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CORPORATION, ELLIOT B. LANDER, M.D.
and MARK BERMAN, M.D.

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
EASTERN DIVISION**

UNITED STATES OF AMERICA,
Plaintiff,

v.

CALIFORNIA STEM CELL
TREATMENT CENTER, INC., a
California corporation, CELL SURGICAL
NETWORK CORPORATION, a
California corporation, and ELLIOT B.
LANDER, M.D., MARK BERMAN,
M.D., individuals,

Defendants.

CASE NO. 5:18-CV-01005-JGB-KK

Hon. Jesus G. Bernal
Riverside, Courtroom 1

**[PROPOSED] FINDINGS OF
FACT AND CONCLUSIONS OF
LAW (LOCAL RULE 52)**

Action Filed: May 9, 2018
Trial Date: May 4, 2021
Closing Agmt.: July 9, 2021

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FINDINGS OF FACT

I. THE SVF SURGICAL PROCEDURE IS A SURGICAL PROCEDURE THAT REMOVES AND RETURNS THE SAME HCT/PS

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4 1. In Defendants’ surgical procedure, a licensed physician targets
5 stromal vascular fraction cells (“SVF Cells”) for extraction and then implants those
6 same cells that were removed back into the same patient during the same procedure
7 (“SVF Surgical Procedure”). (5/12/21 PM Tr. 47:7-11 (Lander)).

8 2. SVF Cells are comprised of multiple cell types found within adipose
9 tissue; these include mesenchymal stem cells (“MSC Cells”), hematopoietic cells,
10 early (progenitors) and mature lineage stages of endothelia, pericyte progenitor
11 cells (also called perivascular cells), red blood cells, white blood cells,
12 lymphocytes, and fibroblasts among other cells. (5/7/21 PM Tr. 28:18-31:8
13 (Yong); 5/12/21 PM Tr. 46:23-47:3 (Lander)). SVF Cells are the naturally
14 occurring part of the adipose tissue that does not contain the adipocytes (fat cells).
15 (5/7/21 PM Tr. 28:18-31:8 (Yong); 5/11/21 AM Tr. 112:20-24 (Berman); 5/12/21
16 PM Tr. 47:4-6 (Lander)).

17 3. Cells are the smallest and most basic functional structural units in the
18 human body. No person or device can remove a stem cell from adipose tissue
19 without also removing other tissue. (5/7/21 PM Tr. 19:9-12 (Yong); 5/11/21 AM
20 Tr. 112:13-19 (Berman)).

21 4. Surgeons routinely work on both tissues and cells that make up
22 tissues. Surgery universally involves dissection (cutting and separation) of tissues
23 through mechanical or chemical means, and has evolved to where surgeons can
24 isolate cells following removal from a patient’s body. (5/12/21 PM Tr. 73:20-74:1
25 (Lander)). Dissected tissues and cells that have been isolated can be surgically
26 relocated and re-purposed to other parts of a patient’s body. (5/12/21 PM
27 Tr. 86:17-88:13 (Lander)).
28

1 5. Surgery is intended for the treatment and prevention of disease in the
2 human body. (5/6/21 AM Tr. 65:12-22 (Lapteva); 5/12/21 PM Tr. 48:16-21
3 (Lander)).

4 6. Surgery can treat chronic and systemic conditions. (5/6/21 AM
5 Tr. 65:8-12 (Lapteva)).

6 7. Surgery is intended to affect the structure or function of the human
7 body. (5/6/21 AM Tr. 65:25-66:4 (Lapteva)).

8 8. There are no FDA-approved or disapproved surgical procedures.
9 (5/4/21 AM Tr. 57:1-6 (Joneckis); 5/11/21 PM Tr. 14:23-15:3 (Berman)).

10 **A. The SVF Surgical Procedure Involves Surgical Removal of**
11 **HCT/Ps**

12 9. SVF Cells are HCT/Ps.¹ (5/7/21 PM Tr. 19:17-20:3 (Yong)).

13 10. The SVF Surgical Procedure targets for removal mesenchymal stem
14 cells and the hemopoietic or angiogenic stem cells located within the adipose
15 tissue, not the adipose tissue itself. (5/11/21 PM Tr. 77:13-17 (Berman); 5/12/21
16 PM Tr. 46:13-18 (Lander)).

17 11. The SVF Surgical Procedure involves collecting the patient's
18 SVF Cells naturally contained in the patient's adipose tissue and relocating those
19 SVF Cells back into the same patient. (5/11/21 PM Tr. 77:18-21 (Berman)). The
20 SVF Cells are already in circulation within the body. (5/11/21 PM Tr. 77:22-24
21 (Berman)). The SVF Surgical Procedure increases the number of available
22 SVF Cells in circulation or around an injured area. (5/11/21 PM Tr. 48:13-15
23 (Berman)).

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28 ¹ HCT/Ps "means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d).

1 12. The entire SVF Surgical Procedure, including the extraction, isolation,
2 and reimplantation of SVF Cells occurs in California during a single, outpatient
3 procedure at a surgical clinic. (5/11/21 PM Tr. 5:6-8, 57:1-10 (Berman)).

4 13. During the SVF Surgical Procedure, a licensed physician collects the
5 patient’s SVF Cells using a technique called “mini-liposuction via subdermal local
6 anesthesia,” which permits the liposuction of the SVF Cells, along with the adipose
7 and connective tissue that contains the SVF Cells, under local anesthesia.
8 (Ex. 453; 5/11/21 PM Tr. 5:6-15 (Berman)). Many cells are mechanically
9 separated (“mechanical cutting”) from the adipose tissue during the liposuction
10 procedure, as is common in all surgeries. (5/11/21 PM Tr. 6:19-22 (Berman);
11 5/12/21 PM Tr. 72:24-73:15 (Lander)).

12 14. Next, the removed adipose tissue is centrifuged to remove the
13 anesthesia and further mechanically dissociate the SVF Cells from the adipose
14 tissue. (Ex. 453; 5/11/21 PM Tr. 7:12-19 (Berman)).

15 15. The physician then uses surgical tools—namely, Liberase enzymes
16 and a centrifuge device—to isolate the SVF Cells from adipocytes (fat cells).
17 (Ex. 453; 5/11/21 PM Tr. 9:4-11 (Berman)).

18 16. The GMP-grade Liberase was specifically developed by Roche
19 Laboratories (“Roche”) in July 2010 for use in the SVF Surgical Procedure. Roche
20 developed a safe, GMP-grade Liberase to avoid any contamination of the SVF
21 Cells during the SVF Surgical Procedure. (5/11/21 AM Tr. 110:19-111:1
22 (Berman); 5/12/21 PM Tr. 60:11-18 (Lander)). Roche entered into a private label
23 agreement with Drs. Berman and Lander to provide the GMP-grade Liberase under
24 the trade-name CSN-TMAX. (5/11/21 AM Tr. 111:2-6 (Berman); 5/11/21 PM
25 Tr. 17:10-12 (Berman)).

26 17. All of the materials used to isolate SVF Cells during the SVF Surgical
27 Procedure are FDA-approved drugs or FDA-cleared devices. (Exs. 384, 385
28 (clearance for Lipokit); 386 (clearance for Cellticator); 387, 388, 389, 390

1 (approval for dextrose lactated ringers solution); 391, 392, 393, 394 (approval for
2 saline); 395, 396, 410 (proof of GMP-grade Liberase); 5/11/21 PM Tr. 13:10-15)
3 (Berman)).

4 18. Further, Drs. Berman and Lander have collected an abundance of data
5 under Institutional Review Board (“IRB”)-approved protocols. (Exs. 15, 36, 48,
6 78, 79, 80, 81, 154, 161; 5/12/21 PM Tr. 63:1-7, 63:22-66:1 (Lander); 5/11/21 PM
7 Tr. 36:18-25 (Berman)). The International Cell Surgical Society (“ICSS”) IRB
8 currently oversees Drs. Berman and Lander’s investigational protocols. (5/11/21
9 PM Tr. 35:18-20 (Berman)). Drs. Berman and Lander do not sit on the ICSS IRB
10 or have any control whatsoever over the ICSS IRB. Drs. Berman and Lander
11 founded ICSS and only control ICSS’s educational resources relating to
12 regenerative medicine. (5/11/21 PM Tr. 35:22-36:14 (Berman); 5/12/21 PM
13 Tr. 54:1-14 (Lander)).

14 19. Liberase chemically separates the SVF Cells from the extracellular
15 matrix, and has been used for more than ten years with thousands of patients.
16 (5/11/21 PM Tr. 9:12-10:6 (Berman)).

17 20. Liberase is then washed out using dextrose lactated ringers solution
18 and centrifugation. (Ex. 453; 5/11/21 PM Tr. 10:20-11:4 (Berman)).² The
19 SVF Cells are concentrated during the “washing” steps. (5/7/21 PM Tr. 63:3-25;
20 65:7-9 (Yong); 5/12/21 PM Tr. 76:5-19 (Lander); 5/11/21 PM Tr. 11:7-15
21 (Berman)).

22 21. Finally, the SVF Cells are filtered through a hundred micron filter and
23 viewed through a special micrograph to ensure that the SVF Cells are free-floating,
24 round, and do not contain “clumps of particles or debris.” (5/11/21 PM Tr. 11:23-
25 12:7 (Berman)).

26
27
28 ² Dextrose lactated ringers solution is a benign crystalloid often used during
surgery. (5/12/21 PM Tr. 77:23-78:8 (Lander)).

1 22. The SVF Cells are then suspended in a sterile saline solution, after
2 which they are relocated back into the patient's body. Saline is a benign
3 crystalloid, widely used in the practice of medicine. (5/12/21 AM Tr. 56:14-19
4 (Berman); 5/12/21 PM Tr. 79:7-18 (Lander)). No new product is created by the
5 use of saline as a delivery mechanism. (5/12/21 AM Tr. 56:20-22 (Berman);
6 5/12/21 AM Tr. 99:15-23 (Reid)).

7 **B. The HCT/Ps That Are Removed From The Patient Are The Same**
8 **HCT/Ps That Are Implanted**

9 23. The SVF Cells are not altered, chemically or biologically, at any point
10 during the SVF Surgical Procedure, as confirmed by Dr. Lola Reid based on her
11 forty-five years of stem cell research and Drs. Berman and Lander's specific
12 testing of the SVF Cells. (5/12/21 AM Tr. 99:24-100:19 (Reid)). There are no
13 genes added to or removed from the SVF Cells during the SVF Surgical Procedure.
14 (5/12/21 AM Tr. 100:20-23 (Reid)). The size of the SVF Cells do not change.
15 (5/12/21 AM Tr. 101:1-2 (Reid)). The genetic makeup of the SVF Cells do not
16 change. (5/12/21 AM Tr. 101:3-5 (Reid)).

17 24. The biological characteristics of the SVF Cells do not change during
18 the SVF Surgical Procedure, including their ability to proliferate. (5/12/21 AM
19 Tr. 101:6-8 (Reid); 5/12/21 PM Tr. 85:12-18 (Lander)). The re-implanted SVF
20 Cells retain all their functions, including regenerative tissue repair, healing, and
21 anti-inflammatory properties. (5/12/21 AM Tr. 85:7-86:8; 89:21-91:1, 101:9-13
22 (Reid)).

23 25. There are several methods to determine whether the SVF Cells have
24 been physically changed during the SVF Surgical Procedure, including cell surface
25 marker expression analysis, gene expression analysis, and proteomic analysis.
26 (5/7/21 PM Tr. 15:9-17 (Yong)).

27 26. Drs. Berman and Lander, in conjunction with numerous other
28 physicians and scientists, have tested the SVF Cells and determined that the SVF

1 Cells have not been altered in any way that would change them from their naturally
2 occurring state (*i.e.*, they have the same DNA, same cell type, same flow
3 cytometry markers). (5/12/21 PM Tr. 88:18-89:8 (Lander)). These tests and
4 analysis have been published in peer reviewed journals. (5/12/21 PM Tr. 89:10-
5 90:1 (Lander)).

