

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK,
by LETITIA JAMES, Attorney General of the
State of New York,

Plaintiff,

-against-

IMAGE PLASTIC SURGERY, LLC d/b/a
PARK AVENUE STEM CELL and JOEL B. SINGER, M.D.,
individually and as principal of IMAGE PLASTIC SURGERY, LLC,

Defendants.
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COMPLAINT

Index No. _____

IAS Part _____

Assigned to Justice

The People of the State of New York, by their attorney, Letitia James, Attorney General of the State of New York, respectfully allege, upon information and belief:

INTRODUCTION

1. Stem cells are sometimes referred to as the body’s “master cells.” They are “the cells that develop into blood, brain, bones, and all of the body’s organs.” Stem cells “have the potential to repair, restore, replace and regenerate cells,” and in the future “could *possibly* be used to treat many medical conditions and diseases.”¹ However, these treatments currently remain unproven. They can also be “particularly unsafe,” leading to administration site reactions, cells changing into inappropriate cell types or multiplying, the failure of cells to

¹ “FDA Warns About Stem Cell Therapies,” <https://www.fda.gov/forconsumers/consumerupdates/ucm286155.htm>, attached hereto as Exhibit A.

function as expected, and tumor growth.² These risks exist even if the stem cells are taken from the patient's own body.³

2. In the United States, stem cell products are regulated by the Food and Drug Administration ("FDA"). Currently, the only stem cell-based products that have been approved by the FDA "consist of blood-forming stem cells (hematopoietic progenitor cells) derived from cord-blood."⁴ The FDA has approved these products only for "limited use in patients with disorders that affect the body system that is involved in the production of blood (called the 'hematopoietic' system)."⁵

3. However, in recent years, for-profit stem cell clinics such as Defendant Park Avenue Stem Cell have proliferated throughout the country. Defendants charge patients thousands of dollars for stem cell treatments using their own adipose tissue, or fat, which they promote on their website and in social media. Defendants claim that they can treat a variety of serious medical conditions, including but not limited to, urologic diseases and erectile dysfunction, neurology diseases, cardiac/pulmonary disease, autoimmune diseases, and orthopedic conditions, even though there is currently no adequate scientific substantiation that these treatments will be effective; in fact, they could be harmful.

4. Defendants also mislead consumers to believe, expressly or through implication, that their treatments are FDA approved or have the endorsement of various medical and scientific organizations. To the contrary, in May 2018, the FDA filed suit for a permanent injunction in the United States District Court for the Central District of California against two

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ *Id.*

stem cell clinics, including Cell Surgical Network (“CSN”), an organization with which Defendant Park Avenue Stem Cell is affiliated, and Drs. Elliot B. Lander, M.D. and Mark Berman M.D., its two head doctors. In its complaint the FDA alleges, among other things, that the stem cell products administered by these entities were “adulterated” and “misbranded” within the meaning of the Federal Food, Drug & Cosmetic Act (“FDCA”) and that “an injunction is necessary to prevent Defendants from experimenting on patients with adulterated and misbranded drugs.” *See U.S. v. California Stem Cell Treatment Center, Inc., et al.*, Index No. 5:18-CV-1005 (C.D. Cal., May 9, 2018). The FDA has also issued warning letters to other stem cell clinics advising that adipose stem cell products are biological drugs requiring FDA approval.

5. The People of the State of New York, by Attorney General Letitia James (the “NYAG”), bring this action for an injunction to stop Defendants’ misleading advertising and equitable relief to redress Defendants’ fraudulent and unlawful conduct, including restitution for Defendants’ stem cell patients. In addition, the NYAG seeks the imposition of civil penalties and costs.

PARTIES AND JURISDICTION

6. Plaintiff is the People of the State of New York, by their attorney, Letitia James, Attorney General of the State of New York.

7. Plaintiff brings this action pursuant to New York Executive Law § 63(12) and GBL §§ 349 and 350. Executive Law § 63(12) empowers the NYAG to seek injunctive relief, restitution, disgorgement, damages, and costs when any person or business entity has engaged in or otherwise demonstrated repeated or persistent fraudulent or illegal acts in the transaction of business. GBL Article 22-A, §§ 349 and 350, authorizes the NYAG to seek injunctive relief, restitution and civil penalties for deceptive acts or practices and false advertising.

8. Image Plastic Surgery, LLC d/b/a Park Avenue Stem Cell (“PASC”) is located at 346 E. 51st Street, New York, New York 10022.

9. PASC has been operating since at least 2015.

10. Dr. Joel B. Singer, M.D. is a principal of Defendant PASC. He operates PASC and is responsible for its practices, including the representations made in PASC’s advertising.

11. From at least June 2016 to December 2018, PASC was affiliated with CSN, a California corporation that controls the stem cell-related operations of approximately one hundred for-profit affiliates. These affiliates are required to follow production instructions and treatment procedures developed by CSN, and also purchase specialized equipment from them.

12. The NYAG has provided pre-litigation notice pursuant to GBL §§ 349(c) and 350.

FACTS

13. PASC obtains the stem cells used in its treatments from the patient’s own adipose tissue, commonly known as fat. The adipose tissue is extracted, and manufactured into a product commonly referred to as stromal vascular fraction or “SVF.” The SVF is then injected or conveyed intravenously back into the patient.

