UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
CIVIL MINUTES—GENERAL

Case No.	**EDCV 18-1005 JGB (KKx)**	Date	January 27, 2020
Title	***United States of America v. California Stem Cell Treatment Center, Inc., et al.***		

Present: The Honorable	JESUS G. BERNAL, UNITED STATES DISTRICT JUDGE

MAYNOR GALVEZ	Not Reported
Deputy Clerk	Court Reporter
Attorney(s) Present for The Government(s):	Attorney(s) Present for Defendant(s):
None Present	None Present

Proceedings: **Order (1) DENYING the Government's Motion for Summary Judgment (Dkt. No. 45); (2) DENYING the Government's Motion to Strike Evidence (Dkt. No. 63); and (3) DENYING AS MOOT Defendants' Motions to Exclude (Dkt. Nos. 65–68). (IN CHAMBERS)**

Before the Court are six motions:

1. Plaintiff United States of America ("the Government")'s Motion for Summary Judgment ("Summary Judgment Motion," Dkt. No. 45);
2. The Government's Motion to Strike Evidence ("Motion to Strike," Dkt. No. 63);
3. Defendants California Stem Cell Treatment Center, Inc., Surgical Network Corporation, Elliot B. Lander, M.D., and Mark Berman, M.D.'s Motion to Exclude Opinions of Carol Yong ("Yong Motion," Dkt. No. 65);
4. Defendants' Motion to Exclude Opinions of Karlton T. Watson ("Watson Motion," Dkt. No. 66);
5. Defendants' Motion to Exclude Opinions of Larissa Lapteva ("Lapteva Motion," Dkt. No. 67);
6. Defendants' Motion to Exclude Opinions of Randa F. Melhem ("Melhem Motion," Dkt. No. 68)

The Court held a hearing on January 13, 2020. Upon consideration of the papers filed in support of and in opposition to the Motions, as well as oral arguments presented by the parties, the Court DENIES the parties' Motions.

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I. BACKGROUND

This case was brought by the United States of America against Defendants for alleged violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 332(a). The Government filed its Complaint against Defendants on May 9, 2018. ("Complaint," Dkt. No. 1.) On July 8, 2019, the Government filed its Summary Judgment Motion along with the following documents:

- Plaintiff's Statement of Undisputed Facts ("PSUF," Dkt. No. 46);
- Declaration of Natalie N. Sanders ("Sanders Declaration," Dkt. No. 47);
    - Order on Motions for Summary Judgment, *United States v. US Stem Cell Clinic, LLC*, No. 18-cv-61047 (S.D. Fla. June 3, 2019), ECF No. 73 ("US Stem Cell," Dkt. No. 47-1);
- Declaration of Karlton T. Watson ("Watson Declaration," Dkt. No. 48);
- Declaration of Carolyn Yong ("Yong Declaration," Dkt. No. 49);
- Declaration of Doran L. Fink ("Fink Declaration," Dkt. No. 50);
- Declaration of Christopher C. Joneckis ("Joneckis Declaration," Dkt. No. 51);
- Declaration of Larissa Lapteva, M.D. ("Lapteva Declaration," Dkt. No. 52);
- Declaration of Randa F. Melhem ("Melhem Declaration" Dkt. No. 53);
- Application to File Documents Under Seal ("Application," Dkt. No. 54);
- Declaration of Natalie N. Sanders in Support of Plaintiff's Application to File Under Seal ("Sanders Application Declaration," Dkt. No. 55).

On August 9, 2019, Defendants opposed the Summary Judgment Motion. ("Summary Judgment Opposition," Dkt. No. 59.) In support of the Summary Judgment Opposition, Defendants submitted the following documents:

- Defendants' Statement of Genuine Dispute of Material Facts and Additional Disputed Facts ("DSUF,"[1] Dkt. No. 59-1);
- Declaration of Elliot Lander, M.D. ("Lander Declaration," Dkt. No. 59-2);
- Declaration of Matthew M. Gurvitz ("Gurvitz Declaration," Dkt. No. 59-3);
    - Expert Report of Lola M. Reid, Ph.D. ("Reid Report," Gurvitz Declaration at 22-128);
    - Transcript of Deposition of Lola A. Reid, Ph.D. ("Reid Deposition," Gurvitz Declaration at 3-17);
- Defendants' Evidentiary Objections to the Declaration of Karlton Watson ("Watson Objections," Dkt. No. 59-4);

[1] The DSUF contains two sets of facts: those facts raised in the PSUF and an additional set of facts. When referring to the facts raised in the PSUF, the Court will use "SUF" along with the fact number. When referring to the additional facts raised for the first time in the DSUF, the Court with use "AMF" along with the fact number.

