

**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 LETITA JAMES, Attorney General of the  
State of New York

Index No.: 450389/19

Plaintiff,

-vs-

**DEFENDANTS' ANSWER AND  
COUNTERCLAIMS**

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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Defendants, by their attorney, Richard A. Jaffe, Esq. submit this ANSWER AND  
COUNTECLAIMS to the COMPLAINT and would show as follows:

**INTRODUCTION**

**The Context of this Case: Stem Cell Transplantation is the Cutting-Edge Standard  
of Care in the United States, as is the Dissemination of Information and Advocacy  
for these Procedures**

1. The complaint commencing this lawsuit focuses on one physician's dissemination of information to the public about an autologous (same person) stem cell surgical procedure he uses in his private medical practice. However, missing from the complaint is the fact that many of the country's leading medical institutions, as well as hundreds of other cutting-edge medical clinics across the nation, are using the same procedure as the Defendants.
2. Furthermore, all of these leading hospitals and other medical facilities are publicly

advocating for this surgical procedure, and relating their clinical experience on their websites and through the media, *just like the Defendants are doing on their website.*

3. This surgical procedure employed by the Defendants and all these other facilities involves surgically removing belly fat (liposuction), separating out the stem cells and growth factors, and re-implanting it back into the patient during the same surgical procedure.
4. This procedure is part of the explosive growth in the field of Regenerative Medicine, which seeks to restore health rather than merely treat disease with the use of human adult stem cells, either someone else's cells (allogenic) or the patient's own cells, (autologous).
5. The procedure utilized by all these major institutions and clinics like the Defendants can now be considered the standard of care, at least at the most advanced medical centers and clinics, in part because of patient demand for more effective treatments for chronic conditions than had been available in the prior century and the first decade of this century.
6. For example, New York City's Weil Cornell Medical Center publicly states:  
"Regenerative medicine is a powerful, new approach that harnesses the body's ability to heal damaged tissue, offering new solutions to people with joint, tendon, and soft tissue injuries. The field of regenerative medicine includes innovative treatments, such as:  
• **Stem cell therapy:** Involves taking stem cells from different areas of the body, which can then be utilized in the form of therapeutic stem cell injections to promote the repair or regeneration of damaged tissue; stem cells are unique in their ability to

develop into many different types of cells through a process called cell differentiation.”

<https://weillcornell.org/regenerative-medicine>.

7. *Is Weil Cornell engaged in the same kind of fraudulent conduct as alleged against the Defendants?*
8. The Cleveland Clinic, which is one of the top hospitals in the US, also uses and advocates these surgical procedures.  
<https://health.clevelandclinic.org/stem-cell-injections-emerging-option-for-joint-pain-relief-2/>.
9. Are the “PEOPLE OF THE STATE OF NEW YORK” going to sue the Cleveland Clinic on behalf of New York consumers who view its website and who have been “harmed” as consumers for seeing the Cleveland Clinic’s stem cell treatment information?
10. The world famous Swedish Medical Center in Seattle offers similar treatments and one of its physicians has gone on local news promoting the benefits of stem cell, regenerative medicine therapies. <https://californiahealthline.org/news/elite-hospitals-plunge-into-unproven-stem-cell-treatments/>.As quoted from that article:

“Swedish is one of a growing number of respected hospitals and health systems — including the Mayo Clinic, the Cleveland Clinic and the University of Miami — that have entered the lucrative business of stem cells and related therapies, including platelet injections. Typical treatments involve injecting patients’ joints with their own fat or bone marrow cells. Many hospitals, like Cedars-Sinai Medical Center in Los Angeles, offer extracts of platelets, the cell fragments known for their role in clotting blood.”

Are all these clinics really engaged in false advertising, deceptive trade practices and

fraud because they talk about the non-FDA approved treatments they are offering? All or most of this content is available to New York consumers and they suffer the same “harm” (whatever that means) as the New York consumer allegedly harmed by Defendants’ content. How does that make any sense?