6 27. Drs. Berman and Lander confirmed via flow cytometry that the
7 SVF Cells retain their natural cell markers after they are isolated. (5/12/21 PM
8 Tr. 88:18-89:18 (Lander)). The SVF Cells isolated during the SVF Surgical
9 Procedure have the capacity to grow in adherent culture, meaning that they retain
10 their inherent biological characteristics. (5/6/21 PM Tr. 13:17-14:14 (Lapteva)).

11 28. Indeed, the SVF Cells all displayed moderate to strong positivity for
12 cell surface markers. (5/7/21 PM Tr. 56:6-24 (discussing cell surface markers for
13 at least two types of SVF Cells); *id.* 60:3-61:2 (discussing cell surface markers for
14 at least four types of SVF Cells) (Yong)).

15 29. The SVF Cells all demonstrated “their multipotency by differentiating
16 into cell types such as osteoblasts, adipocytes, bone, cartilage, and muscle cells.”
17 (5/7/21 PM Tr. 61:3-17 (Yong); 5/12/21 AM Tr. 92:21-93:4 (Reid)).

18 30. The Liberase used to separate the SVF Cells does not break down,
19 damage, or in any way alter the phenotypic traits and biological properties of the
20 SVF Cells. (5/12/21 AM Tr. 79:9-80:1; 93:10-94:2 (Reid); 5/12/21 PM Tr. 76:1-4;
21 88:23-89:8 (Lander)). Liberase has no impact on the viability of the SVF Cells,
22 yield of cells, and, most significantly, has no effect on the phenotype (identifying
23 cell markers), the ability of the SVF Cells to differentiate, to proliferate, or to
24 function in their intended capacity. (5/7/21 PM Tr. 35:7-24; 35:18-37:4; 37:5-19;
25 56:25-57:10 (Yong); 5/12/21 AM Tr. 79:9-80:1; 80:21-24 (Reid)). Liberase does
26 not affect SVF Cells’ ability to differentiate, the cell surface marker expression
27 was similar, and cell viability was not significantly different. (5/7/21 PM
28 Tr. 54:17-24; 55:15-56:2 (Yong); 5/12/21 PM Tr. 89:5-8 (Lander)).

1 31. Liberase does not cross or destroy the surface of the SVF Cells.
2 Rather, Liberase enzymatically digests the extracellular matrix (*i.e.*, the collagen
3 binding the cells together). (5/12/21 AM Tr. 80:5-19 (Reid); 5/12/21 PM
4 Tr. 84:21-85:5 (Lander)).

5 32. Liberase's only effect is to allow the SVF Cells to move from one
6 natural state (quiescent) to another natural state (regenerative), which regularly
7 occurs in the human body. (5/12/21 AM Tr. 79:9-80:1; 89:21-91:1 (Reid)).

8 **C. There Is No Evidence That The SVF Cells Are Modified Or**
9 **Altered In Any Way During The SVF Surgical Procedure**

10 33. Despite the ability to do so, the FDA has never tested a single
11 SVF Cell at issue. (5/6/21 AM Tr. 67:13-15; 67:25-68:2 (Lapteva); 5/7/21 PM
12 Tr. 21:11-13; 22:3-16 (Yong); (5/12/21 PM Tr. 90:2-7 (Lander)).

13 34. The Government relied upon inapplicable studies regarding different
14 enzymes, tissues, and/or incubation times to argue the SVF Surgical Procedure
15 materially changed the SVF Cells. (5/7/21 PM Tr. 27:15-28:9 (Yong; agreeing
16 that different enzymes have different effects on tissues or cells); 5/7/21 PM
17 Tr. 45:7-46:2; 49:4-18; 50:20-51:14; 51:15-52:13 (Yong; testifying that studies she
18 relied upon did not evaluate effect of Liberase on adipose tissue)). The
19 Government relied upon studies focusing on the effect of:

- 20 • Collagenase (most similar to Defendant's Liberase) and dispase
21 on spleen cells using a longer incubation time. (5/7/21 PM
22 Tr. 32:17-22; 33:25-34:2; 34:15-18 (Yong)). The collagenase
23 had no effect on the cell surface markers, and in some cases
24 increased the surface markers. (5/7/21 PM Tr. 35:7-24
25 (Yong)).
- 26 • Tumor Dissociation Enzyme on human ovarian tissue. (5/7/21
27 PM Tr. 39:16-24 (Yong)). Further identifying that Liberase,
28 such as the CSN-TMAX, is "highly purified and formulated for

1 efficient, gentle and reproducible dissociation of tissues from a
2 wide variety of sources” (5/7/21 PM Tr. 41:10-22 (Yong)).

- 3 • Dispace and central nervous system tissue. (5/7/21 PM
4 Tr. 47:11-23 (Yong)).
- 5 • Collagenase and muscle stem cells. (5/7/21 PM Tr. 48:16-49:3
6 (Yong)).
- 7 • Mechanical separation and umbilical cord tissue. (5/7/21 PM
8 Tr. 49:19-50:13 (Yong)).

9 35. None of the articles relied upon by the Government evaluated the
10 effect of Liberase on adipose tissue or SVF Cells. (5/7/21 PM Tr. 52:14-17
11 (Yong)).

12 36. Indeed, Dr. Yong did not know which enzyme the SVF Surgical
13 Procedure utilized. (5/7/21 PM Tr. 72:16-23 (Yong)).

14 37. The FDA has never tested a sample of the Liberase utilized during the
15 SVF Surgical Procedure. (5/7/21 PM Tr. 17-22:2 (Yong)).

16 38. There is no evidence that the temporary change in shape changes the
17 biological characteristics of the SVF Cells. (5/7/21 PM Tr. 44:21-45:5 (Yong);
18 5/12/21 AM Tr. 97:7-98:15 (Reid)).

19 39. The centrifuge does not create any new material during the
20 SVF Surgical Procedure. (5/12/21 PM Tr. 77:21-22 (Lander)).

21 40. The dextrose lactated ringers solution does not create any new
22 material during the SVF Surgical Procedure. (5/12/21 PM Tr. 78:9-11 (Lander)).

23 41. The incubator (Cellticator) does not create any new material during
24 the SVF Surgical Procedure. (5/12/21 PM Tr. 80:11-13 (Lander)).

25 42. There is no new material created by the use of saline during the
26 SVF Surgical Procedure. (5/12/21 AM Tr. 56:20-22 (Berman); 5/12/21 AM
27 Tr. 99:15-23 (Reid)).

28

1 43. The Government did not provide evidence or credible testimony to
2 rebut Drs. Berman, Lander, and Reid’s evidence and testimony that the SVF Cells
3 that are returned to the patient during the SVF Surgical Procedure are the same
4 SVF Cells that were removed during the SVF Surgical Procedure.³

5 **II. THERE IS NO EVIDENCE THAT THE SVF SURGICAL**
6 **PROCEDURE IS AN ADULTERATED DRUG**

7 44. The SVF Surgical Procedure does not create any new material or
8 introduce any foreign article into the body. (5/12/21 AM Tr. 56:4-6 (Berman);
9 5/12/21 PM Tr. 46:10-12 (Lander)). Unlike manufactured drugs, the SVF Surgical
10 Procedure does not create any cellular or tissue-based product that did not
11 previously exist within the patient. (5/7/21 PM Tr. 28:18-31:8 (Yong); 5/11/21
12 AM Tr. 112:20-24 (Berman); 5/12/21 AM Tr. 56:1-3 (Berman)).

13 **A. There Is No Evidence That The SVF Cells Are Held For Sale**
14 **After Traveling In Interstate Commerce**

15 45. Drs. Berman and Lander do not charge for the SVF Cells. (5/11/21
16 PM Tr. 50:15-25 (Berman)).

17 46. Drs. Berman and Lander only charge a surgical fee for the SVF
18 Surgical Procedure. (5/11/21 PM Tr. 50:15-25 (Berman); 5/12/21 AM Tr. 21:1-
19 22:7 (Berman)).

23 ³ Sitting as fact-finder, the trial court judge is tasked with weighing and making
24 factual findings as to the credibility of witnesses. *Earp v. Davis*, 881 F.3d 1135,
25 1145 (9th Cir. 2018) (citing *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564,
26 575 (1985)) (affirming district court’s determination of witness credibility); *Miller*
27 *v. Thane Int’l, Inc.*, 615 F.3d 1095, 1104 (9th Cir. 2010) (same). Indeed, when
28 findings are based on trial court determinations regarding the credibility of
witnesses, even greater deference is given to the court’s findings, “for only the trial
judge can be aware of the variations in demeanor and tone of voice that bear so
heavily on the listener’s understanding of and belief in what is said.” *Trent v.*
Valley Elec. Ass’n, Inc., 195 F.3d 534, 538 (9th Cir. 1999) (citing *Anderson*, 470
U.S. at 575).

1 47. Drs. Berman and Lander have provided the SVF Surgical Procedure
2 free of charge to hundreds of patients who wished to undergo the SVF Surgical
3 Procedure but were unable to pay. (5/12/21 AM Tr. 59:16-24 (Berman)).

4 48. The SVF Cells are extracted and isolated from a patient in California.
5 The SVF Cells are then returned to that patient in California. (5/11/21 PM Tr.
6 57:1-10 (Berman)).

7 49. The SVF Cells are not shipped in interstate commerce after they are
8 isolated. (5/11/21 PM Tr. 57:1-10 (Berman)).

9 50. The Government offered testimony that certain fluids used in the SVF
10 Surgical Procedure cross state lines, but that standard would make every surgical
11 procedure a matter of interstate commerce, which would be contrary to the
12 recognition that surgeries are the practice of medicine and exclusively regulated by
13 State governments. (5/5/21 AM Tr. 11:25-12:8 (Lagud); 5/5/21 PM Tr. 24:11-15
14 (Forster); 5/5/21 PM Tr. 53:18-24 (Christopher); 5/6/21 AM Tr. 75:23-24
15 (Lapteva); 5/11/21 AM Tr. 47:14-19 (Jim)).

16 **B. The SVF Surgical Procedure Complies With All California**
17 **Regulations Regarding Surgical Procedures**

18 51. Drs. Berman and Lander are board certified surgeons. (Ex. 300;
19 5/11/21 AM Tr. 95:10-15 (Berman); (5/12/21 PM Tr. 51:19-52:21 (Lander)).
20 Drs. Berman and Lander and their practices are regulated by the State of California
21 Medical Board. (5/11/21 AM Tr. 98:8-18 (Berman); 5/12/21 PM Tr. 54:25-55:4
22 (Lander)). Dr. Berman’s facility in Beverly Hills is accredited by the
23 Accreditation Association for Ambulatory Health Care (“AAHC”) per California
24 law. (Ex. 302; 5/11/21 AM Tr. 98:23-100:10 (Berman)).⁴

25 _____
26 ⁴Dr. Lander’s Rancho Mirage facility is not an outpatient surgical center; therefore,
27 the California Medical Board’s accreditation requirements do not apply. (5/12/21
28 PM Tr. 55:23-56:17 (Lander)). Further, accreditation is not required for the SVF
Surgical Procedures because only local anesthesia is used. (5/12/21 AM Tr. 63:25-
64:6 (Berman)).

1 52. The operating rooms in which Drs. Berman and Lander perform the
2 SVF Surgical Procedure comply with all health and safety standards established by
3 the California State Medical Board for outpatient procedures. (Exs. 302-322,
4 5/11/21 AM Tr. 98:8-18 (Berman); 5/12/21 PM Tr. 54:25-55:4 (Lander)).

5 53. Surgical environments can never be absolutely closed or acceptably
6 closed to the extent required of actual drug manufacturing. (5/11/21 AM Tr. 21:9-
7 16 (Berman)). The SVF Surgical Procedure is a virtually closed procedure with
8 the exception of slight exposure to the operating room air through the aperture of a
9 syringe. (5/11/21 AM Tr. 21:9-16 (Berman)).

