the destruction of the SVF Product required by the injunction, which they contend is their property. The Court will deny these motions without prejudice. Since the Court amended the injunction to condition the destruction of the SVF Product on a mandate from the Eleventh Circuit as to any appeal of the order of permanent injunction, or the failure of Defendants to so appeal, both the relief requested by the putative intervenors and the appropriate forum for their intervention is entirely dependent upon whether Defendants appeal the order of permanent injunction by August 25, 2019. As such, the Court is unable to rule on the Motions at this time.

However, given the substantial confusion and communication received by this Court from nonparties, and to ensure all parties are apprised of their rights, the Court will also order Defendants to inform their clients with SVF Product subject to the order of permanent injunction of the status of the injunction and the destruction of their SVF product, and to inform those individuals of Defendants' decision as to the appeal of the order of permanent injunction.

III. Conclusion


For the reasons discussed *supra*, it is

ORDERED AND ADJUDGED that the Motions, D.E. 215, D.E. 220, D.E. 228, D.E. 236, are DENIED WITHOUT PREJUDICE. It is further

ORDERED AND ADJUDGED that Defendants US Stem Cell Clinic, LLC, US STEM CELL, INC., AND KRISTIN C. COMELLA, SHALL JOINTLY INFORM any nonparty with SVF PRODUCT subject to the order of permanent injunction of the status of the permanent injunction and the destruction of the SVF Product, as of the date of this order, by **Monday August 5, 2019**. Defendants SHALL FILE A NOTICE with the Court by **August 6, 2019**, confirming compliance with this notification requirement. It is further

ORDERED AND ADJUDGED that Defendants US Stem Cell Clinic, LLC, US STEM CELL, INC., AND KRISTIN C. COMELLA, SHALL JOINTLY INFORM any nonparty with SVF PRODUCT subject to the order of permanent injunction of Defendants' decision as to any appeal of the order of permanent injunction by the deadline of such appeal, **August 25, 2019**. Defendants SHALL FILE A NOTICE with the Court by **August 26, 2019**, confirming compliance with this notification requirement. **FAILURE TO ADHERE TO THIS ORDER AND FILE NOTICES CONFIRMING COMPLIANCE WILL RESULT IN SANCTIONS INCLUDING POTENTIAL MONETARY PENALTIES.**

DONE AND ORDERED in Chambers at Miami, Florida, this _31st_ day of July, 2019.


URSULA UNGARO
UNITED STATES DISTRICT JUDGE

copies provided: counsel of record