11. Here are just a few of the many other New York clinics offering similar surgical procedures and with similar web content information:

<https://www.nationalstemcellcenters.com/contact-us/new-york/>  
<https://stemcellsspecialistny.com/> <https://www.progressivespineandsports.com//regenerative-treatments-stem-cell-injections/>  
<https://advancedcellmedicine.com/save-big-on-stem-cell-treatment/>;  
<https://nycstemcells.com/>  
<http://manhattanspine.com/stem-cell.html>  
<https://nycstemcells.com/>  
<http://manhattanspine.com/stem-cell.html>  
<https://www.stemcellstherapynyc.com/>  
<https://www.samwellpain.com/>  
<http://regenxx.nyc/>  
<https://www.med-stem.com/>

Are all these New York clinics fraudsters as well? If so, where are all the lawsuits against these clinics and all the world-famous clinics cited above who are harming New York citizens by publicizing their surgical procedures and the benefits that might be achieved therefrom?

### **Some Perspective on the Safety and Efficacy of Stem Cell Surgical Procedures Compared to Synthetic Pharmaceuticals agents**

12. Unlike chemical synthetic drugs which only have very limited safety data while going through the full FDA drug approval process, stem cell surgical transplantation procedures have dozens if not hundreds of published studies showing the safety of the procedure. Attached as Exhibit “A” is a short and partial list of publications on the safety data of these surgical procedures.

13. In addition to all these individual studies demonstrating the safety of these surgical procedures, last year a peer reviewed journal article identified every single publicly reported serious adverse effect from stem cell surgical procedures similar to Defendant's procedure. The search found fewer than 40 adverse events reports in the world, including 11 deaths, one of which was in the U.S.
- <https://stemcellsjournals.onlinelibrary.wiley.com/doi/full/10.1002/sctm.17-0282>.
14. By comparison, Fentanyl which is FDA approved as safe and effective is 50 times more potent and addictive than heroin, and killed over 28,000 people in 2017 alone.
- <https://www.cdc.gov/drugoverdose/data/fentanyl.html> In what meaningful and realistic way are autologous stem cell surgical procedures unsafe compared to FDA approved Fentanyl?
15. In terms of efficacy, last year there were 609,000 U.S. cancer deaths.
- <https://www.cancer.gov/about-cancer/understanding/statistics>. Most received one or more FDA approved drugs, and or received treatment via FDA cleared medical devices such as radiation machines. All of these drugs and devices are FDA proven safe and effective for the treatment of cancer, but FDA proven safe and effective doesn't mean they work in the sense of effectuating a cure. Many if not most of cancer drugs are approved by the FDA as effective not because they cure cancer but because they meet some "surrogate endpoint" like a temporary tumor shrinkage.<sup>1</sup>

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<sup>1</sup> "In clinical trials, an indicator or sign used in place of another to tell if a treatment works. Surrogate endpoints include a shrinking tumor or lower biomarker levels. They may be used instead of stronger indicators, such as longer survival or improved quality of life, because the results of the trial can be measured sooner. The use of surrogate endpoints in clinical trials may allow earlier approval of new drugs to treat serious or life-threatening diseases, such as cancer. Surrogate endpoints are not always true indicators or signs of how well a treatment works."

FDA safety and efficacy conclusions are, as evidenced by the above two examples, are relative terms. More to the point, how does the FDA continue to allow a drug on the market which has killed 28,000 people in one year alone, while trying to stop physicians doing surgical procedures using a patient's own body parts, which has a total of 39 reported adverse events in the world, and where the same basic surgical procedure has been used for the last 40 years?<sup>2</sup> Many health scholars have suggested that the problem with the FDA is a result of institutional corruption by the Pharmaceutical industry. See e.g. *Institutional corruption of pharmaceuticals and the myth of safe and effective drugs*, Light DW, et al. J Law Med Ethics. 2013

<https://www.ncbi.nlm.nih.gov/m/pubmed/24088149/>; See also,

<https://ethics.harvard.edu/pharmaceutical-industry-institutional-corruption-and-public-health> ;