- Defendants' Evidentiary Objections to the Declaration of Randa F. Melhm ("Melhm Objections," Dkt. No. 59-5);
- Defendants' Evidentiary Objections to the Declaration of Doran Fink ("Fink Objections," Dkt. No. 59-6);
- Defendants' Evidentiary Objections to the Declaration of Larissa Lapteva ("Lapteva Objections," Dkt. No. 59-7);
- Defendants' Evidentiary Objections to the Declaration of Carolyn Yong ("Yong Objections," Dkt. No. 59-8).

On September 24, 2019, the Government replied to the Summary Judgment Opposition. ("Summary Judgment Reply," Dkt. No. 62.) In support of the Summary Judgment Reply, the Government submitted the following documents:

- The Government's Reply to Defendants' Statement of Disputed Material Facts ("PSUF Reply," Dkt. No. 62-1);
- The Government's Reply to Evidentiary Objections to Declaration of Doran Fink ("Fink Reply," Dkt. No. 62-2);
- The Government's Reply to Evidentiary Objections to Declaration of Larissa Lapteva ("Lapteva Reply," Dkt. No. 62-3);
- The Government's Reply to Evidentiary Objections to Declaration of Randa F. Melhem ("Melhem Reply," Dkt. No. 62-4);
- The Government's Reply to Evidentiary Objections to Declaration of Karlton T. Watson ("Watson Reply," Dkt. No. 62-5);
- The Government's Reply to Evidentiary Objections to Declaration of Carolyn Yong ("Yong Reply," Dkt. No. 62-6);
- The Government's Evidentiary Objections to the Expert Report and Deposition Testimony of Lola M. Reid, Ph. D ("Reid Objections," Dkt. No. 62-7);[2]
- The Government's Evidentiary Objections to the Declaration of Elliot Lander, Ph. D ("Lander Objections," Dkt. No. 62-8);
- Declaration of Natalie N. Sanders ("Sanders Reply Declaration," Dkt. No. 64).

On September 24, 2019, the Government also filed the Motion to Strike. Defendants opposed the Motion to Strike on December 23, 2019. ("Strike Opposition," Dkt. No. 75.) The Government filed its reply in support of the Motion to Strike on December 31, 2019. ("Strike Reply," Dkt. No. 80.)

[2] Defendants opposed these objections on December 23, 2019 and the Government filed a reply in support of them on December 31, 2019. (Dkt. Nos. 76, 79.) Objections are not motions, parties are not entitled to fully brief every one. In summary judgment briefing, the parties are may evidence along with their moving papers. A longer briefing period does not entitle Defendants to file additional papers—such additional briefing is an impermissible surreply. Accordingly, the Court will not consider arguments raised in Defendants' opposition to the objections or the Government's reply.

On November 8, 2019, Defendants filed the four motions to exclude. (Yong Motion; Watson Motion; Lapteva Motion; Melhem Motion.) The Government opposed the motions to exclude on December 23, 2019. ("Exclude Opposition," Dkt. No 73.) Defendants replied in support of the motions to exclude on December 30, 2019. ("Exclude Reply," Dkt. No. 78.)

