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

CASE NO.: 18-CV-61047

UNITED STATES OF AMERICA,

Plaintiff,

v.

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

Defendants.

DEFENDANTS US STEM CELL, INC., US STEM CELL CLINIC, LLC, AND KRISTIN C. COMELLA'S REPLY IN FURTHER SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

I. Introduction.

The Defendants' SVF Surgical Procedure is not subject to regulation by the FDA. The Defendants do not "manufacture" anything, let alone a "drug." Instead, they use a patient's *own* cells, cells that are not transformed into anything else. The Defendants do not expand the cells; they do not combine the cells with a drug; they do not add genes to the cells. Nothing about these cells is materially changed during the Defendants' SVF Surgical Procedure. The cells are just taken out of a person's body, isolated, and put back into that person's body approximately thirty minutes after removal. To call this process the "manufacture" of a "drug" stretches the meaning of those terms beyond recognition.

The Defendants' SVF Surgical Procedure thus fits well within the SSP Exemption. The plain language of the SSP Exemption exempts procedures that occur during a single sitting in

which the human cell or tissue that is put back into the patient is not significantly altered from the form in which it naturally exists in the same patient's body. That is what happens here; nothing more.

II. Defendants' SVF Surgical Procedure is not subject to regulation by the FDA.

A. Defendants' SVF Surgical Procedure falls within the SSP Exemption.

The language of the SSP Exemption is plain on its face—if a party's procedure satisfies the four elements of the SSP Exemption, it is exempt from all regulation by the FDA. Namely, a party is exempt from regulation provided the party's procedure "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).

Here, Defendants' SVF Surgical Procedure is exempt from regulation. Indeed, in its Opposition, Plaintiff does not even dispute that Defendants' SVF Surgical Procedure satisfies the first three criterion of the SSP Exemption. Specifically, the parties do not dispute that the SVF Surgical Procedure involves HCT/Ps, is for autologous use (*i.e.*, the procedure must involve transplanting HCT/Ps into the same patient from whom the HCT/Ps were removed), and occurs during a single sitting.

The only real dispute here—a legal one—involves whether the Defendants' SVF Surgical Procedure uses "such HCT/Ps." It does. The cells put back into the patient during the procedure are the cells taken out.

B. "Such HCT/Ps" cannot mean "what is removed from the patient"; it must mean "what is put back in."

The plain language of the SSP Exemption means that "such HCT/Ps" are the HCT/Ps implanted back into the patient. The FDA, however, argues that "'such HCT/Ps' describes the antecedent HCT/P's" removed from an individual. Dkt. No. 49 at 4. Thus, under the FDA's view,

even though the SVF cells remain unchanged, they nevertheless constitute different HCT/Ps from the adipose tissue, which is first removed from the patient. Accordingly, as the FDA would have it, the SSP Exemption does not apply.

FDA's interpretation is problematic on several, common sense levels. First, if the FDA's interpretation is accepted, then a cell could never satisfy the definition of "such HCT/Ps," despite the fact that the "C" in "HCT/P" stands for cells. A cell is always a component of something else; a cell can only be removed from a patient along with that something else. To put that cell back into the patient, then, it must be isolated in some way from the tissue that surrounds it. Nothing in the record suggests otherwise. But, if the FDA's interpretation of the SSP Exemption is correct, then a "Cell" can never be subject to the SSP Exemption. This cannot be the FDA's intended interpretation in crafting this regulation. If so, then why apply the SSP Exemption to anything other than "Tissue"? Why, in other words, include "Cells" in the SSP Exemption at all?

Second, the FDA's own "current thinking" on the SSP Exemption—as memorialized in its 2017 Guidance—is inconsistent with the FDA's litigation position. In that Guidance, the FDA states that HCT/Ps that undergo "rinsing, cleansing, sizing, or shaping that does not change its 'original form'" are "such HCT/Ps." Thus, according to the FDA's "current thinking," the HCT/P that is put back into the patient will not be the exact HCT/P that is taken out; some of the HCT/P that was taken out will be discarded. That "current thinking," though, does not square with the FDA's litigation position. By "rinsing, cleansing, sizing, or shaping" the "antecedent HCT/Ps," a procedure would, by definition, alter the form of the HCT/Ps removed from the body. Common sense thus tells you that "rinsing, cleansing, sizing, or shaping" the HCT/Ps renders them something different from "such HCT/Ps," thereby putting the procedure outside of the SSP Exemption. The FDA thus cannot make the regulation, its current thinking, and its litigation