<https://www.cbsnews.com/news/fda-corruption-letter-authenticated-lawyers-start-your-engines/> ; <https://www.globalresearch.ca/the-evils-of-big-pharma-exposed/5425382> ;

[https://www.thedailybeast.com/big-pharma-is-americas-new-mafia](https://www.thedailybeast.com/big-pharma-is-americas-new-mafia;);

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<https://www.cancer.gov/publications/dictionaries/cancer-terms/def/surrogate-endpoint>

<sup>2</sup> Liposuction has been in use since the mid-1970's, and autologous stem cell and bone marrow transplants have been used since the 1980s, mostly to repopulate a patient's bone marrow and blood cells after their immune system have been destroyed as a result of high dose chemotherapy as a treatment for advanced cancer.

**There is no Possible Risk of General “Consumer Harm” Raised in this Case.**

16. This case involves a surgical procedure, not the sale of a product. That makes it different than most cases which the Plaintiff files under the false advertising and fraud statutes on behalf of consumers, for the simple reason that Defendants do not deal with internet or even face-to-face consumers. They deal with prospective patients and patients. There is no conceivable harm which could befall or consumer unless he/she becomes a patient.
17. However, the clinic provides patients with detailed informed consent about the surgical procedure they undergo, and the informed consent documents have been approved by a federally registered Institutional Review Board. Therefore, in evaluating the causes of action in the complaint, the finder of fact must consider the informed consent documents and process to determine the “net effect” of the claims made by the Defendants.

**New York Patients Have The New York Constitutional And Privacy Rights To Utilize Their Own Body Parts For Treatment And The First Amendment Rights To Receive All Available Information About These Medical Procedures Without The Government Filtering Content Based On The Plaintiff’s Asserted Position That Patients Are Not Sufficiently Intelligent To Comprehend The Meaning Of The Content On Defendants’ Website**

18. As stated, the surgical procedure involved in this case involves removing fat from the patient, separating the stem cells and growth factors, and re-implanting it back into the patient, during the same surgical procedure. In other words, a patient is using his own body parts to heal him/herself. That makes it different from much of medicine which uses a foreign chemical agent, or biological materials from animals or other humans, because of personal freedom issues/a person’s right to control his/her own

body.

19. Fortunately, there is long-standing New York precedent establishing a New York citizen's right to control their own bodies, and that precedent comes from none other than Judge Benjamin Cardoza, who held that that a person had a right "to determine what shall be done with his own body," *Schloendorff v. Society of the New York Hospital*, 211 N.Y. 125, 129, 105 N.E. 92 (1914) (Cardozo, J.) (*overruled on other grounds by Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 3 (1957)).
20. More recent New York jurisprudence has specifically held that the Cardoza established right to control one's body includes the right to receive unconventional and even non-FDA approved treatment, and that patients can assume the risk of such treatment if provided with proper informed consent. *Schneider v Revici* 817 F.2d 987 (2<sup>nd</sup> Cir. 1987). The right to provide unconventional treatment is now firmly recognized by state statute, namely NY Education law 230 (9). So, even assuming arguendo that some aspects of Defendants' surgical procedures are not considered standard of care, they are nonetheless permitted in New York under the above stated precedent and statute.
21. Furthermore, informed consent requires that the patient be provided with as much information about the treatment as possible, and that would include information about which could be relevant to a patient's decision to undergo a surgical procedure. Plaintiff's position in this action conflicts with or is at odds with the physician's obligation to provide as much information as is available to assist the patient in understanding the risks and benefits of the proposed surgical procedure.
22. The notion that consumers who become patients are too stupid or unsophisticated



to understand that an animal study doesn't mean that the product or procedure will work on humans, might have been a reasonable argument to make in the nineteenth or twentieth centuries, but is antiquated and offensive in the age of the internet.