II. APPLICATION TO FILE UNDER SEAL

The Application seeks to seal documents with confidential information obtained by the Government during the Food and Drug Administration ("FDA")'s investigation of Defendants. (Application at 3.) Defendants do not oppose this Application. Because this matter is a non-sealed civil case, the Government must follow the procedure outlined in Local Rule 79-5.3.3(a) for filing documents under seal. Because the Application is filed in support of a motion for summary judgment, the Government must overcome the strong presumption of public access and show there are compelling reasons to file under seal. See Kamakana v. City and Cty of Honolulu, 447 F.3d 1172, 1178 (9th Cir. 2006). "[C]ompelling reasons sufficient to outweigh the public's interest in disclosure and justify the sealing of court records exist when such court files might have become a vehicle for improper purposes, such as the use of records to gratify private spite, promote public scandal, circulate libelous statements, or release trade secrets." Id.

The Court concludes that the Government has substantially complied with the procedures outlined in the Local Rules for filing under seal. (See Sanders Application Declaration.) In the Sanders Application Declaration, the Government demonstrates that the redacted documents contain information submitted to the FDA, which "fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure." (Sanders Application Declaration ¶ 4); see also 21 C.F.R. § 20.61. The redacted documents also contain medial records. (Sanders Application Declaration ¶ 5.) The litigation related documents the Government seeks to redact contain references to these other two categories of records. (Id. ¶ 6.) A compelling reason to file documents under seal exists where public disclosure of trade secrets could harm competitive standing or result in the improper use of the information by others who might circumvent investing their own time and resources. See Morawski v. Lightstorm Entertainment, Inc., 2013 WL 12122289, at *2 (C.D. Cal. Jan 14, 2013); see also Bauer Bros. LLC v. Nike, Inc., 2012 WL 1899838, at *1 (S.D. Cal. May 24, 2012). Compelling reason also exists to seal documents that reveal confidential medical information. See Gary v. Unum Life Ins. Co. of Am., 2018 WL 1811470, at *3 (D. Or. Apr. 17, 2018) (collecting cases). Accordingly, the Court GRANTS the Application and permits the Government to file the exhibits under seal as redacted in the Sanders Application Declaration.

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III. FACTS & EVIDENCE

A. Undisputed Facts

Except as noted, the following material facts are sufficiently supported by admissible evidence and are uncontroverted. They are "admitted to exist without controversy" for purposes of the Motion. See Fed. R. Civ. P. 56(e)(2); L.R. 56-3.

The "SVF Process" [3] is a medical treatment offered by Defendants. (SUF 2; AMF 6.[4]) During the SVF Process, Defendants recover adipose (fat) tissue from the patient. (SUF 9.[5]) Adipose tissue contains adipocytes (fat cells) along with other cells, including preadipocytes, fibroblasts, vascular endothelial cells, and macrophages. (SUF 65.[6]) Stromal Vascular Fraction ("SVF") is the part of the adipose tissue that does not contain adipocytes. (AMF 8.[7]) After Defendants remove the adipose tissue from the patient, they use collagenase enzymes and a centrifuge device to isolate the SVF and remove the adipocytes. (SUF 16.) The resulting SVF is a liquified mixture of cells and cell debris. (SUF 19.) The SVF cell mixture lacks the cellular matrix of adipose tissue and many of adipose tissue's properties. (SUF 19, 65.) Defendants suspend the SVF cell mixture in a saline solution and implant it back into the patient. (SUF 21.)

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[3] The parties dispute the nature of the treatment at issue: Defendants insist that they perform a surgical procedure on patients while the Government argues that Defendants manufacture a drug. (Compare SUF 2 with AMF 6.) For simplicity of reference, the Court will refer to the treatment as "SVF Process" without making any finding regarding the nature of the treatment. "Treatment" is also used neutrally and without any determination that the "SVF Process" is either a surgical procedure or a manufactured drug.

[4] While AMF 6 and SUF 2 are disputed, both support the listed fact—that Defendants offer a medical treatment involving SVF cells.

[5] Defendants dispute SUF 9 but fail to cite any evidence demonstrating that the SVF Procedure does not involve the recovery of adipose tissue. Moreover, their own briefing and evidence confirms that adipose tissue is recovered during the SVF Procedure. (See, e.g., Lander Declaration ¶ 10.) Accordingly, it is undisputed that adipose tissue is recovered from the patient during the SVF Procedure. See Fed. R. Civ. P. 55(e)(2); L.R. 56-3.