10 **III. THERE IS NO EVIDENCE THAT THE SVF SURGICAL**
11 **PROCEDURE IS A MISBRANDED DRUG**

12 **A. The SVF Surgical Procedure Has Adequate Directions For Use**

13 54. Only licensed medical doctors, such as Drs. Berman and Lander, can
14 perform the SVF Surgical Procedure. (ECF No. 113-1, Stipulated Fact No. 4;
15 Ex. 430; 5/11/21 PM Tr. 59:4-13 (Berman)). The Cell Surgical Network (“CSN”)
16 affiliates—all licensed physicians who are approved and trained in the
17 investigational studies—agree to follow the SVF Surgical Procedure protocols.
18 (Ex. 431; 5/11/21 PM Tr. 60:6-16 (Berman)).⁵

19 55. Drs. Berman and Lander have drafted multiple surgical and physician
20 user manuals regarding how to safely perform the SVF Surgical Procedure,
21 including contraindications, sterilization techniques, and detailed step-by-step
22 instructions on how to extract, isolate, and re-implant the SVF Cells. (*See, e.g.*,
23 Exs. 303-322).

24 56. Drs. Berman and Lander drafted the surgical manual and physician
25 user manual based on their combined 70 years of surgical experience and have
26

27 ⁵ For the reasons stated in II.A., the SVF Cells are not held for sale after traveling
28 in interstate commerce and the FDCA does not apply.

1 continuously updated the manuals to include techniques developed during the
2 thousands of SVF Surgical Procedure that Drs. Berman and Lander and their
3 affiliated physicians have performed. (Exs. 304, 305; 5/11/21 PM Tr. 17:21-20:13
4 (Berman)).

5 57. These surgical manuals were provided to physicians with the CSN-
6 Time Machine® centrifuge and CSN-Time Machine® incubator. The surgical
7 manuals are intended to provide step-by-step instructions so that physicians would
8 have “uniform ability to follow a particular treatment” protocol, involving the
9 same procedure and deployment methods. (5/11/21 PM Tr. 18:10-14; 19:6-12
10 (Berman)).

11 58. Physicians can request additional information regarding how to
12 perform the SVF Surgical Procedure, including attending a demonstration of the
13 entire process. (5/11/21 PM Tr. 58:6-59:3 (Berman)).

14 **B. The Isolated SVF Cells Are Labeled Pursuant To Surgical**
15 **Protocols**

16 59. The SVF Cells isolated during the SVF Surgical Procedure are not
17 placed in any container for preservation, storage, or later use. (5/11/21 PM
18 Tr. 57:1-10 (Berman)). The SVF Cells are transferred between sterile syringes
19 during three washing phases. After the third washing phase, the SVF Cells are re-
20 implanted in the same patient through direct injection or intravenously. (5/11/21
21 PM Tr. 13:2-9 (Berman)).

22 60. The syringes containing the SVF Cells are labeled with the patient’s
23 name, date, and the description “SVF” pursuant to well-defined surgical patient
24 identifier protocols. (5/11/21 PM Tr. 13:6-9 (Berman)).

1 **IV. THERE IS NO EVIDENCE THAT THE EXPANDED MSC**
2 **SURGICAL PROCEDURE IS AN ADULTERATED DRUG AND/OR**
3 **IS MISBRANDED**

4 **A. Defendants Perform A Simple Liposuction In Connection With**
5 **The Expanded MSC Surgical Procedure; They Are Not**
6 **Manufacturing An Adulterated Drug**

7 61. In addition to the SVF Surgical Procedure, Drs. Berman and Lander
8 perform a procedure whereby a patient’s adipose tissue is removed and sent to a
9 GMP-compliant tissue bank to isolate MSC Cells. The MSC Cells are then
10 replicated and stored until the same patients requests that they be returned for
11 implantation into her body (the “Expanded MSC Surgical Procedure”). (5/11/21
12 PM Tr. 66:10-67:22 (Berman)).

13 62. During the Expanded MSC Surgical Procedure, a qualified candidate
14 undergoes liposuction at either Dr. Berman or Dr. Lander’s medical facilities.
15 (5/11/21 PM Tr. 66:10-19 (Berman)). Drs. Berman and Lander do not perform the
16 remainder of the SVF Surgical Procedure on the harvested adipose tissue but send
17 the tissue to a GMP-compliant third party. (5/11/21 PM Tr. 66:20-68:1 (Berman)).

18 63. A patient is eligible for the Expanded MSC Surgical Procedure where
19 the individual has a medical condition that will require multiple treatments, but the
20 individual is unable or unwilling to undergo multiple liposuctions. (5/11/21 PM
21 Tr. 64:9-65:1 (Berman))

22 64. Drs. Berman and Lander do not adulterate, manufacture, process or
23 store the patient’s adipose tissue during the Expanded MSC Surgical Procedure.
24 (5/11/21 PM Tr. 66:20-67:22 (Berman)).

25 65. The third party isolates the MSC Cells from the adipose tissue using a
26 technique that is similar to the SVF Surgical Procedure stated above under GMP
27 laboratory conditions. (5/11/21 PM Tr. 66:20-67:22 (Berman); 5/13/21 PM
28 Tr. 31:20-32:11 (Lander)).

1 66. The third party then places the MSC Cells in a culture, in which the
2 MSC Cells naturally begin to replicate (*i.e.*, expand in number), thereby creating a
3 sufficient number of cells under GMP conditions for multiple treatments (the
4 “Expanded MSC Cells”). (5/11/21 PM Tr. 66:20-67:22 (Berman)). Replication or
5 propagation is a natural state for stem cells and the Expanded MSC Cells retain all
6 of the biological characteristics of the MSC Cells. (5/13/21 PM Tr. 30:24-31:7
7 (Lander)).

8 67. The Expanded MSC Cells retain their cell markers, and do not
9 differentiate while in the culture or during storage. However, the Expanded MSC
10 Cells retain their ability to differentiate into osteoblasts, adipocytes, bone,
11 cartilage, and muscle cells once they are deployed back into the patient. (5/13/21
12 PM Tr. 31:1-15 (Lander)).

13 68. The third party tissue bank places the Expanded MSC Cells into a
14 sterile vial labeled with the patient’s name, date, and description pursuant to well-
15 defined patient identifier protocols. (5/11/21 PM Tr. 13:6-9 (Berman)).

16 69. After receiving the Expanded MSC Cells from the third party in a
17 labeled sterile vial, Drs. Berman and Lander deploy the Expanded MSC Cells into
18 the original patient. (5/12/21 AM Tr. 64:23-65:2 (Berman)).

19 70. Drs. Berman and Lander only utilize GMP facilities to isolate and
20 duplicate the MSC Cells, there is no evidence that MSC Cells are adulterated.
21 (5/13/21 PM Tr. 33:18-23 (Lander); *see also* 5/5/21 AM Tr. 35:22-36:4 (Lagud);
22 5/5/21 PM Tr. 37:4-19, 38:5-9 (Forster, no deviations from GMP regulations);
23 5/5/21 PM Tr. 65:25-66:7 (Christopher); 5/11/21 AM Tr. 69:16-25 (Jim)).

24 71. At the time of the inspection in 2017, Drs. Berman and Lander were
25 sending the adipose tissue to American Cyrostem (“ACS”) for isolation of the
26 MSC Cells and storage of the same. (5/4/21 AM Tr. 89:19-90:4 (Lagud); 5/11/21
27 PM Tr. 66:20-67:22 (Berman)).
28

1 72. Drs. Berman and Lander believed that ACS was a GMP facility based
2 on ACS's representations. (5/11/21 PM Tr. 67:23-68:1 (Berman); 5/13/21 PM
3 Tr. 32:12-17 (Lander)). Drs. Berman and Lander ceased utilizing ACS in
4 connection with the Expanded MSC Surgical Procedure following notice from the
5 FDA that ACS was not complying with GMP regulations. (Ex. 90; 5/11/21 PM
6 Tr. 69:3-12 (Berman)).

7 73. The third party that Drs. Berman and Lander currently use is
8 registered with the FDA and has been inspected by the FDA, with no resulting
9 deficiency letters. This demonstrates that the FDA has found the facility compliant
10 with GMP regulations. (5/12/21 AM Tr. 65:3-14 (Berman)).

11 74. Any conduct relating to Dr. Berman sending material to ACS was
12 outside of the scope of the 2017 FDA investigation. (5/5/21 PM Tr. 36:10-37:5
13 (Forster). The FDA did not document any deficiencies relating to the Expanded
14 MSC Surgical Procedure. (5/5/21 PM Tr. 36:1-9 (Forster)). The FDA did not
15 document any deficiencies relating to the receipt of Expanded MSC Cells as part of
16 the inspection. (5/5/21 PM Tr. 37:6-19 (Forster)).

17 75. The FDA inspected ACS as part of the coordinated inspection of
18 Defendants' facilities. (5/5/21 AM Tr. 6:11-22 (Lagud); 5/5/21 PM Tr. 34:7-10
19 (Forster); 5/5/21 PM Tr. 59:11-16 (Christopher); 5/11/21 AM Tr. 69:7-12 (Jim)).

20 76. The FDA issued Form 483 observations to ACS after the inspection,
21 which detailed deficiencies in ACS's facility. (5/5/21 PM Tr. 35:15-25 (Forster)).
22 The FDA issued a warning letter to ACS on January 3, 2018 ("Warning Letter").
23 (Ex. 90).

24 77. Yet, in September 2020, the FDA allowed an Investigational New
25 Drug ("IND") Phase 1 Clinical Trial to move forward for ACS's ATCell™
26 Expanded Autologous, Adipose-Derived Mesenchymal Stem Cells Deployed via
27 Intravenous Infusion for the Treatment of Post-Concussion Syndrome (PCS) in
28 Retired Military and Athletes. (Ex. 500). In March 2021, ACS announced that it

1 “has begun processing patient’s adipose tissue and expanding mesenchymal stem
2 cells (ATCell™) for use in its FDA approved IND Phase I Clinical Trial.” (Ex.
3 501).

4 78. Drs. Berman and Lander are permitted to perform the SVF treatments
5 on their patients subject to the conditions set forth in the IND approvals for ACS.
6 (5/4/21 AM Tr. 74:21-75:2 (Joneckis)).

7 79. The Government did not present any evidence that Defendants are
8 adulterating any material in connection with the Expanded MSC Surgical
9 Procedure.

10 **B. There Is No Evidence That The Expanded MSC Surgical**
11 **Procedure Is Misbranded Or That Drs. Berman And Lander**
12 **Receive A Misbranded Drug Through The Expanded MSC**
13 **Surgical Procedure**

14 80. Only licensed practitioners, such as Drs. Berman and Lander or the
15 CSN affiliates can perform the Expanded MSC Surgical Procedure. (ECF No.
16 113-1, Stipulated Fact No. 4; Ex. 430; 5/11/21 PM Tr. 59:4-13 (Berman)).

17 81. Drs. Berman and Lander have drafted multiple surgical and user
18 manuals regarding how to safely perform the liposuction procedure, including
19 contraindications, sterilization techniques, and detailed step-by-step instructions on
20 how to harvest the adipose tissue. (Exs. 304, 305; 5/11/21 PM Tr. 17:21-20:13
21 (Berman)).

22 82. At all times, the vials containing the Expanded MSC Cells are labeled
23 with the patient’s name, date, and description pursuant to patient identifier
24 protocols. (Exs. 304; 305).

25 83. The Government did not present any evidence that Defendants label
26 or mislabel any material regulated by the FDA in connection with the Expanded
27 MSC Surgical Procedure.
28

1 84. The Government did not present any evidence regarding the labeling
2 Defendants receive from any GMP facility in connection with the Expanded MSC
3 Surgical Procedure, nor any evidence that any such labeling is deficient.

4 **C. The Expanded MSC Cells Are Not Held For Sale**

5 85. Drs. Berman and Lander do not charge for the Expanded MSC Cells;
6 they only charge a surgical fee for the liposuction procedure. (5/12/21 AM
7 Tr. 21:1-22:7 (Berman)).

8 86. Patients paid a separate facility fee to the third party for the banking
9 or storage of the Expanded MSC Cells. (5/12/21 AM Tr. 21:1-22:7 (Berman)).