Information is instantly available; the positive and negative about the stem cell therapies currently being offered and talked about on the websites like the Defendants, Weil Cornell, the Mayo Clinic, Cleveland Clinic, the Swedish Medical Center and the hundreds of other private clinics advocating and informing the public about regenerative medicine surgical procedures.

23. Finally, the New York courts should have little concern about weighing in on these important health care issues, even though the issues implicate federal law and policy. In the past decade, the states have repeatedly bypassed Congress and federal regulators to address their citizens health concerns, by allowing access to products illegal under federal law, as well as taking action against companies producing legal, but deadly products.

24. For example, medical marijuana is an illegal Schedule 1 substance, for which there is no approved medical use. And yet, the legislatures of 31 states, plus the District of Columbia have laws broadly allowing the use of marijuana and cannabis. <https://www.governing.com/gov-data/safety-justice/state-marijuana-laws-map-medical-recreational.html>. These laws directly contradict federal DEA law and policy, but were deemed necessary to provide people with a treatment thought by many medical authorities to be effective or potentially effective. And the irony shouldn't be lost on the Court that marijuana is now legal in the District of Columbia, the home of the federal government!

25. In the past few years, 41 states have passed so-called “Right-to-Try” laws under which patients have the right to try experimental, unapproved drugs which are in post-Phase 1 clinical trials, despite the fact that the use these drugs outside of clinical trials (and FDA approved special exemption) is a violation of the federal FDA law. Because of nationwide pressure, last year Congress passed a watered-down version of the Right-to-Try law (S204). But until that time, (May 2018) every patient who was treated under a state Right-to-Try law was treated illegally under federal law.
26. In the marijuana and Right-to-Try contexts, the states did what they had to do to help patients to circumvent federal bureaucratic mindless obstinance.
27. Defendants welcome the opportunity to have the New York courts consider these important issues of access to treatment and access to information in the internet age, help move past the paternalist, degrading and offensive public policy arguments manifest in the complaint, and to protect the rights of New York citizens, as the New York courts have done in the past.

#### **DEFENDANTS’ ANSWER TO THE ALLEGATIONS IN THE COMPLAINT**

28. Defendants admit that the FDA issued a press release containing the information set forth in Paragraph 1 of the Complaint, but deny that the press release contains a full and fair description of the state of stem cell therapies and the science behind it.
29. Defendants admit paragraph 2 accurately quotes the FDA press release, but deny that the FDA has ever issued a formal, final or binding determination as to its regulatory authority or its position with respect to stem cell products, as stated in the

FDA press release. FDA guidance documents and press releases are not legally binding on the FDA or any company or individual, according the FDA.

<https://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm073004.pdf>, a position which the FDA has taken in Court as a defense to

a company trying to overturn such informal and non-binding FDA pronouncements.

*Holistic Candles and Consumers Ass'n v. FDA*, 664 F.3d 940 (D.C. Cir. 2012)

30. With regard to paragraph 3, admit that Defendants offer stem therapy using the patient's own adipose tissue for a fee and that data is collected pursuant to Institutional Board Review (IRB), non FDA approved study, and that the information collected from the patients in the study have been submitted to a data base showing the results of treatment, which results have been published in a peer reviewed journal, which showed the general efficacy of such treatment. Defendants refer the Court to their website for a true and accurate description of the conditions treated. Defendants deny the other allegations in the paragraph 3, and specifically deny that the surgical procedure has any proven harm, when administered by properly credentialed and trained physicians.
31. Defendants deny the allegations in the first sentence in paragraph 4. Admit that the FDA has filed a lawsuit against two California stem cell clinics and the CSN, which Defendants herein were previously affiliated through a co-investigator agreement and other related agreements. Defendants refer the Court to the pleadings and other documents in that case for a true and correct recitation of the matters addressed therein.
32. Defendants deny the allegations in paragraph 5 of the Complaint, except that admit that the Attorney General has filed the instant action which sets forth certain relief requested, as set forth therein.

