UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FT. LAUDERDALE DIVISION

CASE NO.: 18-61047-CIV-UNGARO/O'SULLIVAN

UNITED STATES OF AMERICA,

Plaintiff,

v.

US STEM CELL CLINIC, LLC, a Florida limited liability company,
US STEM CELL, INC., a Florida profit corporation, and
KRISTIN C. COMELLA, individual,

Defendants.

PROPOSED ORDER OF PERMANENT INJUNCTION

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter of this action under 21 U.S.C. § 332 and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

2. The Complaint for Permanent Injunction states a cause of action against US Stem Cell Clinic, LLC, a Florida limited liability company; US Stem Cell, Inc., a Florida profit corporation; and individual Kristin C. Comella (collectively, "Defendants") under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.* (the "Act").

3. For purposes of this Order of Permanent Injunction ("Order"), the following definitions shall apply:

A. "CGMP" shall collectively refer to current good manufacturing practice, as set forth in 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-211, the standards applicable to biological products in 21 C.F.R. Parts 600-680, and the requirements for human cells, tissues, and cellular and tissue-based products in 21 C.F.R. Part 1271;

B. "Drug" shall have the meaning given the term in 21 U.S.C. § 321(g)(1) and shall include any HCT/P, as defined below, that does not meet all of the criteria in 21 C.F.R. § 1271.10(a), and the exception in 21 C.F.R. § 1271.15(b) does not apply;

C. "Defendants' facility" shall refer to the facilities located at 12651 West Sunrise Blvd., Suite 704, Sunrise, Florida 33323, and 13794 NW 4th Street, Suite 212, Sunrise, Florida 33325, and any other location(s) at which one or more Defendants, now or in the future, manufacture, process, pack, repack, label, hold, and/or distribute the SVF product, as defined in subparagraph F below, any other drug, or any HCT/P;

D. "HCT/P" shall refer to human cell, tissue, or cellular or tissue-based product, as defined in 21 C.F.R. § 1271.3(d);

E. Stromal vascular fraction ("SVF") is an HCT/P derived from adipose tissue that has been processed to yield a cellular fraction; and

F. The "SVF product" shall refer to any and all products that Defendants prepare or cause to be prepared that contain SVF obtained or derived from adipose tissue.

4. The SVF product does not meet all of the criteria in 21 C.F.R. § 1271.10(a), and no exception in 21 C.F.R. § 1271.15 applies. The SVF product is a drug within the meaning of 21 U.S.C. § 321(g)(1).

5. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. § 352(f)(1) while such drugs, or one or more of their components, are held for sale after shipment in interstate commerce.

6. Upon entry of this Order, Defendants, and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), who have received actual notice of this Order by personal service or otherwise, are hereby permanently restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(k) by causing any article of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) or to become misbranded within the

meaning of 21 U.S.C. § 352(f)(1), while such article is held for sale after shipment of one or more of its components in interstate commerce; and/or

B. Results in the failure to implement and continuously maintain the requirements of this Order.

7. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court from directly or indirectly receiving, manufacturing, processing, packing, repacking, labeling, and/or distributing the SVF product or any other drug, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, repack, label, hold, and distribute such products are established, operated, and administered in conformity with CGMP to FDA's satisfaction;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Expert"), without personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families, who by reason of background, experience, education, and training, is qualified to inspect Defendants' facility to determine whether their methods, facilities, and controls are established, operated, and administered in conformity with CGMP and to evaluate the labeling of the SVF product and any other drugs manufactured, processed, packed, repacked, labeled, and/or distributed by Defendants to determine whether they are in compliance with 21 U.S.C. § 352(f). Defendants shall notify FDA in writing of the identity of the Expert within ten (10) days of retaining such Expert;

C. The Expert performs a comprehensive inspection of Defendants' facility and the methods and controls used to manufacture, process, pack, repack, label, hold, and distribute such products to determine whether such facilities, methods, and controls are, at a minimum, in conformity with CGMP, and to determine whether the labeling of the SVF product and any other drugs manufactured, processed, packed, repacked, labeled, and/or distributed by Defendants is in compliance with 21 U.S.C. § 352(f);

D. The Expert certifies to FDA that:

(1) The Expert has inspected Defendants' facility, methods, controls, and product labeling;

(2) All deviations from CGMP brought to Defendants' attention by FDA, the Expert, or any other source have been corrected;

(3) For the SVF product and any other drugs manufactured, processed, packed, repacked, labeled, and/or distributed by Defendants, Defendants have an approved new drug application, or investigational new drug application ("IND") in effect submitted pursuant to 21 U.S.C. §§ 355(b) or (i) respectively, or have obtained an approved biologics license application; and

(4) Defendants' facility, methods, and controls are in compliance with CGMP and the labeling of the SVF product and any other drugs manufactured, processed, packed, repacked, labeled, and/or distributed by Defendants is in compliance with 21 U.S.C. § 352(f). As part of this certification, the Expert shall include a detailed and complete report of the results of the Expert's inspections. The Expert shall submit his/her report(s) to FDA at the addresses specified in paragraph 24.