10 **V. THERE IS NO EVIDENCE THAT THE SVF/ACAM2000 SURGICAL**
11 **PROCEDURE CAN BE PERFORMED BY DEFENDANTS NOW OR**
12 **IN THE FUTURE OR THAT IT FALLS UNDER FDA AUTHORITY**

13 **A. Defendants Used The SVF/ACAM2000 Surgical Procedure Only**
14 **As Part Of An Institutional Review Board–Approved Research**
15 **Study**

16 87. Drs. Berman and Lander partnered with StemImmune, led by Dr.
17 Aladar Szalay, a pioneer in oncolytic virology studies, to study the safety of
18 utilizing SVF Cells as a mechanism to deliver ACAM2000, an oncolytic virus, to
19 the cancer cells (“SVF/ACAM2000 Surgical Procedure”). (Ex. 48; 5/12/21 PM
20 Tr. 96:13-97:15 (Lander)).

21 88. The SVF/ACAM2000 Surgical Procedure was a limited experimental
22 treatment only available to individuals with terminal cancer for whom traditional
23 treatment had failed. (5/11/21 PM Tr. 71:14-72:4 (Berman)). Drs. Berman and
24 Lander would prepare the SVF Cells using their standard method, then add the
25 ACAM2000 to the SVF Cells ACAM2000 (“SVF/ACAM2000 Cells), before
26 deploying into the same patient’s body. (Ex. 48).

1 89. ACAM2000 is an FDA-approved vaccine. (Ex. 189). There is no
2 evidence that the ACAM2000 utilized in the SVF/ACAM2000 Surgical Procedure
3 was adulterated.

4 90. ACAM2000 is an oncolytic virus, meaning that it has the ability to
5 kill cancer cells. (5/11/21 PM Tr. 70:11-14 (Berman); 5/12/21 PM Tr. 96:11-18
6 (Lander)).

7 91. The federal government maintains exclusive control over ACAM2000
8 as part of the country's Strategic National Stockpile and it may only be distributed
9 by specific government agencies. (Ex. 380; 5/12/21 PM Tr. 102:19-25, 103:10-15
10 (Lander)). It is not publicly available, but researchers may request vials for
11 studies. (Ex. 380).

12 92. Drs. Berman and Lander cannot perform the SVF/ACAM2000
13 Surgical Procedure without access to ACAM2000. (5/11/21 PM Tr. 73:6-9
14 (Berman); 5/12/21 PM Tr. 103:10-15 (Lander)).

15 93. StemImmune was inspected in July 2017 as part of the same overall
16 investigation of Defendants' facilities. (Ex. 503; 5/5/21 PM Tr. 13:7-15 (Forster);
17 5/5/21 PM Tr. 57:10-16 (Christopher)).

18 94. The FDA confiscated vials of ACAM2000 from StemImmune's
19 laboratories at the University of California, San Diego in August 2017. (Ex. 383;
20 (5/4/21 PM Tr. 61:4-10 (Lagud); 5/5/21 PM Tr. 30:1-16 (Forster); 5/5/21 PM
21 Tr. 57:6-8(Christopher)).

22 95. Dr. Berman last performed the SVF/ACAM2000 Surgical Procedure
23 before the FDA's July 2017 inspection. (5/11/21 PM Tr. 72:20-73:5 (Berman)).

24 96. Dr. Lander last performed the SVF/ACAM2000 Surgical Procedure in
25 June 2016. (5/12/21 PM Tr. 103:7-9 (Lander)).

26 97. Drs. Berman and Lander have no desire or intention to perform the
27 SVF/ACAM2000 Surgical Procedure outside of proper FDA regulatory approval
28 or a determination that that SVF/ACAM2000 Cells are not a drug and do not fall

1 under FDCA regulations. (5/11/21 PM Tr. 73:10-13 (Berman); 5/12/21 PM
2 Tr. 103:21-24 (Lander)).

3 **B. The SVF/ACAM2000 Surgical Procedure Is Not Sold And Does**
4 **Not Implicate Interstate Commerce**

5 98. Drs. Berman and Lander did not charge study participants for the
6 SVF/ACAM2000 Surgical Procedure. (5/11/21 AM Tr. 85:15-18 (Jim); 5/11/21
7 PM Tr. 72:5-8 (Berman); 5/12/21 PM Tr. 99:4-6 (Lander)).

8 99. Indeed, Drs. Berman and Lander paid for independent laboratory and
9 radiology fees for study participants. (5/11/21 PM Tr. 72:8-11 (Berman); 5/12/21
10 PM Tr. 99:7-15 (Lander)).

11 100. The entire SVF/ACAM2000 Surgical Procedure occurred in
12 California. (Ex. 48; 5/11/21 PM Tr. 57:1-10 (Berman)).

13 101. The Government did not present any evidence that the
14 SVF/ACAM2000 Cells were shipped in interstate commerce.

15 **C. There Is No Evidence That The SVF/ACAM2000 Surgical**
16 **Procedure Is Misbranded**

17 102. The SVF/ACAM2000 Cells were not placed in any container for
18 preservation, storage, or later use. (See 5/11/21 PM Tr. 57:1-10 (Berman)). They
19 were used as part of the same surgical procedure. (5/11/21 PM Tr. 13:6-9
20 (Berman)). The syringes containing the SVF/ACAM2000 Cells were labeled with
21 the patient's name and date pursuant to well-defined patient identifier protocols.
22 (5/11/21 PM Tr. 13:6-9 (Berman)).

23 103. The SVF/ACAM2000 Surgical Procedure was performed at all times
24 by Drs. Berman and Lander, licensed physicians. (5/11/21 PM Tr. 70:4-72:18
25 (Berman)). Drs. Berman and Lander performed the SVF/ACAM2000 Surgical
26 Procedure pursuant to the IRB-approved study protocols, which included detailed
27 step-by-step instructions on how to extract and isolate the SVF Cells, reconstitute
28 the ACAM2000 vaccine, and implant the SVF/ACAM2000 Cells. (Ex. 48).

1 **VI. LACK OF ADEQUATE NOTICE**

2 104. In 2010, Drs. Berman and Lander began developing the SVF Surgical
3 Procedure as part of their surgical practices and as a cutting-edge surgical
4 procedure designed to address their patients' medical concerns. (5/11/21 AM
5 Tr. 109:13-111:6 (Berman); 5/12/21 PM Tr. 57:21-58:8 (Lander)).

6 105. Drs. Berman and Lander worked with an interdisciplinary team to
7 develop the SVF Surgical Procedure, initially focusing on orthopedic cases.
8 (5/11/21 AM Tr. 107:2-15 (Berman); 5/12/21 PM Tr. 59:7-15 (Lander)).
9 Dr. Berman took the equipment utilized for a fat transfer procedure and refined the
10 equipment to create a nearly closed surgical procedure. (5/11/21 AM Tr. 110:6-18
11 (Berman)).

12 106. Drs. Berman and Lander have successfully performed point of care
13 investigative deployment of autologous adipose SVF Cells since 2010 and through
14 CSN since 2012. (5/11/21 PM Tr. 46:8-11 (Berman)).

15 107. Further, the FDA's 2017 Guidance states that, for some health care
16 providers, the FDA will not allege any violation for three years. Food & Drug
17 Admin., *Regulatory Considerations for Human Cell, Tissues, and Cellular and*
18 *Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance*
19 *for Industry and Food and Drug Administration Staff* at 9-10 (Nov. 2017 and
20 corrected Dec. 2017) [hereinafter "Food & Drug Admin., *Regulatory*
21 *Considerations*"]. However, the FDA did not identify to whom the three-year
22 grace period applies. By filing this lawsuit, the FDA singled out Drs. Berman and
23 Lander yet declined to address medical procedures that involve significantly more
24 manipulation of the HCT/Ps. (*Compare id.*, with ECF No. 1).

25 108. The FDA inspected the two CSCTC facilities in July 2017, before the
26 Guidance was finalized. (Exs. 11, 12). The FDA provided written notices of
27 inspection, to which Drs. Berman and Lander responded. (Exs. 38, 39, 69, 70).
28

1 The FDA provided no further notice to Drs. Berman and Lander before filing this
2 lawsuit. (*See* Exs. 38, 39, 69, 70; ECF No. 1).

3 109. During the same time and as part of a coordinated investigation, the
4 FDA inspected ACS (5/5/21 AM Tr. 6:11-22 (Lagud); 5/5/21 PM Tr. 34:7-10
5 (Forster); 5/5/21 PM Tr. 59:11-16 (Christopher); 5/11/21 AM Tr. 69:7-12 (Jim))
6 and StemImmune (Ex. 503; 5/5/21 PM Tr. 13:7-15 (Forster); 5/5/21 PM Tr. 57:10-
7 16 (Christopher)).

8 110. Instead of providing an opportunity to meet and discuss the findings,
9 the FDA filed the complaint in May 2018, well before the three-year grace period
10 expired. (ECF No. 1).

11 111. The Government does not purport to regulate substantially similar
12 practices. For example, the FDA allows the use of certain stem cells extracted
13 from bone marrow, while attempting to shut Defendant down, even though the
14 cells are essentially identical to the cells found in adipose tissue. (5/12/21 PM
15 Tr. 83:7-9 (Lander)).

16 112. Similarly, in certain abdominal surgeries, called anastomosis, a
17 segment of the bowel is removed and two pieces are sewed together, then a portion
18 of the omentum (a fat-like sheet covering the intestines) is removed and used to
19 cover the anastomosis to prevent leaks and help heal the bowel. (5/12/21 PM
20 Tr. 86:17-88:14 (Lander)).

21 113. As another example, neurosurgeons isolate autologous fat from
22 around the patient's umbilical area, crush that fat with a "Spence Cranioplastic
23 roller" to transform it into a thin foil on a separate table in the operating room, and
24 return that "foil" to the patient during the same procedure to repair, not cushion the
25 brain's lining. (5/12/21 PM Tr. 87:22-88:13 (Lander)). This process involves far
26 more processing of the tissue than the SVF Surgical Procedure, and yet is
27 exempted from FDA regulation, appropriately recognized as the practice of
28 medicine. (5/12/21 PM Tr. 87:22-88:13 (Lander)).

CONCLUSIONS OF LAW

I. CLAIMS ONE AND TWO: THE SVF SURGICAL PROCEDURE IS EXEMPT FROM FDA REGULATION AND ALSO IS NOT A DRUG, NOR IS IT ADULTERATED OR MISBRANDED

1. For Claim One, the Government must prove: (1) that the SVF Surgical Procedure involves a drug, (2) that the SVF Surgical Procedure involves a drug that is held for sale in interstate commerce; and (3) that the methods used in, or the facilities or controls used for, the manufacture of the drug are not in conformity with current Good Manufacturing Practices (“cGMP”). 21 U.S.C. §§ 331(k), 352(a)(2)(B).

2. For Claim Two, the Government must prove: (1) that the SVF Surgical Procedure involves a drug, (2) that the SVF Surgical Procedure involves a drug that is held for sale in interstate commerce; and (3) that it does not contain adequate directions for use or the symbol “Rx.” 21 U.S.C. §§ 352(f), 352(b)(2).

3. “You are not required to comply with the requirements of this part if you are an establishment that removes HCT/P’s from an individual and implants such HCT/P’s into the same individual during the same surgical procedure,” 21 C.F.R. § 1271.15(b) (the “SSP Exception”).

4. The SSP Exception is a complete defense to Claims Ones and Two and Defendants have established that the SSP Exception applies to the SVF Surgical Procedure.

5. Additionally and alternatively, the Government failed to carry its burden because the SVF Surgical Procedure is not a drug, does not travel through interstate commerce, meets surgical sterility requirements, and is accompanied by adequate directions for use.

1 **A. The SSP Exception Applies To The SVF Surgical Procedure And**
2 **Operates As A Complete Defense To Any Alleged Noncompliance**
3 **With FDA Regulations**

4 6. The only legitimate dispute regarding application of the SSP
5 Exception is whether the SVF Cells implanted into the patient are “such HCT/Ps”
6 as were removed from that patient. The answer is unequivocally yes.