[6] Defendants dispute this fact but cite only the properties of adipose tissue, not its cellular composition. Accordingly, the Court concludes that the cellular contents of adipose tissue as detailed in SUF 65 is undisputed. See id.

[7] The Government's only dispute with AMF 8 is that it is not supported by the evidence on the record. It is, however supported by the Lander Declaration. (See Lander Declaration ¶¶ 8,9.) Accordingly, AMF 8 is undisputed. See Fed. R. Civ. P. 55(e)(2); L.R. 56-3.

The SVF mixture that is implanted back into the patient contains the same SVF cell population that previously existed in the patient's body. (AMF 32.[8])

The "SVF/Vaccinia Process" is a treatment that was previously offered by Defendants. (SUF 26; AMF 59.[9]) It is similar the SVF Process but before the SVF is injected back into the patient, it is combined with a Vaccinia Vaccine, Live, a smallpox vaccine also known as ACAM2000. (Id.) Defendants have not offered the SVF/Vaccinia Process since the U.S. Marshal seized five vials of ACAM2000 from them in 2017. (AMF 57, 59.)

B. Evidentiary Objections

1. The Government's Objections

The evidence offered by Defendants in the AMF is based on the Lander Declaration, the Reid Report, and the Reid Deposition. The Government objects to each of these sources as (1) improper expert testimony, (2) improper lay testimony, and (3) hearsay. (See Lander Objections, Reid Objections.) Additionally, it objects to the Reid Report and Reid Deposition as not properly authenticated. (See Reid Objections.) Each of these objections lacks merit.

The Government objects to Dr. Lander's testimony as both improper expert and improper lay opinion. (Lander Objections.) Defendant Lander is a party to this case—not an expert witness. His declaration explains a medical procedure that he developed and currently implements. Therefore, the testimony in the Lander Declaration is based upon his personal knowledge and experience and is neither improper lay nor improper expert testimony. Accordingly, the Court OVERRULES the Government's objections to his testimony.

The Government also objects to Dr. Reid's testimony as both improper expert and improper lay opinion. It contends that although Dr. Reid is Defendants' designated expert, her opinions should be excluded because her report "fails to lay proper foundation as to Dr Reid's knowledge, expertise, and familiarity with the subject matter." (See, e.g., Lander Objections at 6.) Federal Rule of Evidence 702 governs the admissibility of expert testimony:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the

[8] While the Government disputes AMF 32, it states that it "does not dispute that the [SVF mixture] may contain cells isolated from adipose tissue removed from the patient's body." (PSUF Reply at 132.) It also cites no evidence indicating that the cells implanted back into the patient are not cells that originated from that patient. Accordingly, the parties do not AMF 32 as stated herein. See Fed. R. Civ. P. 55(e)(2); L.R. 56-3.

[9] Defendants purport to dispute SUF 26 but fail to cite any conflicting evidence. Accordingly, the Court concludes it is undisputed. See Fed. R. Civ. P. 55(e)(2); L.R. 56-3.

> testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Dr. Reid meets Rule 702's threshold. She is a professor at the University of North Carolina's School of Medicine in the Department of Cell Biology and Physiology. (Reid Report at 1.) Her postdoctoral studies were conducted in the fields of cell biology and virology, and her current research focuses on "the mechanisms governing differentiated cells, particularly matrix chemistry and biology, on stem cell an maturational lineage biology, and the potential of using stem cell therapies for treatment of human diseases and pathologies." (Id.) Additionally, Dr. Reid has published dozens of articles on stem cell-related subjects in peer-reviewed journals and has received several patents for stem cell-related technologies. (Id. at 7–31.) Accordingly, the Court concludes that Dr. Reid is qualified to opine on whether the SVF Procedure "causes any changes to the stem cells collected" and "whether the use of SVF in surgical procedures is safe and well-tolerated." (See Reid Report at 24.) Because Dr. Reid is qualified to give expert opinion about the SVF Procedure, a stem cell technology, the Court OVERRULES the Government's improper expert opinion and improper lay opinion objections to her testimony.