14. The price of PASC’s stem cell procedures begins at \$3995, with the clinic advising many patients that they require multiple injections or intravenous administrations. Between at least March 2016 through late 2018, Defendants led consumers to believe they were paying to be part of a “patient-funded” research study.

Defendants' Misleading Claim That Their Stem Cell Procedures Treat a Wide Range of Serious Medical Conditions

15. Since at least 2016, PASC has advertised its stem cell procedures online, including on its website, www.parkavenuestemcell.com, as well as on Twitter,⁶ Facebook⁷ and YouTube.⁸

16. Although PASC has revised its website over time, including after being made aware of the NYAG's concerns, Defendants have consistently represented, directly and by implication, that PASC's stem cell procedures can be used to effectively "treat" or "improve" a wide range of conditions, including urologic disease, erectile dysfunction, neurology disease, cardiac/pulmonary disease, autoimmune conditions, and orthopedic conditions.

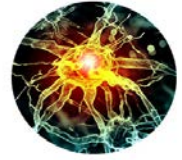


17. For example, PASC's website has prominently displayed the following statements regarding SVF, the product that PASC manufactures from patients' stem cells and then injects or intravenously conveys back into the patient:

⁶ <https://twitter.com/joelsinger12>

⁷ <https://www.facebook.com/parkavenuestemcell/>

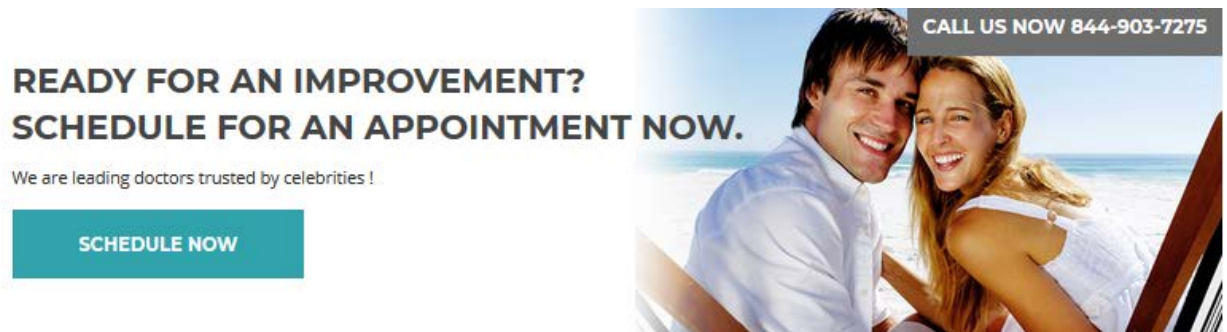
⁸ See, e.g., Dr. Singer discussing his stem cell treatments at https://www.youtube.com/watch?v=GFC_yJFYBEM (May 10, 2016)

FIGURE 1:

<p>ERECTILE DYSFUNCTION</p> <p>We are actively investigating the use of our own SVF in the treatment of ED.</p>	<p>ORTHOPEDIC DISEASE</p> <p>We have an intensive clinical experience in the investigation of the use of SVF to mitigate inflammation and damage in the joints.</p>	<p>UROLOGIC DISEASES</p> <p>We are studying the effects of SVF in the treatment of urological disease including Erectile Dysfunction and Interstitial Cystitis.</p>
		
<p>NEUROLOGY DISEASE</p> <p>We continue to investigate the safety and efficacy of SVF in the treatment of disorders of the nervous system.</p>	<p>CARDIAC / PULMONARY DISEASE</p> <p>Cardiac / Pulmonary Disease investigational studies using autologous SVF are ongoing and have shown great promise.</p>	<p>AUTOIMMUNE DISEASE</p> <p>The use of autologous SVF in the mitigation of Autoimmune Diseases such as Lupus, MS, Scleroderma are also being studied.</p>

18. PASC’s website has also displayed the following statements, leading patients to believe they will experience an “improvement” in their conditions:

FIGURE 2:



**READY FOR AN IMPROVEMENT?
SCHEDULE FOR AN APPOINTMENT NOW.**

We are leading doctors trusted by celebrities !

SCHEDULE NOW

CALL US NOW 844-903-7275

FIGURE 3:

HEAL RESTORE RENEW

ORTHOPEDECS-NEUROLOGY-UROLOGY-CARDIAC/PULMONARY-AUTOIMMUNE DISEASE

346 East 61st Street 1 F New York, NY 10022 (917) 828-0013

19. More recently, Dr. Singer has been running a GoFundMe fundraising campaign seeking funding to perform stem cell treatments at no charge. This GoFundMe solicitation represents that in addition to alleviating severe pain, stem cell therapies can treat “post traumatic brain syndrome, autoimmune diseases, orthopedic injuries and other ailments.”⁹

20. However, while stem cell therapies offer the potential to treat various conditions and diseases, due to the “absence of compelling evidence from adequate, well-controlled clinical trials,” there is currently insufficient competent and reliable scientific evidence to substantiate PASC’s claim that it can use stem cells to effectively treat or improve any of these medical conditions. As the FDA has stated, “[p]ublished data derived primarily from small, uncontrolled trials plus a few well-controlled randomized trials have not reliably demonstrated the effectiveness of stem-cell treatments even in some of the most systematically studied conditions.”¹⁰

21. In contrast to the prominent description of conditions treated by stem cell therapy, Defendants include disclaimers at the bottom of the PASC homepage or on other pages of its website that PASC is not offering stem cell therapy as a cure for any condition or disease.