7 7. In evaluating whether the SVF Surgical Procedure satisfies the
8 requirements of the SSP Exception, the appropriate focus is on the SVF Cells.
9 The SSP Exception unambiguously states that the focus is on the target of the
10 removal—either the cell or the tissue—rather than the largest system removed.
11 This is the only permissible interpretation of the SSP Exception, which explicitly
12 includes both “tissues” and/or “cells,” through its use of the term “HCT/Ps.” *See*
13 21 C.F.R. §§ 1271.3(d); 1271.15(b). Cells can only be removed from a patient
14 along with larger systems, such as the tissues or organs that they comprise.
15 Focusing on the “tissue” removed while ignoring the target “cells” would eliminate
16 the word “cells” from HCT/Ps and violate the canons of statutory construction.⁶

17 8. The SVF Surgical Procedure is autologous because it involves
18 collecting a patient’s cell population naturally occurring in the patient’s adipose
19 tissue and relocating that cell population back into the same patient.

21 ⁶ After the trial on this matter, the Court of Appeals for the Eleventh Circuit issued
22 a decision upholding summary judgment in *United States v. US Stem Cell Clinic,*
23 *LLC*, No. 19-13276, 2021 WL 2213288 (11th Cir. June 2, 2021). This decision is
24 non-precedential and not binding on this Court. Further, this decision is based on a
25 motion for summary judgment, rather than the full factual record developed in this
26 case. The Eleventh Circuit held that both adipose tissue and SVF Cells are
27 HCT/Ps. *Id.* at *5. Despite this, the Eleventh Circuit agreed with the FDA’s
28 position that the relevant HCT/P is the adipose tissue, not the SVF, which has been
rejected by this Court. *Compare id.* at *6, with Order Deny Mot. Summ. J. (ECF
No. 84). As the Government conceded during trial in this case, there is no surgical
procedure or other method to remove only the target cells, thus the FDA’s reading,
adopted by the Eleventh Circuit, fails to give full effect to all words in the SSP
Exception. Further, the Eleventh Circuit did not consider or determine if the
SVF Cells were the same SVF Cells that were removed. For all these reasons, this
Court declines to defer to the Eleventh Circuit’s decision.

1 9. The SVF Surgical Procedure is a single outpatient procedure.

2 10. Drs. Berman and Lander “remove[] HCT/Ps from an individual and
3 implant[] such HCT/Ps ” (*i.e.*, SVF Cells). *See* 21 C.F.R. § 1271.15(b).

4 11. The SSP Exception does not have any requirement that the HCT/Ps be
5 unaltered before reinsertion into the patient. *See* 21 C.F.R. § 1271.15(b). Any
6 reference to whether the HCT/Ps are manipulated and/or altered are located in a
7 different regulation 21 C.F.R. § 1271.10 (discussing “minimal manipulation”).
8 Defendants do not seek nor need to meet the requirements of 21 C.F.R. § 1271.10,
9 which would result in FDA regulation, albeit in a more limited fashion. To the
10 contrary, Defendants’ compliance with the SSP Exception is a complete exemption
11 from all FDA regulation. While the Government argues the application of 21
12 C.F.R. § 1271.10, the regulation is entirely inapplicable and the two tests should
13 not be conflated. Therefore, there is no requirement that the cells be “minimally
14 manipulated.”⁷

15 12. Regardless, the SVF Surgical Procedure does not alter the biological
16 characteristics of the SVF Cells and those cells remain “such HCT/P” that were
17 removed from the patient. There is no evidence that the cells are anything other
18 than autologous cells removed from, belonging to, and returned back to the patient.

19 13. Drs. Berman and Lander specifically studied the effect of Liberase on
20 the SVF Cells, found that they have not been altered in any substantive way to
21 change them from their naturally occurring state (*i.e.*, they have the same DNA,
22 same cell type, same flow cytometry markers). (5/12/21 PM Tr. 88:18-89:8
23 (Lander)). The GMP-grade Liberase does not affect ability of the SVF Cells to
24 differentiate, the cell surface marker expression was similar, and cell viability was
25 not significantly different.

26

27

28

⁷ Even the Eleventh Circuit found it was a mistake for the FDA to conflate the SSP Exception and the minimal manipulation exception. *US Stem Cell Clinic*, 2021 WL 2213288 at *7 n.2.

1 14. Dr. Lola Reid testified that, based on her more than forty-five years of
2 experience studying stem cells, the Liberase used to separate the SVF Cells does
3 not break down, damage, or in any way alter the phenotypic traits and biological
4 properties of the SVF Cells. The Liberase, as used in the SVF Surgical Procedure,
5 has no impact on the viability of the SVF Cells, yield of cells, and, most
6 significantly, has no effect on the phenotype (identifying cell markers), the ability
7 of the cells to differentiate, to proliferate, or to function in their intended capacity.

8 15. Dr. Reid testified that the Liberase does not penetrate the stem cells or
9 destroy the surface of the stem cells, it solely enzymatically digests the
10 extracellular matrix.

11 16. Dr. Reid further testified that the SVF Cells are not altered at any
12 point during the SVF Surgical Procedure. The SVF Cells are not chemically
13 altered. There are no genes added to or removed from the SVF Cells. The genetic
14 makeup of the cells do not change.

15 17. Finally, Dr. Reid testified that the biological and functional
16 characteristics of the SVF Cells do not change, including ability to proliferate.
17 The re-implanted SVF Cells retain all their functional abilities, such as
18 regenerative tissue repair and healing and anti-inflammatory properties.

19 18. The Government did not take samples of or test the SVF Cells or
20 Liberase, despite the ability to do so. The Government did not present any
21 evidence regarding the effect of Liberase on SVF Cells. As such, any Government
22 claim regarding the effect of Liberase or the SVF Cells lacks foundation and
23 credibility.

24 19. The Court finds that Dr. Berman and Dr. Lander are well qualified to
25 opine and testify on the practice of medicine, development of surgical procedures,
26 the SVF Surgical Procedure, and the effect of Liberase on the SVF Cells. The
27 Court finds Defendants' evidence and testimony more credible than Dr. Yong
28 given her failure to analyze the appropriate enzyme, and particularly, her testimony

1 that she did not know which enzyme Drs. Berman and Lander use. Further,
2 Defendants have actually tested the product at issue (as published in a peer-
3 reviewed journal), while the Government has never collected a sample or tested the
4 SVF Cells or Liberase despite the ability to do so.

5 20. In conclusion, the SSP Exception applies to the SVF Surgical
6 Procedure and is a complete defense to Claims One and Two.⁸

7 21. Because the SSP Exception applies to the SVF Surgical Procedure,
8 Defendants do not fall under FDA jurisdiction, are not governed by the FDCA or
9 associated regulations; therefore, the Government is not entitled to injunctive relief
10 against Defendants.

11 1. The FDA's Interpretation Of The SSP Exception Is Not Entitled
12 To Deference Because The Exception Is Unambiguous

13 22. The SSP Exception is unambiguous, thus there is no need for
14 deference to the FDA's interpretation. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2414
15 (2019) (“[T]he possibility of deference can arise only if a regulation is genuinely
16 ambiguous.”); *Christensen v. Harris Cnty.*, 529 US 576, 588 (2000) (“The
17 regulation in this case, however, is not ambiguous To defer to the agency's
18 position would be to permit the agency, under the guise of interpreting a
19 regulation, to create *de facto* a new regulation.”).

20 23. Here, the FDA, under the guise of interpretation, is attempting to
21 substantively change, and thereby create, a new regulation that the HCT/Ps must
22 remain in their “original form.” This language does not appear anywhere in the
23

24 ⁸ The Government completely ignores 21 C.F.R. part 1271, which states that
25 biological drugs are governed by Current Good Tissue Manufacturing Practice
26 (cGTMP) and not the general Current Good Manufacturing Practice (cGMP)
27 regulations. *See* 21 C.F.R. § 1271.20 (“If my HCT/P's do not meet the criteria in
28 1271.10, and I do not qualify for any of the exceptions in 1271.15, what
regulations apply?”). The Government provided no evidence of failure to comply
with cGTMP but focused entirely on the broader and inapplicable cGMP
regulations.

1 SSP Exception. The Supreme Court has repeatedly rebuked such efforts. *See Azar*
2 *v. Allina Health Serv.*, 139 S. Ct. 1804, 1810-11 (2019) (requiring substantive
3 regulatory changes to comply with APA notice and comment requirements and
4 requirements to meet with stakeholders). The adoption of the 2017 Guidance is
5 not a valid modification of the existing regulation because it was not subject to a
6 proper notice and comment period and was not signed by a United States Senate-
7 confirmed officer.

8 24. HCT/Ps are defined as “articles containing or consisting of human
9 cells or tissues that are intended for implantation, transplantation, infusion, or
10 transfer into a human recipient.” 21 C.F.R. § 1271.15(b). The regulation is not
11 ambiguous. Under the explicit terms of the regulations, the SVF Surgical
12 Procedure falls within the exception because the SVF Cells are removed and
13 implanted in the same surgical procedure. The FDA’s recent interpretation that
14 seeks to create ambiguity is not entitled to deference.

15 2. The FDA’s Interpretation Of The SSP Exception Is
16 Unreasonable

17 25. The FDA’s interpretation of the SSP Exception is unreasonable and
18 creates enforcement inconsistency: it makes no logical sense to assert that the SSP
19 Exception applies to a procedure where physical cutting is necessary to isolate
20 needed tissue but not where chemical “cutting” is necessary to isolate needed
21 cells—especially given the use of both “cells” and “tissue” in the SSP Exception.
22 *See Kisor*, 139 S. Ct. at 2415–16 (“[T]he agency’s reading must fall within the
23 bounds of reasonable interpretation . . . a requirement an agency can fail.”).

24 26. A characterization that focuses on the target of the removal is more
25 reasonable than one that includes everything that was removed. Undoubtedly,
26 most if not all surgical removals take out more biological matter than what was
27 targeted. Take, for example, the removal of an artery for implantation back in the
28 body. *See* U.S. Dep’t Health & Human Services, Food & Drug Admin., *Same*

1 *Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers*
2 *Regarding the Scope of the Exception* (Nov. 2017) (“SSP Exception Guidance
3 Document”) (“Examples [of procedures considered same surgical procedures]
4 include autologous skin grafting, and coronary artery bypass surgery involving
5 autologous vein or artery grafting.”). Along with the needed artery, a surgeon may
6 remove some blood. She may also remove more artery tissue than what will
7 ultimately be needed. Similarly, surgeons isolate autologous fat from around the
8 patient’s umbilical area, crush that fat with a “Spence Cranioplastic roller” to
9 transform it into a thin foil on a separate table in the operating room, and return
10 that “foil” to the patient during the same procedure to repair, not cushion the
11 brain’s lining. If a piece of muscle and its overlying fascia (connective tissue)
12 were removed in order to provide a fascial graft to repair large tissue defects, the
13 muscle (tissue) would no longer have its ability to repair, reconstruct or replace,
14 but the “tissue product” (*i.e.* the fascia) would still retain its biological
15 characteristics and could be utilized. But again, the surgeon is not required to
16 implant everything that was removed.

17 27. The SSP Exception does not require that the surgeon implant
18 everything that was removed—including the removed blood and excess artery—for
19 it to apply. The SSP Exception Guidance expressly recognizes that processing
20 steps such as “rinsing [and] cleansing” or “sizing and shaping,” including
21 “dilation,” “cutting,” “meshing,” of HCT/Ps do not take a procedure out of the SSP
22 Exception. *See Food & Drug Admin., Regulatory Considerations.*

23 28. The logic that not all that is removed must be implanted applies to the
24 SVF Surgical Procedure as well. The SSP Exception undoubtedly applies to a
25 procedure that removed only SVF Cells and then implanted only those same SVF
26 Cells back into the patient. But that technology did not and still does not yet exist.
27 Accordingly, Drs. Berman and Lander must remove SVF Cells as part of a larger
28 biological system. And like the surgeon who washes the blood from the artery and

1 cuts it down to the right size, Drs. Berman and Lander use an enzyme and a
2 centrifuge to isolate the targeted HCT/Ps from the unneeded biological material
3 that was also removed.

4 29. The FDA’s unreasonable interpretation is not entitled to deference.