The Government objects to both Dr. Lander and Dr. Reid's testimony as hearsay. (See Reid Objections; Lander Objections.) But neither the Reid Report nor the Lander Declaration contain any statements by another. Instead, they are the declarants' own testimony based on personal knowledge. "Parties may . . . submit affidavits in support of summary judgment, despite the fact that affidavits are often inadmissible at trial as hearsay, on the theory that the evidence may ultimately be presented at trial in an admissible form." Argo v. Blue Cross & Blue Shield of Kansas, Inc., 452 F.3d 1193, 1199 (10th Cir. 2006); see also Fed. R. Civ. Pro. 56(c)(4) ("An affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated.") Because the declarations contain only the proposed testimony of each declarant, they are not hearsay for the purposes of a summary judgment motion. Accordingly, the Court OVERRULES the Government's hearsay objections.

Finally, the Government objects that Dr. Reid's testimony is not authenticated. (See, e.g., Reid Objections at 7.) Federal Rule of Evidence 901(a) permits authentication "by evidence sufficient to support a finding that the matter in question is what the proponent claims." The Reid Deposition is properly authenticated because it includes Dr. Reid's name, the case name, and the court reporter's certification. (Reid Deposition at 3, 4, 7); see Orr v. Bank of Am., NT & SA, 285 F.3d 764, 774 (9th Cir. 2002) ("A deposition or an extract therefrom is authenticated in a motion for summary judgment when it identifies the names of the deponent and the action and includes the reporter's certification that the deposition is a true record of the testimony of the deponent.") The Reid Report is likewise authenticated: Dr. Reid testified that she signed the report and the twenty-five pages of the Reid Report are the same twenty-five pages as the document she signed in her office. (Reid Report at 47; Reid Deposition at 7.) The Court concludes that Defendants sufficiently establish that the Reid Report is what Defendants purport it to be: an expert report submitted by Dr. Lola M. Reid. Because the Reid Report and Reid Deposition are properly authenticated, the Court OVERRULES the Government's objection.

2. Defendants' Objections

Of the SUF facts considered by the Court, only one—SUF 65—relies on any evidence objected to by Defendants. The Government cites paragraph 16 of the Yong Declaration to support SUF 65. (PSUF 65.) Defendants make five objections to paragraph 16 of the Yong Declaration: (1) improper legal conclusion, (2) lack of personal knowledge, (3) improper lay opinion, (4) best evidence rule, (5) lack of foundation. (Yong Evidentiary Objections at 4.) The Court OVERRULES Defendants' first objection—paragraph 16 provides a scientific description of the properties of adipose tissue; it does not apply those facts to any law or provide any legal opinions. Because Carol Yong is a designated expert, not a fact witness, Defendants' second and third objection are also OVERRULED. Moreover, because she is an expert witness designated to testify regarding the SVF Process and has reviewed the SVF Process, the Government has established the proper foundation for her testimony regarding the properties of adipose tissue.[10] (Yong Declaration ¶¶ 9, 12.) Defendants' fifth objection, therefore, is OVERRULED. Finally, because paragraph 16 makes no reference to any documents, Defendants' fourth objection is OVERRULED. Because no other objected to evidence submitted the Government was considered by the Court, all other evidentiary objections made by Defendants are OVERRULED AS MOOT.

C. Defendants' Motions to Exclude Expert Testimony

Defendants move to exclude the testimony of expert witnesses Carol Yong, Larissa Lapteva, Randa F. Melhem, and Karlton T. Watson on the basis that the experts' testimony includes legal opinion. (Yong Motion; Lapteva Motion; Melhem Motion; Watson Motion.) The Court did not consider any of the purported legal opinions in this decision. Accordingly, all four motions to exclude are DENIED AS MOOT.