⁹ See <https://www.gofundme.com/help-people-with-chronic-pain>

¹⁰ Marks et al., “Clarifying Stem-Cell Therapy’s Benefits and Risks,” 376 NEW ENGLAND J. OF MEDICINE 1007 (Mar. 16, 2017), https://www.nejm.org/doi/full/10.1056/NEJMp1613723?query=featured_home&, expressing views of the FDA (available upon request).

However, these disclaimers, which readers must scroll through the website to find or which are presented in dense or difficult-to-read text, fail to change the net impression of PASC's website that stem cells will effectively treat a variety of serious medical conditions.

A. Urologic Diseases and Erectile Dysfunction

22. As set forth in paragraph 16, Defendants highlight urological diseases as one of the areas for which they use stem cell treatments.

23. At various times between 2016 and 2018, PASC has made the following statements on its website:

- “We use stem cell treatment for urological disease including Erectile Dysfunction and Interstitial Cystitis.”
- “We are studying the effects of SVF in the treatment of urological disease including Erectile Dysfunction and Interstitial Cystitis.”
- “We are actively investigating the use of our own SVF in the treatment of ED.”

24. PASC has also posted on Facebook and Twitter links to articles with titles like “Stem Cell Treatment Helping to Improve Erectile Dysfunction.”¹¹ The full text of such articles is only viewable by clicking the title. Even if consumers were capable of understanding and assessing the studies on which the articles are based, the studies themselves do not reach definitive conclusions about the benefits of stem cell treatments. For example, the aforementioned article explains that the study at issue still required follow-up with “a randomized blinded placebo controlled trial among continent men.”¹²

¹¹ See <https://facebook.com/parkavenuestemcell>, July 19, 2018.

¹² <https://www.worldhealth.net/news/stem-cell-treatment-helping-improve-erectile-dysfunction/>

25. Through such statements, Defendants have represented, directly and by implication, that PASC can effectively treat or improve urological conditions, including erectile dysfunction, using stem cells.

26. In fact, Defendants lack competent and reliable scientific evidence to substantiate such claims.

B. Cardiac/Pulmonary Disease

27. As set forth in paragraph 16, Defendants highlight cardiac and pulmonary diseases as one of the areas for which they use stem cell treatments.

28. At various times between 2016 and 2018, PASC has stated on its website:

- “There is a great deal of excitement about using stem cells to treat Cardiac/Pulmonary Disease.”
- “Cardiac/Pulmonary Disease investigational studies using autologous SVF are ongoing and have shown great promise.”

29. PASC has also posted on Facebook and Twitter links to articles with titles like “Stem cell therapy to treat heart failure.”¹³ The full text of such articles is only viewable by clicking the title. Even if consumers were capable of understanding and assessing the studies on which the articles are based, the studies themselves do not reach definitive conclusions about the use of stem cell treatments. For example, the aforementioned article explains that the study at issue was conducted on macaque monkeys and not on humans.¹⁴ Absent adequate scientific evidence demonstrating that the results of a study on monkeys can be generalized to humans,

¹³ See <https://facebook.com/parkavenuestemcell>, July 3, 2018.

¹⁴ https://www.business-standard.com/article/news-ians/stem-cell-therapy-to-treat-heart-failure-118070300638_1.html

study results related to monkeys are insufficient scientific support for claims for effects of a treatment on humans.

30. Through such statements, Defendants have represented, directly and by implication, that PASC can effectively treat cardiac and pulmonary diseases using stem cells.

31. In fact, Defendants lack competent and reliable scientific evidence to substantiate these claims.

C. Neurology Diseases

32. As set forth in paragraph 16, Defendants highlight neurological diseases as one of the areas for which they use stem cell treatments.

33. At various times between 2016 and 2018, PASC has stated on its website:

- “There is a great deal of excitement about using stem cells to treat currently incurable diseases of the nervous system.”
- “We continue to investigate the safety and efficacy of SVF in the treatment of disorders of the nervous system,” and provides information about the treatment of multiple sclerosis, muscular dystrophy, Amyotrophic Lateral Sclerosis (“ALS”), Parkinson’s disease and stroke.

34. PASC has also posted on Facebook and Twitter links to articles with titles like “Fighting Parkinson’s Disease with Stem Cells.”¹⁵ The full text of such articles is only viewable by clicking the title. Even if consumers were capable of understanding and assessing the studies on which the articles are based, the studies themselves do not reach definitive conclusions about the use of stem cell treatments. For example, this particular article explains that the study it references was conducted on monkeys, not humans. Absent adequate scientific evidence demonstrating that the results of a study on monkeys can be generalized to humans, study results

¹⁵ See <https://facebook.com/parkavenuestemcell>, June 25, 2018.

related to monkeys are insufficient scientific support for claims for effects of a treatment on humans.

35. Through such statements, Defendants represent, directly and by implication, that PASC can effectively treat or improve neurological diseases, such as Parkinson's, using stem cells.

36. In fact, Defendants lack competent and reliable scientific evidence to substantiate such claims.¹⁶

D. Autoimmune Diseases

37. As set forth in paragraph 16, Defendants highlight autoimmune diseases as one of the areas for which they use stem cell treatments.