5 3. The FDA’s Interpretation Should Not Be Considered Because It
6 Constitutes Unfair Surprise

7 30. The FDA’s interpretation of “such HCT/Ps” under the 2017 Guidance
8 pronounces an entirely new position regarding the applicability of the SSP
9 Exception, and directly contradicts twenty years of FDA pronouncements on the
10 issue, resulting in “unfair surprise” to Drs. Berman and Lander and others
11 providing autologous SVF surgical therapies. *See Kisor*, 139 S. Ct. at 2418 (“And
12 a court may not defer to a new interpretation, whether or not introduced in
13 litigation, that creates ‘unfair surprise’ to regulated parties.”); 21 C.F.R. §
14 1271.15(b) (2001) (adopting regulatory scheme initially proposed in 1997).

15 31. Further, the FDA informed the public, including Drs. Berman and
16 Lander, that they would have a three-year grace period (until December 2020) to
17 determine how best to regulate procedures involving HCT/Ps. *See Food & Drug*
18 *Admin., Regulatory Considerations* at 21. The FDA did not wait for that three-
19 year period to end for Drs. Berman and Lander, even though Drs. Berman and
20 Lander are one of the few organizations that had actually been working with the
21 FDA on an Investigational Device Exemption (Ex. 323) through the Center for
22 Biological Evaluation and Research for the overarching surgical system, as each
23 individual medical device was already FDA-cleared.

24 32. The FDA’s interpretation constitutes unfair surprise and is not entitled
25 to deference.

1 **B. Even If The SSP Exception Did Not Apply, The SVF Surgical**
2 **Procedure Is Not A Drug And Is Not Introduced Into Interstate**
3 **Commerce**

4 1. The FDA Lacks Authority To Regulate Physicians Performing
5 Surgery, Instead This Is Exclusively Within A State’s
6 Jurisdiction

7 33. Pursuant to the FDCA, the FDA has the authority to regulate drugs
8 introduced into interstate commerce (21 U.S.C. § 321), and pursuant to the Public
9 Health Service Act (42 U.S.C. § 201), the authority to regulate biological products
10 introduced into interstate commerce. “Drugs” are defined as “articles intended for
11 use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.”
12 However, this definition is irrelevant to the Court’s analysis because a surgical
13 procedure is also intended for the “diagnosis, cure, mitigation, treatment, or
14 prevention of disease in man.”

15 34. Congress explicitly rejected any attempt to “limit or interfere with the
16 authority of a health care practitioner to prescribe or administer any legally
17 marketed device to a patient for any condition or disease within a legitimate health
18 care practitioner-patient relationship.” 21 U.S.C. § 396. Indeed, Congress
19 recognized the limitations of the FDA and rejected “any intent to directly regulate
20 the practice of medicine.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341,
21 351 n.5 (2001) (citing Beck & Azari, FDA, Off-Label Use, and Informed Consent:
22 Debunking Myths and Misconceptions, 53 Food & Drug L.J. 71, 72 (1998) (stating
23 that “[o]ff-label use is widespread in the medical community and often is essential
24 to giving patients optimal medical care, both of which medical ethics, FDA, and
25 most courts recognize”)); *U.S. ex rel. Modglin v. DJO Glob. Inc.*, 114 F. Supp. 3d
26 993, 999 (C.D. Cal. 2015), *aff’d sub nom. United States v. DJO Glob., Inc.*, 678 F.
27 App’x 594 (9th Cir. 2017).

1 35. Drs. Berman and Lander are physicians, practicing medicine and
2 performing surgery using FDA-cleared medical devices and FDA-approved
3 prescription pharmaceuticals through their medical practices California Stem Cell
4 Treatment Center (“CSCTC”) and CSN. Title 21 of the United States Code section
5 360 exempts “practitioners licensed by law to prescribe or administer drugs or
6 devices and who manufacture, prepare, propagate, compound, or process drugs or
7 devices solely for use in the course of their professional practice” from registering
8 with the FDA. Section 360 recognizes that the FDA does not have authority over a
9 licensed physician practicing medicine entirely within the State of California using
10 FDA-approved and FDA-cleared pharmaceuticals and devices. The FDA cannot
11 modify this law via regulation, particularly not in a manner that violates notice and
12 comment procedure and the Appointments Clause (U.S. Const. Article II, § 2, cl.
13 2). And, as courts have recognized, the FDA generally does not regulate doctors—
14 particularly those using office-based drugs or biologicals for the sole use of their
15 patients. *Buckman*, 531 U.S. at 350; *see also Houston v. Medtronic, Inc.*, No. 2:13-
16 cv-01679-SVW (SHx), 2014 WL 1364455, *1 n.1 (C.D. Cal. April 2, 2014)
17 (“Physicians are permitted to use Class III devices in off-label manners”); *U.S., ex*
18 *rel. Modglin*, 114 F. Supp. 3d at 999; *Amarin Pharma, Inc. v. FDA*, 119 F. Supp.
19 3d 196, 200 (S.D.N.Y. 2015). Thus, at a minimum, Drs. Berman and Lander’s
20 actions are exempt from regulation and/or protected by statute as lawful “off-label”
21 uses of FDA-approved drugs and medical devices.

22 36. Indeed, allowing the FDA to expand its regulatory authority to
23 encompass Drs. Berman and Lander’s surgical procedures would allow the FDA to
24 regulate not only an individual’s private relationship with her physician, but also
25 the individual’s use of her body and medical decisions. *See Roe v. Wade*, 410 U.S.
26 113 (1973). These activities implicate fundamental rights of privacy and bodily
27 autonomy. *See Griswold v. Connecticut*, 381 U.S. 479, 485 (1965). Thus, to hold
28 that the FDA can regulate the SVF Surgical Procedure as if the SVF Cells were a

1 saleable commodity ignores the fundamental and constitutional differences
2 between drugs and an individual’s right to control her body and the cells that
3 comprise it.

4 37. Drs. Berman and Lander can use FDA-cleared medical devices and
5 FDA-approved pharmaceuticals in any manner that they determine is best to care
6 for and treat their patients. While SVF Cells are not a drug for the reasons stated
7 above, and even if they were, each step of the SVF Surgical Procedure uses FDA-
8 cleared and/or approved medical devices and pharmaceuticals. *See* 21 U.S.C.
9 § 396.

10 38. Drs. Berman and Lander are practicing medicine, not creating
11 pharmaceuticals.

12 2. The Government Has No Authority Over Defendants Because
13 The SVF Surgical Procedure Does Not Involve The Sale Of
14 Cells And Does Not Implicate Interstate Commerce

15 39. The SVF Cells used in each procedure are not fungible goods and
16 cannot be sold or patented—Defendants do not sell the SVF Cells. *See Ass’n for*
17 *Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 579 (2013) (holding
18 that naturally-occurring human body parts that are a “product of nature and not
19 patent eligible merely because it has been isolated.”). As the cells cannot be
20 patented, the cells cannot be owned by anyone other than the patient from whom
21 they were removed, nor could they be “sold back” to the patient.

22 40. Finally, the uniqueness of the SVF Cells used in each surgical
23 procedure present further constitutional implications. The Government is seeking
24 to regulate not only an individual’s private relationship with her physician, but also
25 the individual’s use of her body and medical decisions. These are not a “class of
26 activities’ that have a substantial effect on interstate commerce.” *Gonzales v.*
27 *Raich*, 545 U.S. 1, 17 (2005). Rather, these are activities that implicate
28 fundamental rights of privacy and bodily autonomy. *See Griswold*, 381 U.S. at

1 485. This Court rejects the Government’s invitation to regulate the SVF Surgical
2 Procedure and its related procedures as if the SVF Cells were any other
3 commodity, which ignores the fundamental and constitutional difference between
4 drugs shipped in interstate commerce and an individual’s right to control his/her
5 own body and the cells therein.

6 41. Indisputably, the SVF Cells are not shipped or introduced into in
7 interstate commerce because the entire procedure takes place in California.

8 42. This Court rejects the Government’s attempt to extend federal
9 regulations to an article that does not affect interstate commerce, as required by the
10 Commerce Clause, U.S. Const. art. I, § 8, cl. 3, and that is not introduced or
11 shipped in interstate commerce, as defined by the FDCA, 21 U.S.C. § 321(b).

12 43. Because the SVF Cells are not shipped or sold in interstate commerce,
13 the Government’s claims against Defendants not only exceed the scope of the
14 Commerce Clause, but they also exceed the FDA’s statutory authority.⁹ *See 62*
15 *Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S.
16 593, 600 (1951) (“In our anxiety to effectuate the congressional purpose of
17 protecting the public, we must take care not to extend the scope of the statute
18 beyond the point where Congress indicated it would stop.”); *see Panama Ref. Co.*
19 *v. Ryan*, 293 U.S. 388, 430 (1935) (“[T]here are limits of delegation which there is
20 no constitutional authority to transcend.”). Section 331(k) prohibits “any . . . act
21 with respect to a food, drug, device, tobacco product, or cosmetic, if such act is
22 done while such article is held for sale (whether or not the first sale) **after**
23 **shipment in interstate commerce** and results in such article being adulterated or
24 _____

25 ⁹ Each of the FDA Investigators recognized this constitutional and statutory
26 limitation on FDA authority: the mere use during surgery of a product that traveled
27 through interstate commerce is not sufficient to create FDA jurisdiction.
28 Accordingly, the use of common surgical crystalloid fluids, including saline and
dextrose lactated ringers solution, during the SVF Surgical Procedure does not give
rise to FDA jurisdiction. (5/5/21 AM Tr. 11:25-12:8 (Lagud); 5/5/21 PM Tr.
24:11-15 (Forster); 5/5/21 PM Tr. 53:18-24 (Christopher); 5/11/21 AM Tr. 47:14-
19 (Jim)).

1 misbranded.” 21 U.S.C. § 331(k) (emphasis added). The FDCA defines
2 “interstate commerce,” as “(1) commerce between any State or Territory and any
3 place outside thereof, and (2) commerce within the District of Columbia or within
4 any other Territory not organized with a legislative body.” 21 U.S.C. § 321(b).
5 Because the article must be *introduced or shipped* in interstate commerce, rather
6 than merely affect interstate commerce, the scope of the FDCA does not reach the
7 full extent of the Commerce Clause.

8 **C. There Is No Adulteration Because Defendants Meet All California**
9 **Regulations Governing Surgical Facilities**

10 1. California Law Governs The Safety Of Surgical Facilities

11 44. Drs. Berman and Lander have continually complied with California
12 law governing their medical practices. California law provides that “[n]o
13 association, corporation, firm, partnership, or person shall operate, manage,
14 conduct, or maintain an outpatient setting in this state, unless the setting is []: . . .
15 [a]n outpatient setting accredited by an accreditation agency approved by the
16 division pursuant to this chapter.” Cal. Health & Safety Code § 1248.1(g).
17 Further, the Medical Board of California has set standards for accreditation, which
18 each accreditation agency must adopt to ensure the health and safety of outpatient
19 procedures. *Id.* at § 1248.15(a). These requirements relate to (1) proper licensing
20 of health staff, (2) facility safety and emergency training requirements,
21 (3) maintenance of clinical records, (4) a system for patient care and monitoring
22 procedures, and (5) quality assessment and improvement. *Id.* The accreditation
23 agency must inspect the facility as often as necessary and no less often than once
24 every three years. *Id.* at § 1248.35.

25 45. Defendants have complied with California law governing health and
26 safety requirements of medical facilities. Defendants met all requirements
27 governing patient rights and responsibilities; governance; administration; quality of
28 care; quality management and improvement; maintenance of clinical records and

1 health information; infection prevention, control, and safety; general safety;
2 facilities and environment, anesthesia services; surgical and related services; and
3 pharmaceutical services.

4 46. The FDA introduced no evidence that Defendants do not comply with
5 California law governing medical facilities.

6 2. The SVF Surgical Procedure Does Not Manufacture Drugs

7 47. Unlike traditionally manufactured pharmaceutical drugs, SVF Cells—
8 like the BRCA1 and BRCA2 genes at issue in *Ass’n for Molecular Pathology*, 569
9 U.S. 576—cannot be patented because they are naturally occurring human body
10 parts that are a “product of nature and not patent eligible merely because it has
11 been isolated.” *Id.* at 579. Thus, applying a regulatory regime crafted to oversee
12 the pharmaceutical drug industry to naturally occurring autologous stem cells
13 simply makes no practical sense; especially where the SVF Cells are the sole
14 property of the patient and could never be sold.