D. The Government's Motion to Strike the Lander Declaration

The Government moves to strike the Lander Declaration as the opinion of an untimely disclosed expert. (See Motion to Strike.) It argues that because Dr. Lander—a defendant in this case—has specialized knowledge about a process that he created and the Government has sued him over it, he should have been designated as a non-retained expert. (Id.) That argument is a waste of the Court's time. The Government sued Dr. Lander, alleging that his "SVF Process" violates FDA regulations. Therefore, any testimony Dr. Lander provides in his own defense explaining the "SVF Process" is fact testimony based on his personal knowledge—not expert testimony. See Hoffman v. Lee, 474 F. App'x 503, 505 (9th Cir. 2012) (holding that a treating physician need not be designated as an expert physician where "he could testify to matters rationally based on his perception"); see also Fed. R. Evid. 701(a) ("If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is . . . rationally based on the witness's perception.").

[10] Defendants have not objected to Dr. Yong's qualifications to testify as an expert witness regarding the SVF Process.

Moreover, as Defendants point out, requiring Dr. Lander to designate himself as a non-retained expert would also require him to waive attorney-client privilege. (See Strike Opposition at 5–6); United States v. Sierra Pac. Indus., 2011 WL 2119078, at *8–9 (E.D. Cal. May 26, 2011) (holding attorney-client privilege waived between a testifying non-retained expert and counsel). Following the Government's logic, any defendant with specialized knowledge on the subject matter of the case would be forced to choose between two untenable options: either designate himself as a non-retained expert witness and waive attorney-client privilege or remain silent and unable to defend himself. Such an outcome would violate due process rights. Finally, the Government's argument that it is unduly surprised by Mr. Lander's testimony strains credulity—it is unreasonable to expect that a medical doctor sued by the Government for a procedure he invented and performed would not give testimony regarding that procedure. (See Strike Reply at 9–10.) Accordingly, the Motion to Strike is DENIED.

IV. LEGAL STANDARD

Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party has the initial burden of identifying the portions of the pleadings and record that it believes demonstrate the absence of an issue of material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Where the non-moving party bears the burden of proof at trial, the moving party need not produce evidence negating or disproving every essential element of the non-moving party's case. Id. at 325. Instead, the moving party need only prove there is an absence of evidence to support the nonmoving party's case. Id.; In re Oracle Corp. Sec. Litig., 627 F.3d 376, 387 (9th Cir. 2010). The moving party must show that "under the governing law, there can be but one reasonable conclusion as to the verdict." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

If the moving party has sustained its burden, the non-moving party must then show that there is a genuine issue of material fact that must be resolved at trial. Celotex, 477 U.S. at 324. The non-moving party must make an affirmative showing on all matters placed at issue by the motion as to which it has the burden of proof at trial. Celotex, 477 U.S. at 322; Anderson, 477 U.S. at 252. A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the non-moving party." Anderson, 477 U.S. at 248. "This burden is not a light one. The non-moving party must show more than the mere existence of a scintilla of evidence." In re Oracle, 627 F.3d at 387 (citing Anderson, 477 U.S. at 252).

When deciding a motion for summary judgment, the court construes the evidence in the light most favorable to the non-moving party. Barlow v. Ground, 943 F.2d 1132, 1135 (9th Cir. 1991). Thus, summary judgment for the moving party is proper when a "rational trier of fact" would not be able to find for the non-moving party based on the record taken as a whole. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

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V. DISCUSSION

The Government moves for summary judgment on its claims that the SVF Process violates the FDCA. (Summary Judgment Motion at 1–2.) It also seeks a permanent injunction preventing Defendants from performing the SVF Process. (Summary Judgment Motion at 30–32.) Defendants dispute that the FDCA applies to the SVF Process at all. (Summary Judgment Opposition.)

The parties' central dispute is whether FDCA's same surgical procedure exception ("SSP Exception") exempts the SVF Process from FDA oversight. See 21 C.F.R. § 1271.15(b). The SSP Exception exempts any "establishment that removes HCT/P's from an individual and implants such HCTP's into the same individual during the same surgical procedure" from FDA oversight. Id. "HCT/P's" is an acronym for "[h]uman cells, tissues, or cellular or tissue-based products," which the FDCA defines as "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).

The parties agree that both adipose tissue and SVF cells are HCT/P's. (See AMF 47; Summary Judgment Motion at 26 ("Adipose tissue [is] the HCT/P removed from patients").) They also agree that the SVF Procedure implants HCT/P's back into the same patient from whom they were removed. (SUF 6.[11]) They disagree, however, whether the HCT/P's that are implanted are "such HCT/P's" that were removed.