38. At various points between 2016 and 2018, PASC has stated on its website:

- “There is a great deal of excitement about using stem cells to treat Autoimmune Disease.”
- “The use of autologous SVF in the mitigation of Autoimmune Diseases such as Lupus, MS, Scleroderma are also being studied.”

39. PASC has also posted on Facebook and Twitter links to articles with titles like “Stem cell treatment offers new hope for multiple sclerosis patients.”¹⁷

40. The full text of such articles is only viewable by clicking the title. Even if consumers were capable of understanding and assessing the studies on which these article are based, the studies themselves do not reach definitive conclusions about the use of stem cell treatments. For example, this particular article is based on the “interim results” of an

¹⁶ <https://www.asianscientist.com/2018/06/in-the-lab/embryonic-stem-cell-parkinsons-monkey/>

¹⁷ See <https://facebook.com/parkavenuestemcell>, March 19, 2018.

international trial.¹⁸ Moreover, Defendants do not even perform the procedure discussed in the article, which involves “wiping out a patient’s immune system using cancer drugs and then rebooting it with a stem cell transplant.”¹⁹

41. Through such statements, Defendants represent, directly and by implication, that PASC can effectively treat or improve the effects of autoimmune diseases, such as multiple sclerosis, using stem cells.

42. In fact, Defendants lack competent and reliable scientific evidence to substantiate these claims.

E. Orthopedic Conditions

43. As set forth in paragraph 16, Defendants highlight orthopedic diseases as one of the areas for which they use stem cell treatments.

44. At various times between 2016 and 2018, PASC has made the following statements on its website:

- “Our center focuses on utilizing your own stem cells and targeting them for orthopedic purposes, so that your body can repair itself, without any invasive treatments.”
- “We have an [sic] intensive clinical experience in the investigation of the use of SVF to mitigate inflammation and damage in the joints.”

45. Currently, the PASC website states: “Our Park Avenue Location in NYC focuses on utilizing your own personal cells and targeting them for orthopedic purposes, so that your body can repair itself, without any invasive treatments.”

¹⁸ <https://www.bbc.com/news/health-43435868>

¹⁹ <https://www.telegraph.co.uk/science/2018/03/19/stem-cell-treatment-offers-new-hope-multiple-sclerosis-patients/>

46. PASC has also posted statements on Facebook and Twitter, such as “Stem cells work very well for osteoarthritis and other knee injuries and in many cases can obviate the need for surgery.”²⁰

47. Through such statements, Defendants represent, directly or by implication, that PASC can effectively treat or improve orthopedic conditions using stem cells.

48. In fact, Defendants lack competent and reliable scientific evidence to substantiate these claims.

F. Sports Related Injuries

49. The PASC website has claimed that PASC offers orthopedic and neurological sports medicine treatments.

50. The PASC website currently states: “We specialize in using your body’s own stem cells, growth factors, and other healing mediators to help relieve pain, improve function and promote bio-restoration of joints, tendons, ligaments, nerves and other related structures.”

51. The PASC website has further previously stated that in addition to treating orthopedic sports injuries, “We try to take it a step further and use Stem Cells to treat the entire body not just the injured body part . . . We welcome all athletes to visit our practice and learn about the benefits of Stem Cell Therapy for the treatment of Concussions and other medical conditions.”

52. Through such statements, Defendants represent, directly and by implication, that PASC can effectively treat or improve orthopedic injuries and concussions using stem cells.

²⁰ See <http://twitter.com/joelsinger12>, July 20, 2018.

53. In fact, Defendants lack competent and reliable scientific evidence to substantiate these claims.

Defendants’ Misleading Statements Regarding FDA Approval of Their Stem Cell Procedures

54. Between at least 2016 and late 2018, PASC has represented on its website, directly and by implication, that consumers receiving stem cell treatments from PASC will be participating in an FDA approved study. Thus, until recently, its website stated “This research is part of an FDA approved preliminary study IRB numbers ICSS-2016-001 through ICSS-2016-21.”

FIGURE 4



55. In fact, the FDA does not approve preliminary studies.

56. Moreover, the Institutional Review Board (IRB) is not a governmental entity.

While an IRB must register with the FDA, an IRB-approved study does not mean the study is

approved by the FDA or that the participant will experience any improvement in his or her medical condition by participating in the study.

Defendants’ Misleading References to the Existing Scientific Literature and its Participation in Clinical Studies

57. To reinforce the impression that Defendants can safely and effectively treat various conditions and that PASC’s claims about its stem cell treatments are scientifically substantiated, Defendants include references to various “scientific” studies and articles on the PASC website.

58. Between at least 2016 and late 2018, PASC’s website referred consumers to “‘A Prospective Safety Study of Autologous Adipose Derived Stromal Vascular Fraction Using a Specialized Surgical Processing System’ . . . for additional information”²¹ about its stem cell procedures.

59. However, this study does not provide sufficient substantiation for the claims that stem cells can be used to effectively treat the medical conditions referenced on PASC’s website.