15 48. Defendants perform the SVF Surgical Procedure for the benefit of
16 their patients; therefore, they are not drug manufacturers and fall outside of the
17 purview of the FDA. *See* 21 U.S.C. §§ 360, 396.

18 **D. There Is No Misbranding Because Each Procedure Is Completed**
19 **By A Trained Physician And Defendants Provide Adequate**
20 **Directions For Use**

21 49. Labels on prescription drugs and devices provide the physician, a
22 learned intermediary, with all of the information that the physician needs to make
23 an informed decision regarding course of conduct. *See, e.g., T.H. v. Novartis*
24 *Pharm. Corp.*, 4 Cal. 5th 145, 164 (2017) (“In the context of prescription drugs, a
25 manufacturer’s duty is to warn physicians about the risks known or reasonably
26 known to the manufacturer If the manufacturer provides an adequate warning
27 to the prescribing physician, the manufacturer need not communicate a warning
28 directly to the patient who uses the drug.”); *Motus v. Pfizer Inc.*, 196 F. Supp. 2d

1 984, 990-91 (C.D. Cal. 2001) *aff'd sub nom.* 358 F.3d 659 (9th Cir. 2004)
2 (“California follows the learned intermediary doctrine”).

3 50. Defendants provide surgical manuals, user manuals, and the detailed
4 IRB-approved deployment protocols with the CSN-Time Machine® centrifuge and
5 CSN-Time Machine® incubator. *See* 21 U.S.C. § 321(m) (defining “labeling” as
6 any material accompanying a drug or device). Additionally, physicians can request
7 additional information regarding how to perform the SVF Surgical Procedure or
8 Expanded MSC Surgical Procedure including attending a demonstration of the
9 entire procedure. These manuals and instructions provide physicians with all
10 information that she needs to make an informed decision regarding course of
11 conduct for her patient.

12 51. The information contained within the surgical manuals, user manuals,
13 and deployment protocols are based upon clinical proof as shown by the numerous
14 articles demonstrating both effectiveness and safety of the SVF Surgical
15 Procedure.

16 52. Defendants’ clinical studies have continuously operated under an IRB
17 protocol and review. *Contra United States v. Cole*, 84 F. Supp. 3d 1159, 1169 (D.
18 Or. 2015) (granting summary judgment where the defendants “conducted no
19 controlled studies and collected no clinical data”). The IRB is independent from
20 Drs. Lander and Berman, and they do not and have never served in any capacity on
21 the ICSS IRB.

22 53. Additionally, the Government’s allegation that there should be an
23 “Rx” symbol is irrational. The procedures do not require any prescription labeling
24 because they are surgical procedures. The SVF Cells are not placed in any
25 container for preservation, storage, or later use. The SVF Cells are transferred
26 between sterile syringes during three washing phases. After the third washing
27 phase, the SVF Cells are placed in syringes labeled with the patient’s name, date,
28 and the description “SVF” pursuant to well-defined patient identifier protocols.

1 Immediately thereafter, the SVF Cells are re-implanted in the patient through
2 direct injection or intravenously.

3 **II. CLAIMS THREE, FOUR, AND FIVE: THE GOVERNMENT FAILED**
4 **TO SHOW THAT DEFENDANTS MANUFACTURE A DRUG OR**
5 **THAT DEFENDANTS RECEIVE A MISBRANDED DRUG**

6 54. For Claim Three, the Government must prove: (1) that the Expanded
7 MSC Surgical Procedure involves a drug, (2) that the Expanded MSC Surgical
8 Procedure involves a drug that is held for sale in interstate commerce; and (3) that
9 the methods used in, or the facilities or controls used for, the manufacture of the
10 drug are not in conformity with current Good Manufacturing Practices (“cGMP”).
11 21 U.S.C. §§ 331(k), 352(a)(2)(B).

12 55. For Claim Four, the Government must prove: (1) that the Expanded
13 MSC Surgical Procedure involves a drug, (2) that the Expanded MSC Surgical
14 Procedure involves a drug that is held for sale in interstate commerce; and (3) that
15 it does not contain adequate directions for use of the symbol “Rx.” 21 U.S.C. §§
16 352(f), 352(b)(2).

17 56. For Claim Five, the Government must prove: (1) that the Expanded
18 MSC Surgical Procedure involves a drug, (2) that the Expanded MSC Surgical
19 Procedure involves a drug that is held for sale in interstate commerce; and
20 (3) Defendants received a misbranded drug for pay or otherwise.

21 57. First, the Government failed to carry its burden that Defendants do
22 any processing that would be considered adulteration. Second, the Government
23 failed to carry its burden that Defendants misbranded any product or that the
24 labeling received was inadequate. Third, there is no interstate commerce because
25 the patient does not pay for Expanded MSC Cells but only for the Expanded MSC
26 Surgical Procedure.

1 A. **The Government Failed To Carry Its Burden That Defendants**
2 **Process Or Manufacture Expanded MSC Cells**

3 58. The Government must concede that Defendants do not process the
4 adipose tissue as part of the Expanded MSC Surgical Procedure. During
5 Drs. Berman and Lander’s Expanded MSC Surgical Procedure, a qualified
6 candidate undergoes liposuction at either Dr. Berman or Dr. Lander’s medical
7 facilities. There can be no doubt that this is the practice of medicine. Indeed, an
8 FDA Investigator admitted that any conduct relating to Defendants sending
9 adipose tissue to ACS (a third party tissue bank) was outside of the scope of the
10 investigation.

11 59. Drs. Berman and Lander do not perform the remainder of the
12 SVF Surgical Procedure on the harvested adipose tissue but send the tissue to a
13 GMP-compliant third party in a sterile transport container.

14 60. The evidence established that Defendants always intended to, and the
15 Expanded MSC Cells are currently, isolated in an FDA-registered, GMP-compliant
16 tissue bank.

17 61. Drs. Berman and Lander currently use a tissue bank in Florida, which
18 is registered with the FDA, has undergone GMP compliance inspections, and has
19 not received any Form 483 Observations, meaning that the FDA has found the
20 tissue bank to be GMP-compliant.

21 62. The Government failed to establish any adulteration of the Expanded
22 MSC Cells by Defendants. Instead, each of the Government Investigators
23 confirmed that there was no evidence that the Expanded MSC Cells were
24 adulterated.

25 63. As a matter of law, the Government cannot prove that Defendants are
26 manufacturing, much less adulterating the Expanded MSC Cells, thus there is no
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1 FDA jurisdiction. (See 5/5/21 PM Tr. 19:6-15 (Forster, admitting no jurisdiction if
2 no manufacturing occurring); *id.* at 57:23-59:7 (Christopher, same)).¹⁰

3 **B. The Government Failed To Carry Its Burden That Defendants**
4 **Misbrand Expanded MSC Cells**

5 64. Again, the Government concedes that Defendants do not label the
6 Expanded MSC Cells—a third party tissue bank does. Drs. Berman and Lander
7 solely perform the liposuction surgical procedure, then ship the adipose to the third
8 party GMP facility in a sterile transport container. No labeling of Expanded MSC
9 Cells occurs in Defendants’ medical facilities.

10 65. The Government failed to establish any misbranding of the Expanded
11 MSC Cells by Defendants. Instead, the evidence showed that Defendants sent the
12 adipose tissue to the third-party facility for further processing and labeling.

13 66. As a matter of law, the Government cannot prove that Defendants
14 misbranded the Expanded MSC Cells because Defendants did not create any such
15 labels.

16 **C. The Government Failed to Carry Its Burden That Defendants**
17 **Received Misbranded Expanded MSC Cells, Regardless 21 U.S.C.**
18 **§ 360 Permits Receipt Of Propagated Products**

19 1. **The Government Failed To Provide Any Evidence Of The**
20 **Labeling Received From The Third Party Tissue Banks**

21 67. The Government did not introduce any evidence regarding the
22 labeling associated with the Expanded MSC Cells received from the GMP third
23 party. Nor did the Government introduce any evidence regarding the current
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27 ¹⁰ *United States v. Regenerative Scis., LLC*, 741 F.3d 1314 (D.C. Cir. 2014), is not
28 applicable because the Government sued the facility where the MSC Cells were
isolated and expanded. Here, the Government did not sue ACS; therefore, the
purported manufacturer is not a party to this litigation. Defendants cannot be
enjoined for the actions of a non-party.

1 labeling. Any argument that the Expanded MSC Cells were misbranded is entirely
2 speculative.

3 68. The FDA Investigators did not collect samples of the labeling. The
4 FDA Investigator admitted that the receipt of materials from ACS was within her
5 investigation, and she did not find any deviations in GMP (which includes labeling
6 requirement (*see* 21 C.F.R. § 1271.250). (5/5/21 PM Tr. 37:4-19 (Forster)). There
7 is no evidence regarding the labeling accompanying any Expanded MSC Cells
8 upon receipt by Defendants.

9 69. The Government argues that because of the nature of the Expanded
10 MSC Cells, there is no labeling that would be sufficient for physicians to make an
11 informed decision. However, given the FDA's recent IND approval of ACS's
12 Expanded MSC Cells, the ATCell™ Product, which would have considered safety
13 data and proposed protocols relating to appropriate use, the FDA must have
14 determined that the safety data and protocols support proceeding to human use.
15 (5/7/21 AM Tr. 41:10-42:10 (Lapteva)).

16 2. Defendants Are Permitted To Use Any Propagated Product For
17 The Care Of Their Patients

18 70. When Defendants receive the Expanded MSC Cells from the GMP
19 tissue bank, Defendants may use those cells in connection with the treatment and
20 care of their patients without separately having to register with the FDA. *See* 21
21 U.S.C. § 360.

22 71. Each of the tissue banks that Defendants have used or currently use
23 are registered with the FDA. Defendants are expressly exempted from registering
24 with the FDA if they are manufacturing, preparing, propagating, compounding, or
25 processing drugs solely for the use of their patients. 21 U.S.C. § 360. It is
26 undisputed that Defendants receive Expanded MSC Cells solely for the use of their
27 patients and the Government has not provided any evidence to demonstrate
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1 otherwise. Accordingly, Defendant do not need to independently register with the
2 FDA or otherwise comply with FDA regulations to receive propagated products.

3 72. Further, because there is an existing IND for ACS’s Expanded MSC
4 Cells, Drs. Berman and Lander are permitted to use Expanded MSC Cells for the
5 care and treatment of their patients without falling under FDA jurisdiction. *See* 21
6 U.S.C. §§ 360, 396. Defendants are permitted to use the FDA-approved IND
7 protocols in an off-label purpose to care for their patients. *See* 21 U.S.C. § 396;
8 *see also Houston*, 2014 WL 1364455, *1 n.1; Right to Try Act of 2017, Pub. L.
9 No. 115-176 (codified at 21 U.S.C. § 360-bbb-0a).

10 73. The Government has not established that Defendants receive a
11 misbranded drug. Regardless, Congress has expressly exempted Defendants, as
12 physicians, from FDA statutes and regulations regarding receipt of propagated
13 products.

14 **D. The Expanded MSC Cells Are Not Sold In Interstate Commerce**

15 74. The patients are not paying for Expanded MSC Cells (nor could they
16 pay for their own cells) but are instead paying Drs. Berman and Lander for the
17 surgical procedure, including a mini liposuction. Further, there is no interstate
18 commerce as the Expanded MSC Cells are not fungible goods and cannot be
19 patented or sold. *See Ass’n for Molecular Pathology*, 569 U.S. at 579 (holding that
20 naturally-occurring human body parts that are a “product of nature and not patent
21 eligible merely because it has been isolated.”); *Gonzales*, 545 U.S. at 17 (2005).

22 75. Again, the Expanded MSC Surgical Procedure is a personal decision
23 between a physician and her patient. The Government is overreaching and seeking
24 to implicate fundamental rights of privacy and bodily autonomy by controlling a
25 patient’s access to medical care. *See Griswold*, 381 U.S. at 485. This is well
26 beyond the FDA’s authority.