The term "such HCT/P's" is unambiguous. It directly refers to the HCT/P previously cited in the sentence—i.e., the removed HCT/P. (See US Stem Cell ("The text of § 1271.15(b) unambiguously supports [the] interpretation[] that 'such HCT/P's' refers to the antecedent HCT/P removed from the patient. . . .").) The SSP Exception, therefore, requires that the implanted HCT/P's are the same HCT/P's as those that were removed. If an HCT/P is removed from Patient One and then an HCT/P from Patient Two is implanted into Patient One, the exception clearly does not apply—the implanted HCT/P is not "such HCT/P" as was removed. Likewise, a procedure where the doctor removes an HCT/P, mutates it, then implants it back into the patient would also not fall within the SSP Exception. Again, the implanted HCT/P is not "such HCT/P" as was removed.

The Government characterizes the SVF Procedure as a removal of adipose tissue followed by implantation of SVF cells. (Summary Judgment Motion at 26 ("Adipose tissue [is] the HCT/P removed from patients . . . . [and is] not the HCT/P that is later implanted").) Indisputably, SVF cells are not the same as adipose tissue: adipose tissue contains a cellular

[11] Defendants dispute SUF 6 because they dispute the Government's characterization of the SVF Procedure as a product. However, both parties agree that the SVF Procedure involves autologous use of the patient's cells, which refers to the "implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered." See 21 C.F.R. § 1271.3(a).

matrix that SVF cells do not and adipose tissue has properties that SVF cells lack. (SUF 19, 65.) And therefore, on this characterization, the implanted HCT/P's are not "such HCT/P's" as were removed.

Defendants' alternative characterization is as follows: the SVF Procedure removes SVF cells from a patient and implants those same SVF cells into the same patient. (Summary Judgment Opposition at 14–17.) While the Government's characterization of the removal focuses on the largest system that was removed (i.e., adipose tissue), Defendants' characterization focuses on the target of the removal, the SVF cells. This second characterization meets the "such HCT/P's" requirement because SVF cells, which the parties agree are HCT/P's, are removed and such cells are implanted back into the same patient. (See AMF 47, 32.) Moreover, this alternative characterization of the SVF Procedure is no less accurate than the Government's—while Defendants do remove adipose tissue, because the adipose tissue contains SVF cells, they also remove SVF cells. (See AMF 8.)

The question is then whether the text of the SSP Exception favors the Government's characterization of the SVF Procedure or Defendants'. Through use of the term HCT/P's, the SSP Exception explicitly includes both "cells" and "cellular-based products." See 21 C.F.R. § 1271.3(d). Because cells make up tissues and organs, cells can only be removed from a patient along with those larger systems.[12] (Summary Judgment Opposition at 14; AMF 2.) As Defendants point out, if the SSP Exception demanded the removal to be characterized by the largest system that was removed, it could never be applied to the removal and implantation of a cell. (Summary Judgment Opposition at 14–15.) Therefore, such an interpretation would render the words "cells" and "cellular-based systems" superfluous.[13] (Summary Judgment Opposition at 14–15.) Canons of interpretation require that regulations be interpreted in a way that gives all words effect. TRW Inc. v. Andrews, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.") The SSP Exception, therefore, cannot be interpreted to require a characterization based on the largest biological system removed—it must permit characterizations focused on smaller units.

The Government responds that Defendants' interpretation of the SSP Exception reads the word "tissues" out of the definition. (Summary Judgment Reply at 4.) That is not the case. An interpretation of the SSP Exception that focuses on the target of the removal and implantation gives effect to both "tissue" and "cell" as some procedures target tissues and others target cells (for example, the SVF Process targets cells and an artery transplant targets

[12] At the hearing, the Government attorney asserted that technology to remove only cells did exist. However, no evidence was submitted on this point. Moreover, counsel was not clear on whether blood was removed from the patient and the cells were separated from the blood or only the cells were removed.