**PARTIES AND JURISDICITON**

33. Defendants admits the allegation in paragraph 6.
34. With respect to paragraph 7, Defendants admit that New York Executive Law and GBL Article 22-A contain the statutes cited in this paragraph, but deny that these statutes support the relief set forth therein against the Defendants.
35. Defendants admit the allegations in paragraph 8.
36. Defendants admit the allegations in paragraph 9.
37. Defendants admits the allegations in paragraph 10.
38. With regard to paragraph 11, Defendants admit that Defendant Singer is a co-investigator of various non FDA clinical trials sponsored by individuals who are affiliated with the Cell Surgical Network (CSN), that pursuant to investigator and various other documents Defendant Singer is obligated to follow the clinical study protocols (as all co-investigators in all clinical studies are required to do) regarding, *inter alia*, the administration of the study materials, and other aspects set forth in the protocol and other documents relating thereto. The Court is referred to those documents for the exact terms, conditions and obligations for a true and correct understanding of the relationship between CSN and Dr. Singer. Defendants deny the other allegations in this paragraph.

**DEFENDANTS' STATEMENT OF PARTIES**

39. Defendant Joel Singer is a graduate of Queens College, CUNY and the Yale University School of Medicine. He did his post graduate training in surgery and plastic surgery in New Haven at Yale and Rhode Island at Brown University Hospitals leading

to board certification in plastic surgery. During this time, Dr. Singer served as a Captain in the US Army Medical Corp Reserves during the Vietnam conflict.

40. After his training, Dr. Singer worked in private practice and as a part time clinical attending in the department of plastic surgery at Yale University School of Medicine, and did research in wound healing. In 1991 he started doing missionary work on behalf of Healing the Children, PE, and led plastic surgery trips to Columbia, and to Mainland China for 15 years to collaborate with the local plastic surgeons to take care of birth defects in children.

41. He was attracted to plastic surgery because of its emphasis on wound healing and reconstruction, so when Dr. Singer learned of the new technology that was developed in 2008 allowing for the extraction of stem cells from adipose tissue, he was very intrigued. After attending numerous scientific meetings, he started doing these procedures in his practice. Using stem cells to heal from within was just an extension of everything he understood about plastic surgery. The cells were found to improve healing from burns, soften scar tissue damaged from radiation treatment and enhance the longevity of fat transfer procedures.

42. Dr. Singer focused his efforts to perfect his stem cell extraction techniques and starting in 2015 focused his practice in the use of stem cells to help improve the lives of many people. Stem cell therapy has the potential to heal the human body in a natural way. His clinical work also involved the collection of patient data so that these techniques could be compared to the work of his colleagues. In order to do this best, he participated in the data collection being done by the Cell Surgical Network.

**FACTS**

43. Defendants admit the allegations in paragraph 13.
44. Defendants admit the allegations in paragraph 14, and in fact, the patients did participate in what is described in the complaint as patient funded research, which resulted in reporting of results and the publishing of articles about the results of these patient funded studies. Defendants admit that there is a website on which there is a great deal of information about stem cell therapy and the basic science of stem cells as stated or implied in paragraph 15. Defendants deny that the website is properly characterized as simply advertising. It also involves informational content about specific conditions, treatment options, and discussion about the promise of stem cell therapy. As such, the content is protected by the First Amendment.
45. Defendants deny the allegations in paragraph 16, and refer the Court to the content referred to for an accurate description and characterization of said content.
46. Defendants admit that the content set forth in paragraph 17 comes from Defendants' website.
47. With respect to paragraph 18, Defendants admit that the quoted and depicted content comes from Defendants' website, refer the Court to the content for a true and accurate determination of the proper characterization thereof and deny the remaining allegations or implications in paragraph 18.
48. Defendant Singer admits that he has used the GoFundMe on-line vehicle as set forth in paragraph 19.
49. Deny the allegations in paragraph 20. Specifically, paragraph 20 quotes some unreferenced isolated statements by the FDA about stem cells in general, and falsely

states or implies that these statements concerning lack of substantiation of “stem cells” were made by the FDA concerning PASC’s surgical procedure or have anything to do with PASC’s specific medical practice.