position all line up. The only way to square all of the relevant terms—"such;" "rinsing, cleansing, sizing, or shaping;" "original form"—is to interpret the SSP Exemption as the Defendants do. When the unit of comparison is the HCT/P that is put back in—as Defendants contend—then any "rinsing, cleansing, sizing, or shaping" does not alter the "original form" of the HCT/Ps taken from the body. The "rinsing, cleansing, sizing, or shaping" affects only the tissue that is discarded, and not the tissue that is put back into the patient, which is what happens here. Because the SVF is unchanged from the time it is removed from the body (as part of the adipose tissue, some of which is discarded) until it is put back into the body, it remains "in the form removed from the body." Dkt. No. 41-1 at 13. The SVF is, therefore, "such HCT/Ps."

Third, avoiding common sense, the Government looks to "legalese," in the form of legal dictionaries, to define the term "such." That is improper. A legal definition is not the plain meaning of a term. Plaintiff boldly asserts that Defendants "cherry pick[ed] from several dictionary definitions," but, ironically, concludes that the ordinary or plain meaning of a word is, instead, the "legal definition" of a word. Dkt. No. 49 at 6. This reading of ordinary or plain meaning is contrary to the interpretation of other federal courts. *See, e.g.*, *Dish Network Corp. v. Arch Specialty Ins. Co.*, 989 F. Supp. 2d 1137, 1144 (D. Colo. 2013), *aff'd sub nom. Dish Network Corp. v. Arrowood Indem. Co.*, 772 F.3d 856, 875 (10th Cir. 2014) ("Not only should strained constructions be avoided in favor of common constructions, but technical and legal definitions should also be avoided. In other words, the plain meaning of the words should be employed in a lay manner consistent with what would be understood by a person of ordinary intelligence."), *and Schumacher v. Cargill Meat Sols. Corp.*, 515 F.3d 867, 871 (8th Cir. 2008) ("In the absence of a statutory definition or clear contrary legislative intent," the court turned to Merriam-Webster's

Collegiate Dictionary to ascertain the "commonly understood meaning" of a term because it is a "commonly used dictionary." (internal citation omitted)).

Instead, "[w]hen a term has no statutory or administrative definition, we look to its ordinary or natural meaning." *Sumpter v. Sec'y of Labor*, 763 F.3d 1292, 1296 (11th Cir. 2014). Although courts occasionally utilize legal definitions when a regulation uses a "legal term of art,"[1] "such" is certainly not a "legal term of art." Indeed, the fact that many other legal dictionaries do not contain definitions for the word "such" only solidifies this point. *See* Bouvier's Law Dictionary; *see also* Ballentine's Law Dictionary, 3rd Edition. Consequently, the word "such" should be construed in the "lay manner consistent with what would be understood by a person of ordinary intelligence"—not the legal manner. Therefore, the non-legal definition of "such," which is considered "of a kind or character of that or those indicated or implied," "of the same class, type or sort," and "like or similar," should be used. *See* Such, Webster's New International Dictionary; *see also* Such, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/such (last visited Mar. 29, 2019); Such, Dictionary.com, https://www.dictionary.com/browse/such (last visited Mar. 29, 2019).

Accordingly, the SVF cells naturally existing in an individual's body at the time of removal constitute "such HCT/Ps" when implanted into the same individual's body as part of the SVF Surgical Procedure. In short, the Defendants' SVF Surgical Procedure falls within the SSP Exemption, and Plaintiff has not demonstrated otherwise. Thus, Defendants' SVF Surgical Procedure is exempt from regulatory oversight by the FDA.

[1] *Morris v. Nielsen*, 17-CV-04001 (NGG), 2019 WL 1260622 (E.D.N.Y. Mar. 17, 2019) ("when a regulation uses a phrase or word with an established legal meaning—a legal "term of art"—courts should assume the regulation incorporates that meaning absent evidence to the contrary.")

C. The Government's claims that the Defendants' interpretation of the SSP Exemption will cause the sky to fall are hyperbole.

