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

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

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

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

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

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

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

cell surface marker expression remains similar, and their viability does not significantly change.

21. The Court finds that Dr. Berman and Dr. Lander are well qualified to opine and testify on the practice of medicine, development of surgical procedures, the SVF Surgical Procedure, and the effect of Liberase on the SVF Cells. The Court finds Defendants' evidence and testimony more credible than Dr. Yong given her failure to analyze the appropriate enzyme. Further, Defendants have actually tested the product at issue (as published in a peer-reviewed journal), while the Government has never collected a sample or tested the SVF Cells or Liberase.

22. In conclusion, the SSP Exception applies to the SVF Surgical Procedure and is a complete defense to Claims One and Two. Because the SSP Exception applies to the SVF Surgical Procedure, Defendants do not fall under FDA jurisdiction and are not governed by the FDCA or associated regulations; therefore, the Government is not entitled to injunctive relief against Defendants.

23. Further, the SSP Exception is unambiguous, thus there is no need for deference to the FDA's interpretation. See Kisor v. Wilkie, 139 S. Ct. 2400, 2414 (2019) ("[T]he possibility of deference can arise only if a regulation is genuinely ambiguous."); Christensen v. Harris Cnty., 529 US 576, 588 (2000) ("The regulation in this case, however, is not ambiguous . . . . To defer to the agency's position would be to permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation.").

24. The SSP Exception does not require that the surgeon implant everything that was removed—including the removed blood and excess artery—for it to apply. The SSP Exception Guidance expressly recognizes that processing steps such as "rinsing [and] cleansing" or "sizing and shaping," including "dilation," "cutting," "meshing," of HCT/Ps do not take a procedure out