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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA - EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL TREATMENT
CENTER, INC., et al.

Defendants.

Case No.
EDCV 18-1005 JGB (KKx)

**FINDINGS OF FACT AND
CONCLUSIONS OF LAW**

1 This is a statutory injunction proceeding in which the United States, on
2 behalf of the U.S. Food and Drug Administration (“FDA”), seeks to permanently
3 enjoin Defendants California Stem Cell Treatment Center, Inc., Cell Surgical
4 Network Corporation, and Drs. Elliot B. Lander, M.D., and Mark Berman, M.D.,
5 from performing various stem cell treatments on patients. The United States
6 alleges these treatments violate the Federal Food, Drug, and Cosmetic Act
7 (“FDCA”). Specifically, the United States alleges that three of Defendants’
8 stromal vascular stem cell treatments violate: 21 U.S.C. § 331(k) by causing the
9 adulteration of drugs; 21 U.S.C. § 331(k) by causing the misbranding of drugs; and
10 21 U.S.C. § 331(c) by receiving drugs that are misbranded.

11 The case was tried to the Court on May 4, 5, 6, 7, 11, 12, and 13, 2021. Oral
12 closing arguments occurred on August 20, 2021. Because of the ongoing Covid-19
13 pandemic, the United States appeared via videoconference. At the August 20,
14 2021 closing arguments, the Court ordered supplemental briefing, which was
15 submitted by both sides on August 27, 2021, and September 1, 2021. (“Pl’s Supp
16 Br.,” Dkt. No. 179; “Def’s Supp Br.,” Dkt. No. 178; “Pl’s Supp Opp.,” Dkt. No.
17 181; “Def’s Supp Opp.,” Dkt. No. 180.)

18 The Court, having considered all the evidence presented by the parties, the
19 written submissions from both sides, and the argument of counsel, issues the
20 following Findings of Fact and Conclusions of Law.
21

22 I. FINDINGS OF FACT

23 A. General Facts

- 24 1. Defendant California Stem Cell Treatment Center (“CSCTC”) is a
25 California professional corporation founded in 2010, with its principal place
26 of business located at 72-780 Country Club Drive, Suite 301, Rancho Mirage,
27 California 92270 (“CSCTC Rancho Mirage”). California Stem Cell
28

1 Treatment Center has a second location at 120 South Spalding Drive, Suite
2 300, Beverly Hills, California 90212 (“CSCTC Beverly Hills.”). (“Stip.
3 Facts,” Dkt. No. 113-1 ¶ 1.)

4 2. Defendant Elliot B. Lander, M.D., a surgeon and board-certified urologist, is
5 the co-owner and Co-Medical Director of CSCTC. He is the most
6 responsible individual at CSCTC Rancho Mirage and performs his duties
7 there, within the jurisdiction of this Court. He manages all firm employees
8 at CSCTC Rancho Mirage. (“Pl. SOF,” Dkt. No. 169-1 ¶ 3.)

9 3. Defendant Mark Berman, M.D., a board-certified cosmetic surgeon, is the
10 co-owner and Co-Medical Director of CSCTC.¹ He performs his duties at
11 the CSCTC Beverly Hills facility, within the jurisdiction of this Court. He is
12 the most responsible individual at CSCTC Beverly Hills. (Id. ¶ 4.)

13 4. Defendant Cell Surgical Network Corporation (“CSN”) is a California
14 corporation founded and owned by Dr. Berman and Dr. Lander that is
15 registered to do business at 72-780 Country Club Drive, Suite 301, Rancho
16 Mirage, California 92270, the same address as CSCTC Rancho Mirage.
17 (Stip. Facts ¶ 2.)

18 5. CSN operates a one-employee warehouse in Palm Desert, California, from
19 which equipment and supplies are shipped to CSN affiliates. (Id. ¶ 3.)

20 6. Drs. Berman and Lander are the co-owners and Co-Medical Directors of
21 CSN. They are also the co-owners of Cells On Ice, Inc., which has assisted
22 in the recovery of adipose tissue sent outside of the State of California. (Pl.
23 SOF ¶ 6.)