E. Defendants ensure that the labeling for the SVF product and any other drugs that they manufacture, process, pack, repack, label, and/or distribute bear adequate directions for use within the meaning of 21 U.S.C. § 352(f)(1) and all applicable regulations, or are in full compliance with a regulatory exemption to 21 U.S.C. § 352(f)(1) in 21 C.F.R. Part 201 Subpart D;

F. Defendants report to FDA in writing the actions they have taken to:

(1) Correct the CGMP deviations brought to Defendants' attention by FDA, the Expert, and any other source;

(2) Ensure that the methods used in, and the facilities and controls used for, receiving, manufacturing, processing, packing, repacking, labeling, holding, and distributing the SVF product and any other drug are operated and will be continuously administered in conformity with CGMP; and

(3) Ensure that the SVF product and any other drug that Defendants manufacture, process, pack, repack, label, and/or distribute are not misbranded within the meaning of 21 U.S.C. § 352(f)(1);

G. FDA representatives inspect Defendants' facility to determine whether the requirements of this Order have been met, and whether Defendants' facility is otherwise operated in conformity with CGMP and any drugs that they manufacture, process, pack, repack, label, and/or distribute are labeled in conformity with 21 U.S.C. § 352(f)(1); and

H. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 7.A-F.

8. After Defendants have complied with paragraphs 7.A-F., and FDA has notified them pursuant to paragraph 7.H, Defendants shall retain an independent person or persons who shall meet the criteria described in paragraph 7.B (hereafter, the "Auditor") to conduct audit inspections of Defendants' facility to determine whether Defendants are in compliance with this Order, the Act, and its implementing regulations, including whether Defendants' facility is operated in conformity with CGMP and whether any drugs that Defendants manufacture, process, pack, repack, label, and/or distribute are labeled in conformity with 21 U.S.C. § 352(f)(1). The Auditor shall conduct such audit inspections at least once every six (6) months, for a period of no less than two (2) years, and then at least once every twelve (12) months thereafter. If Defendants choose, the Auditor may be the same person or persons retained as the Expert in paragraph 7.B.

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with this Order, the Act, and its implementing regulations, including whether Defendants' facility is operated in conformity with CGMP and whether any drugs that Defendants manufacture, process, pack, repack, label, and/or distribute are labeled in conformity with 21 U.S.C. § 352(f)(1), and identifying any deviations ("audit report observations"). As a part of every audit report, except the first audit report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date the audit inspection(s) is completed. In addition, Defendants shall maintain the audit reports in separate files at Defendants' facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with this Order, the Act, and/or its implementing regulations, Defendants shall, within fifteen (15) calendar days after receiving the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than fifteen (15) calendar days, Defendants shall, within five (5) calendar days after receiving the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days after Defendants receive an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

9. If Defendants manufacture, process, pack, repack, label, and/or distribute any HCT/P that meets all of the criteria in 21 C.F.R. § 1271.10(a), Defendants shall continuously ensure that the HCT/P and Defendants' facility comply with all of the requirements in Part 1271.

10. Within thirty (30) calendar days after the entry of this Order, Defendants, under FDA's supervision, shall destroy any and all SVF product that is in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any SVF product in a manner contrary to the provisions of the Act, any other federal law, or the laws of any state or territory, as defined in the Act, in which the drugs are disposed.

11. If, at any time after entry of this Order, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants or the Expert or Auditor pursuant to this Order, or any other information, that Defendants have failed to comply with any provision of this Order, or have violated the Act and/or applicable regulations, and/or that additional corrective actions are necessary to achieve compliance with this Order, the

Act, and/or applicable regulations, FDA may, as and when it deems necessary, direct Defendants in writing to take appropriate actions. Such actions may include, but are not limited to, the following:

A. Cease receiving, manufacturing, processing, packing, repacking, labeling, and/or distributing the SVF product, any other drugs, and HCT/Ps (as defined in 21 C.F.R. § 1271.3(d));

B. Recall, at Defendants' sole expense, any products that are adulterated or misbranded or are otherwise in violation of this Order, the Act, or applicable regulations; and/or

C. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with this Order, the Act, or applicable regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Order or under the law.