60. For example, this study was conducted by the Cell Surgical Network and Drs. Elliot B. Lander, M.D. and Mark Berman, M.D., which as alleged above, are all currently being sued by the FDA “to prevent Defendants from experimenting on patients with adulterated and misbranded drugs.”²² Additionally, patients in the study included people with potential conflicts of interest, such as Dr. Berman’s nurse anesthetist and his wife.²³ Moreover, none of the initial patients were subject to placebo testing, which makes it difficult to determine whether the study’s results were caused by the treatment or by chance.²⁴ In fact, the study itself notes the

²¹ The American Journal of Cosmetic Surgery 1-14, Mark Berman, M.D. and Elliot Lander, M.D., 2017

²² FDA Complaint, ¶ 1

²³ *Id.* at 10.

²⁴ *Id.*

need for further rigorous evaluation and the need for double-blinded studies to ultimately validate the article's observations and disprove any placebo effect.²⁵ The study further notes that there was a low rate of follow-up with patients.²⁶

61. PASC's website currently provides consumers with a list of "Reference Articles and Studies," which imply that stem cells can effectively treat, cure or mitigate the symptoms of a variety of medical conditions, including but not limited to, neurological and autoimmune conditions, erectile dysfunction, cardiovascular conditions, orthopedic and urological conditions.

62. However, these articles do not provide sufficient substantiation for the claim that stem cells can be used to effectively treat the medical conditions referenced on PASC's website.

63. For example, some of these articles are based on animal studies and therefore may not be predictive for humans.

64. Other articles are based on studies that do not have appropriate controls, were not double-blinded or do not have enough participants to be statistically significant.

65. In fact, these articles often conclude themselves that additional research is needed to determine the efficacy of stem cell treatments in humans.

66. Furthermore, between at least 2016 and late 2018, PASC stated on its website that it was conducting "patient funded" research and that "we have maintained an extensive database that now includes more than 5000 patients."

67. PASC currently states on its homepage "At Park Avenue Stem Cell we are dedicated [to] continuing clinical research to gather data about the safety and the efficacy of personalized cell treatments."

²⁵ *Id.* at 13.

²⁶ *Id.*

68. Such claims overstate the scientific legitimacy of PASC’s treatments and create the impression that PASC is participating in a clinical trial or scientific research that is either FDA approved or follows generally accepted scientific protocols.

69. True clinical trials are generally designed and intended to benefit future patients and are funded by drug developers and government agencies. In fact, most clinical studies are not patient funded. In contrast, treatment funded by the patient that is intended to benefit the patient is considered medical treatment.²⁷

70. Universities, hospitals and other institutions offer controlled stem cell clinical trials that generally do not charge patients for the cost of treatment and monitoring.

71. In addition, by referencing its “extensive database” of more than 5000 patients, PASC creates the impression both that stem cell treatments are effective and that PASC has successfully treated thousands of consumers.

72. PASC fails to disclose that the database is not limited to PASC patients, but rather contains information on any patients who received stem cell procedures through the larger Cell Surgical Network.

Defendants’ Misleading References to Medical and Scientific Organizations

73. Between 2016 and late 2018, PASC also featured on its website the logos of various medical and scientific organizations, including the American Board of Surgery, American Society of Plastic Surgeons, American Board of Plastic Surgery, New York Regional Society of Plastic Surgeons, IFATS, International College of Surgeons, Regentech Alliance, New England Society of Plastic and Reconstructive Surgeons, Inc., and ISAPS.

²⁷ See <https://www.fda.gov/ForPatients/ClinicalTrials/ClinicalvsMedical/default.htm>

FIGURE 5



74. These logos create the impression that PASC’s stem cell treatments have been endorsed by these organizations.

75. However, these organizations have not endorsed PASC or any of its treatments.²⁸ Instead, they appear on the PASC website because Dr. Singer claims to be a member of these organizations, but this fact is not disclosed.

Defendants’ Misleading Use of Endorsements and Testimonials

76. Additionally, on its website, Facebook page, and GoFundMe solicitation, PASC has featured endorsements and testimonials from celebrities and other patients.

77. The Federal Trade Commission has published guidelines concerning the use of endorsements and testimonials. The guidelines are intended to set forth certain standards for determining whether endorsements and testimonials are deceptive. 16 CFR § 255.0. The guidelines are available at www.ftc.gov/opa/2009/10/endortest.shtm.

78. The guidelines provide that when advertisements contain testimonials or endorsements representing that the products or treatments advertised are effective, the advertiser

²⁸ After discussions with the NYAG, Defendants removed certain logos, including the logos for IFATS, the International College of Surgeons, and the Cell Surgical Network. In late 2018 or early 2019, after subsequent discussions with the NYAG, Dr. Singer changed the PASC website to state that he is simply a member of the organizations listed on the website.

must have competent and reliable evidence that such products or treatments are effective in achieving such results. The guidelines note that disclaimers such as “results not typical” are likely to be deceptive unless the advertiser has adequate substantiation that other users will experience similar results. 16 CFR § 255.2

79. The guidelines further provide that advertisers disclose material connections between themselves and the individuals providing testimonials or endorsements, including whether the endorser has received compensation. 16 CFR § 255.5.

80. On the PASC website and Facebook page, Curtis Sliwa, a radio show host and media personality, has stated in a video testimonial that the stem cell treatment he received at PASC alleviated his shoulder pain and that he plans to use stem cells for colitis and ileitis.