[13] Notably, other than a conclusory statement that its interpretation satisfies cannons of statutory interpretations, the Government fails to address the argument that its interpretation of the SSP Exception renders the word "cell" superfluous. (See Summary Judgment Reply at 4–6.)

tissue). Conversely, an interpretation of the SSP Exception that demands a characterization based on the largest system removed eliminates the possibility of a cell removal and implantation. Because it is the only interpretation that gives full effect to all words, the SSP Exception unambiguously demands that the characterization of the removal focus on the target of the removal—either the cell or the tissue—rather than the largest system removed. (Contra US Stem Cell (holding that the SSP Exception is silent on which characterization of the removal is required).)

Moreover, a characterization that focuses on the target of the removal is more reasonable than one that includes everything that was removed. Undoubtedly, most if not all surgical removals take out more biological matter than what was targeted. Take for example the removal of an artery for implantation back in the body. See U.S. Dep't Health & Human Services, Food & Drug Admin., *Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception* (Nov. 2017) ("SSP Exception Guidance Document")[14] ("Examples [of procedures considered same surgical procedures] include autologous skin grafting, and coronary artery bypass surgery involving autologous vein or artery grafting.") Along with the needed artery, a surgeon may remove some blood. She may also remove more artery tissue than what will ultimately be needed. The SSP Exception does not require that the surgeon implant everything that was removed—including the removed blood and excess artery—for it to apply. The SSP Exception Guidance recognizes that processing steps such as "rinsing [and] cleansing" or "sizing and shaping," including "dilation," "cutting," "meshing," of HCT/P's do not exclude a procedure from the SSP Exception. See SSP Exception Guidance at 9–10.

The logic that not all that is removed must be implanted applies to the SVF Procedure as well. The SSP Exception would unobjectionably apply to a procedure that removed only SVF cells and then implanted only those same SVF cells back into the patient. But presumably that technology does not yet exist or is inaccessible. So Defendants must remove SVF cells as part of a larger biological system. And like the surgeon who washes the blood from the artery and cuts it down to the right size, Defendants use enzymes and a centrifuge to isolate the targeted HCT/P's from the unneeded biological material that was also removed.

[14] While the Court cites the SSP Exception Guidance for illustrative purposes, the FDA's interpretation of the SSP Exception advanced therein, specifically that the SVF Process does not fall within the SSP Exception, is not entitled to deference. First, as explained above, the SSP Exception is unambiguous. See Kisor v. Wilkie, 139 S. Ct. 2400, 2414 (2019) ("[T]he possibility of deference can arise only if a regulation is genuinely ambiguous.") Second, the interpretation advanced is unreasonable and creates enforcement inconsistency: it makes no logical sense assert that the SSP Exception applies to a procedure where physical cutting is necessary to isolate needed tissue but not to a procedure where chemical "cutting" is necessary to isolate needed cells—especially given the use of both "cells" and "tissue" in the SSP Exception. See id. at 2415–16 ("[T]he agency's reading must fall within the bounds of reasonable interpretation . . . a requirement an agency can fail.")

Finally, this reading of the SSP Exception is entirely consistent with the Government's assertion that the implanted HCT/P's be "in the form removed from the patient." (See Summary Judgment Reply at 4.) It is also consistent with the Guidance Document's statement that "[a]n HCT/P remains 'such HCT/P' when it is in its original form." Guidance Document at 7. If SVF cells are removed from a patient and those same cells are implanted back into the same patient without alteration of the cells themselves, they are "in the form removed" and "in [their] original form"—even when they were removed along with other biological material that was not ultimately implanted back.

While the SSP Exception could apply to a procedure that removes SVF cells by removing adipose tissue from a patient and implants only extracted SVF cells back into the same patient, it only applies if those SVF cells remain unaltered. The parties dispute whether the SVF Procedure alters the SVF cells. (Summary Judgment Opposition at 15–17.) Because both parties have submitted competing evidence on this point, there is a triable issue of fact and summary judgment is not appropriate.

VI. CONCLUSION

For the reasons above, the Court DENIES the Government's Summary Judgment Motion.

IT IS SO ORDERED.