24 **B. The “SVF Surgical Procedure”**

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¹ There have been news accounts of Mr. Berman’s death in May 2022. The parties have not filed a judicially noticeable document verifying the accounts. The

- 1 7. Defendants offer patients a treatment called the “SVF Surgical Procedure.”
2 In this procedure, a licensed physician targets stromal vascular fraction cells
3 (“SVF Cells”) for extraction and then implants those same cells that were
4 removed back into the same patient during the same procedure. (“Defs.
5 SOF,” Dkt. No. 168-1 ¶ 1.)
- 6 8. SVF Cells are comprised of multiple cell types found within adipose tissue;
7 these include mesenchymal stem cells (“MSC Cells”), hematopoietic cells,
8 early (progenitors) and mature lineage stages of endothelia, pericyte
9 progenitor cells (also called perivascular cells), red blood cells, white blood
10 cells, lymphocytes, and fibroblasts among other cells. SVF Cells are the
11 naturally occurring part of the adipose tissue that does not contain the
12 adipocytes (fat cells). (Id. ¶ 2.)
- 13 9. Surgeons routinely work on both tissues and cells that make up tissues.
14 Surgery universally involves dissection (cutting and separation) of tissues
15 through mechanical or chemical means, and has evolved to where surgeons
16 can isolate cells following removal from a patient’s body. Dissected tissues
17 and cells that have been isolated can be surgically relocated and re-purposed
18 to other parts of a patient’s body. (Id. ¶ 4.)
- 19 10. Surgery is intended for the treatment and prevention of disease in the human
20 body. It can treat chronic and systemic conditions, and it is intended to
21 affect the structure or function of the human body. There are no FDA-
22 approved or disapproved surgical procedures. (Id. ¶¶ 5-8.)
- 23 11. Accordingly, the surgical treatments at issue here have not been licensed or
24 approved by the United States Food and Drug Administration. There are
25 not now, nor have there ever been, any approved new drug applications for
26 the surgical treatments (“NDAs”) filed with FDA pursuant to 21 U.S.C. §
27 355(b) or (j). And there are not now, nor have there ever been any approved
28

1 biologics license applications (“BLAs”) filed with FDA pursuant to 42
2 U.S.C. § 262 for the treatments. (Stip. Facts ¶¶ 7-9.)

3 12. The SVF Surgical Procedure targets for removal mesenchymal stem cells
4 and the hemopoietic or angiogenic stem cells located within the adipose
5 tissue, not the adipose tissue itself. (Defs. SOF ¶ 10.)

6 13. The SVF Surgical Procedure involves collecting the patient’s SVF Cells
7 naturally contained in the patient’s adipose tissue and relocating those SVF
8 Cells back into the same patient. The SVF Cells are already in circulation
9 within the body. The SVF Surgical Procedure increases the number of
10 available SVF Cells in circulation or around an injured area. (Id. ¶ 11.)

11 14. The entire SVF Surgical Procedure, including the extraction, isolation, and
12 reimplantation of SVF Cells occurs in California during a single, outpatient
13 procedure at a surgical clinic. (Id. ¶ 12.)

14 15. During the SVF Surgical Procedure, a licensed physician collects the
15 patient’s SVF Cells using a technique called “mini-liposuction via
16 subdermal local anesthesia,” which permits the liposuction of the SVF Cells,
17 along with the adipose and connective tissue that contains the SVF Cells,
18 under local anesthesia. Many cells are mechanically separated (“mechanical
19 cutting”) from the adipose tissue during the liposuction procedure, as is
20 common in all surgeries. Next, the removed adipose tissue is centrifuged to
21 remove the anesthesia and to further mechanically dissociate the SVF Cells
22 from the adipose tissue. The physician then uses surgical tools—namely,
23 Liberase enzymes and a centrifuge device—to isolate the SVF Cells from
24 adipocytes (fat cells). Finally, the SVF Cells are filtered through a hundred
25 micron filter and viewed through a special micrograph to ensure that the
26 SVF Cells are free-floating, round, and do not contain clumps of particles or
27 debris. The SVF Cells are then suspended in a sterile saline solution, after
28 which they are relocated back into the patient’s body. Saline is a benign

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