81. The PASC Facebook page also features a testimonial by National Football League (“NFL”) player Darrel Reid in the form of an interview, which Dr. Singer participates in. During this video testimonial, Dr. Singer suggests that players get stem cell treatments as a preemptive treatment for pain, and that it could be used instead of anti-inflammatory drugs like Tordol. He also claims that stem cells can speed up the healing process for NFL players, and that there are no side effects from the cells themselves.

82. While the PASC website included a fine-print, written disclaimer after the Sliwa testimonial, stating “Disclaimer: **Results of these treatments vary from individual to individual and it is not possible to predict or guarantee the outcome of any medical procedure,” this disclaimer failed to counteract the net impression of the website that stem cells are effective in treating the specified medical conditions.

83. In fact, there is no competent and reliable scientific evidence to substantiate the direct and implied claims made through these testimonials that stem cells can effectively treat shoulder pain, colitis, ileitis, or be used as a preemptive treatment for pain.

84. Moreover, upon information and belief, Mr. Sliwa and Mr. Reed received free stem cell services from PASC in exchange for their testimonials.

85. However, nowhere on PASC's website or Facebook page is it disclosed that Mr. Sliwa and Mr. Reid received free stem cell services from PASC in exchange for their testimonials.

86. The PASC website, Facebook page, and GoFundMe solicitation also contain video testimonials from patients who claim to experience an improvement in their knee and shoulder issues as well as issues related to diabetes, multiple sclerosis, Lyme disease, and chronic pain.

87. These video testimonials do not disclose that the results experienced by these patients may not be typical.

88. Moreover, there is no competent and reliable scientific evidence to support the claims Defendants make through these endorsements, namely that stem cells can effectively treat orthopedic issues, or issues related to diabetes, multiple sclerosis, Lyme disease, or chronic pain.

Additional False Claims on the PASC Website

89. PASC has recently added additional statements to the PASC website that misrepresent, directly or by implication, the nature of PASC's stem cell procedures.

90. For example, the website's homepage now states stems cells can be procured by "*minimal manipulation*" and that "[h]omologous deployment of your own cells can be accomplished by direct injection into the affected area in *the same surgical procedure.*"

(emphasis added). The website further states, next to a photograph of Dr. Singer: “These cells are *minimally manipulated* and used in an *homologous manner* in clinical research in order to obtain data to provide information about the safety and efficacy of these treatments.” (emphasis added).

FIGURE 6



91. These phrases – “same surgical procedure,” “minimally manipulated” and used in a “homologous manner” – are the factors that are considered by the FDA in determining whether stem cell products and treatments are subject to regulation under the Federal Food, Drug and Cosmetic Act (“FDCA”) and must be licensed or approved by the FDA as new drugs or biological products.

92. As noted above, the FDA filed a lawsuit against California Stem Cell Treatment Center, Inc. (“CSCTC”) and Cell Surgical Network (“CSN”) in May 2018 seeking a permanent injunction against CSCTC and CSN and their principals from marketing stem cell products without FDA approval.

93. The lawsuit alleged that CSCTC products were being used for the experimental treatment of patients who suffer from a variety of serious diseases or conditions, including cancer, arthritis, stroke, amyotrophic lateral sclerosis (ALS), multiple sclerosis (MS), macular degeneration, Parkinson’s disease, chronic obstructive pulmonary disease (COPD) and diabetes.

94. According to the FDA’s lawsuit against CSN, CSN controls the SVF-related operations of approximately 100 for-profit affiliates or licensees and requires all affiliates who join the CSN network to follow production instructions and treatment procedures and protocols developed by the CSCTC and CSN defendants. As an affiliate of CSN, PASC was therefore required to follow production instructions and treatment procedures developed by CSN and purchase specialized equipment from them.

95. Upon information and belief, while the PASC website recently no longer makes reference to CSN, PASC has not materially changed its procedures from those mandated by CSN.

96. Furthermore, according to the FDA lawsuit the products produced by CSCTC and required to be used by CSN affiliates are “human cells, tissues, or cellular or tissue-based products” (“HCT/Ps”). HCT/Ps are required to be regulated as drugs or biological products unless they meet the criteria in 21 C.F.R. § 1271.10, including that they are “intended for homologous only,” 21 CFR § 1271.10(a)(2), and are only “minimally manipulated,” 21 CFR 1271.10(a)(1). In addition, HCT/Ps are not required to be regulated as drugs if they are removed

and implanted into the same individual during the “same surgical procedure.” 21 CFR § 1271.15(b).

97. “Minimal manipulation” means “processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement.” 21 C.F.R. § 1271.3(f)(1).

98. “Homologous use” means “the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.” 21 C.F.R. § 1271.3 (c).

99. According to the FDA, using stem cells to treat conditions such as arthritis, stroke, ALS, MS, Parkinson’s disease and COPD, “bear[s] no resemblance to any function of adipose tissue, which provides cushioning and support to, among other areas, skin and organs” and therefore does not constitute “homologous use” within the meaning of the FDA regulations.²⁹

100. According to the FDA, the type of procedure used by PASC, which “alters the original relevant characteristics of the adipose tissue” constitutes more than “minimal manipulation” within the meaning of the FDA regulations.³⁰

101. According to the FDA, PASC would not qualify for the same surgical procedure exception, “because, among other things, the adipose tissue recovered from individuals is subjected to processing rendering the . . . products no longer ‘such HCT/Ps,’ but a collection of cellular components isolated from adipose tissue.”³¹

²⁹ FDA Complaint, ¶ 41.

