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' ANSWER TO PLAINTIFF'S COMPLAINT

Defendants US Stem Cell Clinic, LLC, US Stem Cell, Inc., Kristin C. Comella and Theodore Gradel (collectively, "Defendants") submit the following Answer in response to Plaintiff's Complaint. Defendants deny each and every allegation of the Complaint that is not expressly admitted in the Answer.

1. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph, and specifically deny that Defendants' procedure is subject to regulation under the FDCA.

Jurisdiction and Venue

2. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph.

3. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph.

18. Defendants deny the characterization of the SVF procedure as a "product," deny the characterization of the SVF as "manufactured," and deny that Defendants Gradel and US Stem Cell Clinic, LLC were involved in providing training to physicians. Defendants US Stem Cell, Inc.

USSCC's SVF Products Are Drugs Under the FDCA

24. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

25. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

26. The first sentence of this paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations contained in the first sentence of this paragraph. The allegations contained in subparts (a), (c), and (d) of this paragraph purport to characterize the content of publicly-available sources, and Defendants specifically deny the characterization of those sources to the extent such characterizations are incomplete or inaccurate, and respectfully refer the Court to the full text of those sources. Defendants otherwise deny the remaining allegations contained in this paragraph, and specifically deny that the SVF procedure is subject to regulation under the FDCA.

27. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

28. Defendants deny the allegations contained in this paragraph.

29. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

Defendants' SVF Product Is a Biological Product Under the PHSA

[redacted]

37. Defendants reference and incorporate their Answer to paragraphs 7 and 26 of Plaintiff's Complaint in response to the second sentence of this paragraph. Defendants further respond that the remaining allegations of this paragraph contain legal conclusions and do not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

38. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

39. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

40. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

41. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

Defendants' SVF Product Is Adulterated

42. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

43. Defendants admit the allegations contained in the first and third sentences of the opening paragraph. This remaining allegations of this paragraph contain legal conclusions and do not require an answer. To the extent an answer is required, Defendants deny the remaining allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

44. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

Adverse Events

45. Defendants lack sufficient knowledge or information to form a belief as to the records reviewed and therefore deny the allegations in this paragraph.

Defendants' SVF Product Is Misbranded

46. This paragraph contains legal conclusions and does not require an answer. To the extent an answer is required, Defendants deny the allegations in this paragraph. Defendants specifically deny that the SVF procedure is subject to regulation under the FDCA.

Defendants Violate the FDCA

47. Defendants deny the allegations in this paragraph and specifically deny that the SVF procedure is subject to regulation under the FDCA.

48. Defendants deny the allegations in this paragraph and specifically deny that the SVF procedure is subject to regulation under the FDCA.

Continuing Noncompliance

49. Defendants deny the allegations in this paragraph and specifically deny that the SVF procedure is subject to regulation under the FDCA.

50. Defendants deny the characterization of the SVF procedure as a "product." Defendants admit that in October and December 2015, FDA investigators conducted inspections at USSCC. Defendants further admit that the FDA investigators issued a Form 483 to Ms. Comella, and that Ms. Comella sent a written response to the FDA regarding the inspections and responding to the Form 483. This written submission, among other things, demonstrates that Defendants' practices are not subject to FDA oversight. Defendants deny any remaining allegations in this paragraph, and expressly deny that the FDA has jurisdiction over Defendants' SVF procedure.

51. Defendants admit that in April and May 2017, FDA investigators conducted inspections at USSCC. Defendants further admit that the FDA investigators issued a Form 483 to Ms. Comella, and that Ms. Comella sent a written response to the FDA regarding the inspections and responding to the Form 483. This written submission, among other things, demonstrates that Defendants' practices are not subject to FDA oversight. Defendants deny any remaining allegations in this paragraph, and expressly deny that the FDA has jurisdiction over Defendants' SVF procedure.

52. Defendants admit that in August 2017, USSCC received a purported Warning Letter from the FDA, and that Ms. Comella and the Defendants' legal counsel sent a written response to the Warning Letter. These written submissions, among other things, demonstrate that Defendants' practices are not subject to FDA oversight. Defendants deny any remaining allegations in this paragraph, and expressly deny that the FDA has jurisdiction over Defendants' SVF procedure.

53. Defendants deny the allegations in this paragraph.

PLAINTIFF'S PRAYER FOR RELIEF

I. Defendants deny Plaintiff is entitled to such relief.

II. Defendants deny Plaintiff is entitled to such relief.

III. Defendants deny Plaintiff is entitled to such relief.

AFFIRMATIVE DEFENSES

Further responding to the Complaint and as additional defenses thereto, Defendants assert the following affirmative defenses, without admitting any allegations of the Complaint not previously admitted, and without admitting that the Defendants bear the burden of proof or burden of persuasion on any matter set forth herein.

FIRST AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction to hear this action.

SECOND AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's claim fails because the SVF procedure falls within the "same surgical procedure exception."

FOURTH AFFIRMATIVE DEFENSE

The relief sought in the Complaint is barred by the due process clause of the United States Constitution.

FIFTH AFFIRMATIVE DEFENSE

The relief sought in the Complaint is barred as a violation of the Administrative Procedure Act.

SIXTH AFFIRMATIVE DEFENSE

The relief sought in the Complaint is barred under the Tenth Amendment to the United States Constitution.

SEVENTH AFFIRMATIVE DEFENSE

The relief sought in the Complaint violates patients' right to privacy guaranteed by the United States Constitution.

EIGHTH AFFIRMATIVE DEFENSE

The relief sought in the Complaint is barred by the doctrines of laches and estoppel.

RESERVATION OF DEFENSES

Defendants reserve the right to assert additional affirmative defenses in the event that clarification of Plaintiff's allegations and/or discovery reveals any such defenses to be appropriate.

DEMAND FOR JURY TRIAL

Defendants reserve the right to a jury trial as permitted by law.

REQUEST FOR RELIEF

WHEREFORE, Defendants respectfully request that the Court render a judgment as follows:

(a) That Plaintiff be denied all forms of relief requested in the Complaint;

(b) That the Complaint be dismissed with prejudice and judgment entered in favor of Defendants;

(c) That Defendants be awarded their costs and attorneys' fees to the extent allowable by law; and

(d) For such other and further relief as the Court deems just and proper.

Dated: August 3, 2018

Respectfully submitted,

/s/ Isaac J. Mitrani
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 3, 2018, a true and correct copy of the foregoing Answer to Plaintiff's Complaint 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.

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