In its Opposition, the government seeks to characterize the Defendants' sensible interpretation of the SSP Exemption as an attempt to apply the exemption so broadly as to nullify its impact. The Government makes the wild claim that the Defendants' interpretation would allow anyone to take HCT/Ps, do anything to them, and use them in any surgical procedure at any time. Not so. Materially altering the relevant HCT/Ps, combining the relevant HCT/Ps with drugs, injecting the HCT/Ps into patients other than the patient from whom they are taken, using the HCT/Ps in separate surgical procedures—none of those things would qualify for the SSP Exemption under the Defendants' interpretation. It is simply an exaggeration to claim, as the Government does, that the Defendants' interpretation creates some kind of "vast loophole." Dkt. No. 49 at 8.

Nor would the Defendants' interpretation exclude from regulation procedures that the Government seems concerned about, at least in its briefing. Nothing in that interpretation would allow for the unregulated use of "expand[ed] cells or tissues." Dkt. No. 49 at 13. Expanding cells or tissues would fall outside of the SSP Exemption as those HCT/Ps would be materially changed. Even further, the HCT/Ps at issue in *United States v. Regenerative Scis., LLC*, a case in which the defendants sought to apply the same SSP Exemption, still would not qualify for the SSP Exemption as that procedure involved the addition of antibiotics. 741 F.3d 1314 (D.C. Cir. 2014).

The Defendants' interpretation of the SSP Exemption is appropriately limited, and applies to the Defendants' SVF Surgical Procedure, a limited procedure that allows a licensed medical professional to relocate unaltered cells from a patient's body into another part of that same patient's body, on the same day and in the same facility. That SVF Surgical Procedure is hardly a "vast loophole."

III. Conclusion

For the foregoing reasons, this Court should grant Defendants' Motion for Summary Judgment.

Dated: April 1, 2019

Respectfully submitted,

/s/ Isaac J. Mitrani
Isaac J. Mitrani
Florida Bar No. 348538
Loren H. Cohen
Florida Bar No. 303879
MITRANI, RYNOR,
ADAMSKY & TOLAND, P.A.
301 Arthur Godfrey Road, Penthouse
Miami Beach, FL 33140
Tel.: 305-358-0050
Fax: 305-358-0050
imitrani@mitrani.com
lcohen@mitrani.com
dbitran@mitrani.com
ctenn@mitrani.com
miamidocketing@mitrani.com

Todd A. Harrison (admitted pro hac vice)
Todd H. Halpern (admitted pro hac vice)
Stephen R. Freeland (admitted pro hac vice)
Mary M. Gardner (admitted pro hac vice)
Venable LLP
600 Massachusetts Avenue NW
Washington, DC 20001

Attorneys for Defendants US Stem Cell Clinic, LLC, US Stem Cell, Inc., Kristin C. Comella and Theodore Gradel

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 1, 2019, a true and correct copy of the foregoing Defendants' Reply in Further Support of their Motion for Summary Judgment was filed with the Clerk of the Court via CM/ECF and the CM/ECF system will send a notice of electronic filing to all counsel and parties of record listed on the Service List Below.

/s/ Isaac J. Mitrani
Isaac J. Mitrani
Florida Bar No. 348538
MITRANI, RYNOR,
ADAMSKY & TOLAND, P.A.
301 Arthur Godfrey Road, Penthouse
Miami Beach, FL 33140
Tel.: 305-/358-0050
Fax: 305/358-0050
imitrani@mitrani.com
dbitran@mitrani.com
ctenn@mitrani.com
miamidocketing@mitrani.com

Attorneys for Defendants US Stem Cell Clinic, LLC, US Stem Cell, Inc., Kristin C. Comella and Theodore Gradel

SERVICE LIST

Roger J. Gural
Trial Attorney
Consumer Protection Branch
United States Department of Justice
P.O. Box 386
Washington, DC 20044
Roger.gural@usdoj.gov

Counsel for United States of America

James A. Weinkle
Assistant United States Attorney
Office of the United States Attorney
99 N.E. 4th Street, Suite 300
Miami, FL 33132
james.weinkle@usdoj.gov

Counsel for United States of America

Of Counsel:

Rebecca K. Wood
Chief Counsel
Food and Drug Administration

Perham Gorji
Deputy Chief Counsel for Litigation

Michael D. Helbing
Associate Chief Counsel for Enforcement
United States Dept. of Health and Human Services
Office of the General Counsel
White Oak 31, Room 4426A
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002