1 **III. CLAIMS SIX AND SEVEN: THE GOVERNMENT LACKS**
2 **STANDING TO ENJOIN THE SVF/ACAM2000 SURGICAL**
3 **PROCEDURE, AND IT CONSTITUTES PERMISSIBLE OFF-LABEL**
4 **USE**

5 76. For Claim Six, the Government must prove: that (1) the
6 SVF/ACAM2000 Surgical Procedure involves a drug, (2) the SVF/ACAM2000
7 Surgical Procedure involves a drug that is held for sale in interstate commerce; and
8 (3) the methods used in, or the facilities or controls used for, the manufacture of
9 the drug are not in conformity with current Good Manufacturing Practices
10 (“cGMP”). 21 U.S.C. §§ 331(k), 352(a)(2)(B).

11 77. For Claim Seven, the Government must prove: (1) that the
12 SVF/ACAM2000 Surgical Procedure involves a drug, (2) that the
13 SVF/ACAM2000 Surgical Procedure involves a drug that is held for sale in
14 interstate commerce; and (3) that it does not contain adequate directions for use of
15 the symbol “Rx.” 21 U.S.C. §§ 352(f), 352(b)(2).

16 78. The Government fails to prove that it has standing for injunctive
17 relief.

18 79. Additionally and alternatively, Defendants used an FDA-approved
19 medication in a permissible off-label manner as part of a clinical research study.
20 The patients did not pay for any of the treatment and it was never available to the
21 general public.

22 1. **The Government Lacks Standing To Seek Injunctive Relief For**
23 **The SVF/ACAM2000 Surgical Procedure**

24 80. Article III standing requires a present case or controversy, and it is
25 well-settled that “[p]ast exposure to illegal conduct does not in itself show a
26 present case or controversy regarding injunctive relief” *Lujan v. Defenders of*
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1 *Wildlife*, 504 US 555, 564 (1992).¹¹ The Ninth Circuit has explained that to satisfy
2 the standing requirements under *Lujan*, a plaintiff seeking prospective injunctive
3 relief “must demonstrate that he has suffered or is threatened with a concrete and
4 particularized legal harm, coupled with a sufficient likelihood that he will again be
5 wronged in a similar way.” *Bates v. United Parcel Serv., Inc.*, 511 F.3d 974, 985
6 (9th Cir. 2007) (citations and quotations omitted); *see also Chapman v. Pier 1*
7 *Imports (U.S.) Inc.*, 631 F.3d 939, 946 (9th Cir. 2007) (en banc) (citations and
8 quotations omitted) (holding a plaintiff “must demonstrate a real and immediate
9 threat of repeated injury in the future” for Article III injunctive relief standing).
10 The party asserting the claim has the burden of establishing these elements.
11 *Chandler v. State Farm Mut. Auto. Ins. Co.*, 598 F.3d 1115, 1122 (9th Cir. 2010).
12 A plaintiff must demonstrate standing separately for each form of relief sought.
13 *Los Angeles v. Lyons*, 461 U.S. 95, 109 (1983) (notwithstanding the fact that
14 plaintiff had standing to pursue damages, he lacked standing to pursue injunctive
15 relief).

16 81. The Government has not met its burden of establishing standing to
17 pursue injunctive relief regarding the SVF/ACAM2000 Surgical Procedure
18 because Drs. Berman and Lander stopped performing the procedure by June 2017,
19 well before the initiation of this lawsuit and before the seizure of the ACAM2000.

20 82. Defendants cannot perform the SVF/ACAM2000 Surgical Procedure
21 without the ACAM2000, which is in the exclusive control of the Government and
22 otherwise inaccessible to Defendants.

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25 ¹¹ Defendants acknowledge that the Government has Article III standing under
26 *Lujan* and does not need to establish the general requirements for standing to bring
27 an action. *See Consumer Fin. Protection Bureau v. Gordon*, 819 F.3d 1179, 1187.
28 However, the Government is still required to make a showing that it has standing
to pursue injunctive relief, *i.e.*, that there is a showing that the defendants’ conduct
is likely to recur. *Id.* at 1197-98.

1 83. The Government has no evidence of Drs. Berman and Lander’s
2 medical practices or SVF/ACAM2000 Surgical Procedure since July 2017.

3 84. Drs. Berman and Lander have no desire or intention of performing the
4 SVF/ACAM2000 Surgical Procedure absent formal regulatory approval or
5 confirmation that the SVF/ACAM2000 Surgical Procedure is not governed by the
6 FDCA, but rather is the practice of medicine.

7 2. Defendants Are Permitted To Compound Products For The
8 Care Of Their Patients

9 85. Defendants are expressly exempted from registering with the FDA if
10 they are compounding, *i.e.*, combining, solely for the use of their patients. 21
11 U.S.C. § 360. Here, it is undisputed that ACAM2000 is an FDA-approved
12 vaccine. Defendants are permitted to compound ACAM2000 with the patient’s
13 SVF Cells as a matter of law.

14 86. Drs. Berman and Lander exclusively used the SVF/ACAM2000
15 Surgical Procedure for the benefit of their patients; therefore, they are not drug
16 manufacturers and fall outside of the purview of the FDA. *See* 21 U.S.C. § 360.

17 87. Drs. Berman and Lander used ACAM2000 for an off-label purpose,
18 which is explicitly permitted under the FDCA. 21 U.S.C. § 396. Physicians may
19 utilize any FDA-approved drug for an off-label purpose that they determine is the
20 best course of treatment for their patients. *Houston*, 2014 WL 1364455, *1 n.1
21 *Modglin*, 114 F. Supp. 3d at 999. Thus, Drs. Berman and Lander’s actions were
22 protected as lawful “off-label” uses of FDA-approved drugs and medical devices.

23 3. The SVF/ACAM2000 Surgical Procedure Was Not Sold In
24 Interstate Commerce And Did Not Travel Through Interstate
25 Commerce

26 88. First, the study participants did not pay for the SVF/ACAM2000
27 Surgical Procedure. Second, the compounded SVF/ACAM2000 Cells were not
28 held for sale after shipment in interstate commerce and the isolation of the SVF

1 Cells and combination with ACAM2000 all occurred within California. *See* 21
2 U.S.C. § 331(k) (prohibiting act “*after shipment in interstate commerce*[, which]
3 results in such article being adulterated or misbranded” (emphasis added)).

4 89. There was no interstate commerce as the SVF/ACAM2000 Cells were
5 not fungible goods and could not be patented or sold. *See Ass’n for Molecular*
6 *Pathology*, 569 U.S. at 579 (holding that naturally-occurring human body parts that
7 are a “product of nature and not patent eligible merely because it has been
8 isolated.”); *Gonzales*, 545 U.S. at 17.

9 90. Again, the Expanded SVF/ACAM2000 Surgical Procedure was a
10 personal decision between a physician and her patient and is protected from
11 Government overreach into bodily autonomy. *See Griswold*, 381 U.S. at 485.
12 This is well beyond the FDA’s authority.

13 **IV. THE GOVERNMENT HAS ARBITRARILY ENFORCED THE SSP**
14 **EXCEPTION, AND DEPRIVED DEFENDANTS OF APPROPRIATE**
15 **NOTICE**

16 91. The Government’s actions depriving Drs. Berman and Lander of their
17 property are arbitrary and capricious and fail to provide adequate due process. Due
18 process “bar[s] certain [arbitrary wrongful] government actions regardless of the
19 procedures used to implement them.” *Daniels v. Williams*, 474 US 327, 331
20 (1986). An agency’s decision to modify regulations must be rational, based on
21 relevant factors and within the scope of the agency’s authority. *Motor Veh. Mfrs.*
22 *Ass’n v. State Farm Ins.*, 463 U.S. 29, 42-43 (1983). An agency cannot create a
23 regulation to nullify existing statutes—21. U.S.C. §§ 360, 396—which explicitly
24 recognize that the practice of medicine is not governed by the FDCA or PHSA.
25 The exacting standards placed on agency decision is required because “the strength
26 of the modern government[] can become a monster which rules with no practical
27 limits on its discretion.” *New York v. United States*, 342 U.S. 882, 884 (1951)
28 (dissenting opinion). Finally, where a defendant has modified its behavior based

1 on the prior statements, the agency's action is subject to closer review. *See Nat.*
2 *Gas Pipeline Co. of Am. v. Fed. Energy Reg. Comm.*, 590 F2d 664 (7th Cir. 1979)
3 (finding agency acted unreasonably when it substantively modified requirements
4 after the company relied on them and acted to its detriment).

5 92. As explained above, the nonbinding 2017 Guidance substantively
6 amends 21 C.F.R. § 1271.15 by adding new language (and requirements) to the
7 SSP Exception. The FDA fails to provide any meaningful analysis as to why its
8 longstanding understanding of the SSP Exception required change. The FDA's
9 decision to modify the regulations is irrational.

10 93. Further, the 2017 Guidance states that, for some health care providers,
11 it will not allege any violation for three years. However, the FDA fails to identify
12 to whom the three-year grace period applies. Instead, the FDA has arbitrarily
13 enforced the new requirement, singling out Drs. Berman and Lander while
14 permitting medical procedures that involve significantly more manipulation of the
15 HCT/Ps. Indeed, the FDA inspected two additional facilities, ACS and
16 StemImmune, at the same time as Defendants and did not file a complaint against
17 either.

18 94. The Government fails to provide any reasoning for its arbitrary and
19 capricious actions. The FDA's actions cannot stand, especially here where
20 Drs. Berman and Lander relied upon the longstanding regulations to develop a
21 successful new surgical technique and expand their business. An agency decision
22 can be overturned if it is (a) arbitrary and capricious, (b) illegal (fails to follow the
23 APA) or (c) unconstitutional (violating Appointments Clause and property and
24 privacy rights). The FDA's decisions and actions in this case meet all three
25 standards and Drs. Berman and Lander are entitled to attorneys' fees due to
26 wrongful prosecution of invalid regulations.

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1 **V. DEFENDANTS ARE ENTITLED TO ATTORNEYS' FEES**

2 95. Congress enacted the Equal Access to Justice Act under 28 U.S.C.
3 § 2412 (“Section 2412”) to limit the United States government’s immunity to an
4 award for costs and fees. Section 2412 was designed as a gap-filler and applies in
5 the absence of another statute that addresses the issue of attorneys’ fees in the case
6 at issue. 28 U.S.C. § 2412(b), (d) (“except as otherwise specifically provided by
7 statute . . .”). Section 2412 is generally applicable whenever the federal
8 government is a party in a civil action. 28 U.S.C. § 2412(d).

9 96. Given the Government’s vast resources and power, Congress
10 determined that parties should be entitled to attorneys’ fee where the Government
11 lacks substantial justification for bringing a civil action. Accordingly, Section
12 2412(d) permits a court to award attorneys’ fees and other expenses to a prevailing
13 party unless the Court finds that the Government was “substantially justified.” The
14 Supreme Court has concluded that the standard for substantial justification is no
15 different than a “reasonable basis” test. *Pierce v. Underwood*, 487 U.S. 552, 565
16 (1988). The Court makes one determination regarding the action as a whole, not to
17 each cause of action. *See Ibrahim v. U.S. Dept. of Homeland Sec.*, 835 F.3d 1048,
18 1054–57 (2016) (holding that court’s decision regarding substantial justification
19 requires a “single inquiry focused on the government’s conduct in the case as a
20 whole”).

21 97. Here, the Government has acted unreasonably in contravention of
22 well-established regulatory law. First, the SSP Exception applies to the SVF
23 Surgical Procedure on its face. Second, the Government’s attempt to rely upon the
24 nonbinding 2017 Guidance violates well-established principles of administrative law
25 and is not substantially justified. Third, the Government has continued to pursue
26 injunctive relief as to the Expanded MSC and SVF/ACAM2000 Surgical
27 Procedures even though Drs. Berman and Lander have (1) ceased using the non-
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1 GMP facility for the Expanded MSC Surgical Procedure, and (2) cannot perform
2 the SVF/ACAM2000 Surgical Procedure due to lack of access to ACAM2000.

3 98. Accordingly, Drs. Berman and Lander are awarded attorneys' fees
4 because the Government lacked substantial justification for continuing the
5 litigation.

6
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8 Dated: _____

9 HONORABLE JESUS G. BERNAL
10 United States District Judge

11 Presented by:

12 /s/ Celeste M. Brecht

13 Celeste M. Brecht
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