12. Any cessation of operations or other action described in paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, the Act, and its implementing regulations, and that Defendants may resume operations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in such compliance, and, if so, issue to Defendants a written notification permitting, as appropriate, resumption of operations. In no circumstance shall FDA's silence be construed as a substitute for written notification. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraph 11, including the cost of travel incurred by specialized investigatory and expert personnel, shall be borne by Defendants at the rates specified in paragraph 14.

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' facility and take any other measures necessary to monitor and ensure continuing compliance with this Order. During inspections, FDA representatives shall be permitted to: have immediate access to buildings, equipment, in-process or unfinished and finished materials, containers, packaging material, labeling, and other promotional material therein; take photographs and make video recordings; take samples of Defendants' in-process or unfinished and finished materials, containers, packaging material,

labeling, and other promotional material; and examine and copy all records relating to the receipt, manufacture, processing, packing, repacking, labeling, holding, and distribution of any and all SVF product, drugs, HCT/Ps, and their components. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

14. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Order or that FDA deems necessary to evaluate Defendants' compliance with this Order, including the travel incurred by specialized investigatory and expert personnel. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of February 2019, these rates were: $95.39 per hour and fraction thereof per representative for inspection work; $114.33 per hour or fraction thereof per representative for analytical or review work; $0.58 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

15. This Order does not apply to drugs that are both (A) the subject of an application approved pursuant to 21 U.S.C. § 355(b) or a biologics license application approved by FDA and (B) not manufactured, processed, packed, or labeled by Defendants.

16. In the event that any Defendant(s) or Associated Persons, as defined in paragraph 18, submit an IND, including, but not limited to, an Individual Patient Expanded Access IND, Form FDA 3926, and FDA finds such IND does not meet:

A. The requirements in 21 C.F.R. § 312.23; and/or

B. As applicable, the requirements for all expanded access uses in 21 C.F.R. § 312.305, or the additional criteria, submission requirements, or safeguards that apply to specific types of expanded access, as described in 21 C.F.R. §§ 312.310 through 312.320, including, but not limited to, providing with Form FDA 3926, a Letter of Authorization granting FDA the right to reference another application or suitable Master File for information to satisfy

the IND submission requirements, such as a description of the manufacturing facility, chemistry, manufacturing and controls information, and pharmacology and toxicology information; FDA may notify any such Defendant(s) or Associated Persons, in writing, that the IND has not been received by FDA, as the term "receives" is used under 21 C.F.R. §§ 312.40(b) and 312.305(d)(1), and that such IND is not in effect. Absent an IND being in effect, the investigational new drug shall not be used in a clinical investigation.

17. Defendants shall immediately post a copy of this Order in a common area at Defendants' facility and at any other location at which Defendants conduct business and shall ensure that the Order remains posted for as long as the Order remains in effect.

18. Within ten (10) calendar days after the entry of this Order, Defendants shall provide a copy of this Order, by personal service or registered mail, to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (referred to collectively as "Associated Persons"). Within thirty (30) calendar days after the date of entry of this Order, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Order.

19. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Order, Defendants immediately shall provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within thirty (30) calendar days of each time any of the Defendants becomes associated with any such additional Associated Person(s), Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Order pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

20. Defendants shall notify FDA at least fifteen (15) calendar days before any change in ownership, character, or name of their businesses, including incorporation, reorganization, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure or identity of US Stem Cell Clinic, LLC, or US Stem Cell, Inc., or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Order. Defendants shall provide a copy of this Order to any potential successor or assign at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

21. If Defendants fail to comply with any provision of the Act, its implementing regulations, and/or this Order with respect to any of Defendants' products and/or Defendants' facility, including any time frame imposed by this Order, then, on written notice of FDA in this proceeding, Defendants shall pay to the United States of America: fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues; an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation; and further additional sum equal to the retail value of drugs or HCT/Ps that have been received, manufactured, processed, packed, repacked, labeled, held, and/or distributed in violation of the Act, its implementing regulations, and/or this Order. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Order or the law.

22. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Order shall be vested in FDA's discretion and, if contested, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Order shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

23. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such action.

24. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Order shall be marked "Permanent Injunction Correspondence" and shall be sent to both the Director, Office of Biological Products Operations, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, White Oak Building 31, Room 3548, Silver Spring, MD 20993, and Director, Office of Compliance and Biologics Quality, CBER, 10903 New Hampshire Avenue, White Oak Building 71, Room 5030 HFM-600, Silver Spring, MD 20993.

25. If any deadline in this Order falls on a weekend or holiday, the deadline is continued to the next business day.

26. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this _____ day of _____, 2019.

_____

UNITED STATES DISTRICT JUDGE