³⁰ *Id.*, ¶ 43.

³¹ *Id.*, ¶ 45.

102. For all of the above reasons, Defendants' representations that their procedures involve "minimal manipulation," "homologous use," and the "same surgical procedure" are false and misleading.

Individual Liability of Defendant Dr. Singer

103. Defendant Dr. Singer has participated in and has knowledge of the fraudulent, deceptive and illegal acts alleged in the Complaint.

104. Dr. Singer is a principal and operates Defendant PASC.

105. He is currently the sole doctor working at PASC, and personally prescribes and administers the stem cell procedures described in the Complaint.

106. Upon information and belief, Dr. Singer is directly responsible for and has approved the representations on PASC's website, social media and other advertising.

107. He has personally appeared in videos on the PASC website, touting the benefits of PASC's stem cell procedures. For example, in one video previously featured on the PASC website, Dr. Singer personally stated "if you have an illness or injury of almost any kind, stem cells can actually help and can help heal the area more quickly and more readily than anything else," and the likelihood of complications are very low.

108. He has also appeared in a YouTube video dated May 10, 2016,³² in which he personally makes additional statements on behalf of PASC about stem cells that are clearly unsubstantiated.

109. For example, Dr. Singer states that PASC "utilize[s] the cells to treat various illnesses" and that stem cells can be used to treat arthritis, neurologic disorders, including

³² https://www.youtube.com/watch?v=GFC_yJFYBEM

Parkinson's, autoimmune diseases and other ailments. He also states that PASC is conducting research under an IRB that has to be FDA reviewed and compliant.

110. These statements are misleading because Respondents lack competent and reliable scientific evidence that stem cells can be used to effectively treat any of these conditions. Moreover, these statements falsely imply that the FDA has approved the treatments offered by PASC. As stated above, an IRB-approved study does not mean the study is approved by the FDA or that the participant will experience any improvement in his or her medical condition by participating in the study.

111. Additionally, Dr. Singer uses a personal Twitter account, <https://twitter.com/joelsinger12>, to promote PASC's stem cell procedures.

112. Moreover, as alleged above, the PASC Facebook page features a testimonial by NFL player Darrel Reid in the form of an interview, in which Dr. Singer participates.

FIRST CAUSE OF ACTION
VIOLATION OF EXECUTIVE LAW § 63(12)
FRAUD

113. The NYAG repeats and re-alleges paragraphs 1- 112 as if fully set forth herein.

114. Executive Law § 63(12) authorizes the NYAG to bring an action when any person or entity engages in repeated fraudulent acts in the operation of a business.

115. Executive Law § 63(12) broadly defines fraud to include “any device, scheme or artifice to defraud and any deception, misrepresentation, concealment, suppression, false pretense, false promise or unconscionable contractual provisions.”

116. Defendants have engaged in repeated fraudulent acts and practices in the marketing of stem cell procedures by:

- a. Representing, directly or by implication, that stem cells can effectively treat, cure, or mitigate certain medical conditions, including, but not limited to, urologic conditions, erectile dysfunction, cardiac, pulmonary, and neurological issues, autoimmune conditions, and orthopedic conditions, when these claims are either false or unsubstantiated;
- b. Falsely representing, directly or by implication, that their stem cell procedures are FDA approved or do not require FDA approval;
- c. Falsely representing, directly or by implication, that PASC is endorsed by scientific and medical organizations, including, but not limited to, the American Board of Surgery, American Society of Plastic Surgeons, American Board of Plastic Surgery, New York Regional Society of Plastic Surgeons, IFATS, International College of Surgeons, Regentech Alliance, New England Society of Plastic and Reconstructive Surgeons, Inc., and ISAPS; and
- d. Using customer testimonials without possessing competent and reliable scientific evidence regarding the effectiveness of stem cell treatments and without disclosing the existence of material connections between the customer and PASC, including the fact that the customer was compensated for the testimonial.

117. By reason of the conduct alleged above, all Defendants have engaged in repeated and persistent fraudulent conduct in violation of Executive Law § 63(12).

SECOND CAUSE OF ACTION
PURSUANT TO EXECUTIVE LAW § 63(12)
VIOLATION OF GBL § 349

118. The NYAG repeats and re-alleges paragraphs 1- 112 as if fully set forth herein.

119. Executive Law § 63(12) authorizes the NYAG to bring an action to enjoin repeated illegal acts or persistent illegality in the carrying on, conducting, or transaction of business.

120. GBL § 349 prohibits deceptive acts and practices in the conduct of any business, trade, or commerce in the state of New York.

121. Defendants have engaged in repeated and persistent deceptive acts and practices in the marketing of stem cell procedures including but not limited to:

- a. Representing, directly or by implication, that stem cells can effectively treat, cure or mitigate certain medical conditions, including, but not limited to, urologic conditions, erectile dysfunction, cardiac, pulmonary, and neurological issues, autoimmune conditions, and orthopedic conditions, when these claims are either false or unsubstantiated;
- b. Falsely representing, directly or by implication, that its stem cell procedures are FDA approved or do not require FDA approval;
- c. Falsely representing, directly or by implication, that PASC is endorsed by scientific and medical organizations, including, but not limited to, the American Board of Surgery, American Society of Plastic Surgeons, American Board of Plastic Surgery, New York Regional Society of Plastic Surgeons, IFATS, International College of Surgeons, Regentech Alliance, New England Society of Plastic and Reconstructive Surgeons, Inc., and ISAPS; and

- d. Using customer testimonials without possessing competent and reliable scientific evidence regarding the effectiveness of stem cell treatments and without disclosing the existence of material connections between the customer and PASC, including the fact that the customer was compensated for the testimonial.

122. By their actions in violation of GBL § 349, Defendants have engaged in repeated and persistent illegal conduct in violation of Executive Law § 63(12).

THIRD CAUSE OF ACTION
PURSUANT TO GBL § 349(b)
VIOLATION OF GBL § 349

123. The NYAG repeats and re-alleges paragraphs 1- 112 as if fully set forth herein.

124. GBL § 349(b) authorizes the NYAG to bring an action to enjoin deceptive acts or practices in the conduct of any business, trade, or commerce in the state of New York.

125. GBL § 349 prohibits deceptive acts and practices in the conduct of any business, trade, or commerce in the state of New York.

126. Defendants have engaged in deceptive acts and practices in the marketing of stem cell procedures including but not limited to:

- a. Representing, directly or by implication, that stem cells can effectively treat, cure or mitigate certain medical conditions, including, but not limited to, urologic conditions, erectile dysfunction, cardiac, pulmonary, and neurological issues, autoimmune conditions, and orthopedic conditions, when these claims are either false or unsubstantiated;
- b. Falsely representing, directly or by implication, that its stem cell procedures are FDA approved or do not require FDA approval;

- c. Falsely representing, directly or by implication, that PASC is endorsed by scientific and medical organizations, including, but not limited to, the American Board of Surgery, American Society of Plastic Surgeons, American Board of Plastic Surgery, New York Regional Society of Plastic Surgeons, IFATS, International College of Surgeons, Regentech Alliance, New England Society of Plastic and Reconstructive Surgeons, Inc., and ISAPS; and
- d. Using customer testimonials without possessing competent and reliable scientific evidence regarding the effectiveness of stem cell treatments and without disclosing the existence of material connections between the customer and PASC, including the fact that the customer was compensated for the testimonial.

127. By their actions, Defendants have violated GBL § 349.

FOURTH CAUSE OF ACTION
PURSUANT TO EXECUTIVE LAW § 63(12)
VIOLATION OF GBL § 350

128. The NYAG repeats and re-alleges paragraphs 1- 112 as if fully set forth herein.

129. Executive Law § 63(12) authorizes the NYAG to bring an action to enjoin repeated illegal acts or persistent illegality in the carrying on, conducting, or transaction of business.

130. GBL § 350 prohibits false advertising in the conduct of any business, trade, or commerce in the State of New York

131. Defendants have engaged in deceptive acts and practices in the marketing of stem cell procedures including but not limited to:

- a. Representing, directly or by implication, that stem cells can effectively treat, cure or mitigate certain medical conditions, including, but not limited to, urologic conditions, erectile dysfunction, cardiac, pulmonary, and neurological issues, autoimmune conditions, and orthopedic conditions, when these claims are either false or unsubstantiated;
- b. Falsely representing, directly or by implication, that its stem cell procedures are FDA approved or do not require FDA approval;
- c. Falsely representing, directly or by implication, that PASC is endorsed by scientific and medical organizations, including, but not limited to, the American Board of Surgery, American Society of Plastic Surgeons, American Board of Plastic Surgery, New York Regional Society of Plastic Surgeons, IFATS, the International College of Surgeons, Regentech Alliance, New England Society of Plastic and Reconstructive Surgeons, Inc., and ISAPS; and
- d. Using customer testimonials without possessing competent and reliable scientific evidence regarding the effectiveness of stem cell treatments and without disclosing the existence of material connections between the customer and PASC, including the fact that the customer was compensated for the testimonial.

132. By their actions in violation of GBL § 350, Defendants have engaged in repeated and persistent illegal conduct in violation of Executive Law § 63(12).

PRAYER FOR RELIEF

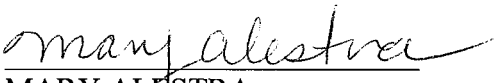
WHEREFORE, Plaintiff requests an order and judgment:

- a. Permanently enjoining Defendants from engaging in the fraudulent, deceptive, and illegal acts and practices alleged in the Complaint;
- b. Directing Defendants to render an accounting to the NYAG of the name and address of each former and current customer of Defendants, and the amount of money received from each such former and current customer;
- c. Directing Defendants to make full monetary restitution and pay damages to all injured persons or entities;
- d. Directing Defendants to produce an accounting of profits and to disgorge all profits resulting from the fraudulent and illegal practices alleged herein;
- e. Directing Defendants to pay a civil penalty to the State of New York of up to \$5,000.00 for each violation of GBL Article 22-A, pursuant to GBL § 350-d;
- f. Awarding Plaintiff additional costs of \$2,000.00 against each Defendant pursuant to CPLR § 8303(a)(6); and
- g. Granting such other and further relief as the Court deems just and proper.

Dated: New York, New York
April 3, 2019

Respectfully submitted,

LETITIA JAMES
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