50. With regard to paragraph 21 of the complaint, admit that there are disclaimers on PASC’s home page and on other pages that the treatment is not a cure for any condition or disease. Denys that the disclaimers fail to change the net impression that stem cells will effectively treat a variety of conditions. Defendants refer the Court to the website for a true and complete reference to placement, net impression and other issues raised in this allegation.

**A. Urological Conditions**

51. Defendants admit the allegations in paragraph 22.
52. Defendants admit the allegations in paragraph 23. All the quoted statements in this paragraph accurately reflect the conditions for which Defendants’ treatment has been employed.
53. With respect to paragraph 24, Defendants admit that they have made the posts set forth in the first sentence. Admit that the full text of the articles referred to is only viewable by clicking on the title, as set forth in the second sentence of paragraph 24. With respect to the remaining allegations, Defendants deny that consumers lack the mental capacity to understand the articles referenced therein, as stated or implied in the third sentence of paragraph 24. Defendants admit that some of the articles explain that further follow-up for additional studies are required, as set forth in the fourth sentence of paragraph 24. Defendant maintains that consumers and patients have the mental capacity to understand the meaning and implications of the statement that further

studies are needed to confirm results.

54. Deny the allegations in paragraph 25 and refer the Court to the representations on Defendants' website.

55. With respect to paragraph 26, deny that the standard to be used in this case is "competent and reliable scientific evidence to substantiate such claims." Defendants maintain that the state of the scientific literature and clinical experience is sufficient to allow the use of the surgical procedure and to make the representations made on Defendants' website.

#### **B. Cardiac/Pulmonary Disease**

56. Defendants admit the allegations contained in paragraph 27 of the complaint.

57. Defendants admit the allegations contained in paragraph 28 of the complaint.

58. With respect to paragraph 29 of the complaint, Defendants admits to the Facebook and Twitter posts and links to articles as set forth in the first paragraph of paragraph 29. Defendants deny the implication set forth in the second sentence of paragraph 29 that consumers do not have the mental capacity to understand the significance and implications of the studies referred to on Defendants' website. Further, Defendants deny that consumers do not have the capacity to understand the difference between a study on humans and one done on monkeys, which is stated or implied by the fourth sentence of paragraph 29. Deny the remaining allegations of paragraph 29 regarding the role of large animal studies on the representations made on Defendants' website.



59. Defendants deny the allegations in paragraph 30, and respectfully refer the Court to the website for a determination of what representations were made or implied therefrom.

### **C. Neurological Diseases**

60. Defendants admit the allegations in paragraph 32 of the complaint.

61. Defendants admit the allegations contained in paragraph 33 of the complaint.

With respect to paragraph 34, defendants admit that they made the posts on Facebook and Twitter with the link set forth in the first sentence of paragraph 34. Defendants admit that the full text of such articles are only viewable by clicking on the title as set forth in the second paragraph of 34. Defendants deny this stated or implied view that consumers do not have the mental capacity to understand or assess the studies referenced therein, or cannot understand that the study specifically states that no definitive conclusions about stem cells can be reached. As stated above, with respect to the allegations in the complaint about other diseases, Defendants deny that consumers are unable to understand the difference between a large animal study and a human study, as stated or implied in the third sentence of paragraph 34. Defendants deny the remaining allegations of this paragraph.

62. Defendants deny the allegations in paragraph 35 of the complaint and respectfully refer the Court to the website for a true and accurate view of the representations made therein.

### **D. Autoimmune Disease**

63. Defendants admit the allegations contained in paragraph 36 of the complaint.

64. Defendants admit the allegations contained in paragraph 37 of the complaint.

65. Defendants admit the allegations contained in paragraph 38 of the complaint.
66. Defendants admit the allegations contained in paragraph 39 of the complaint,
67. With respect to paragraph 40 of the complaint, Defendants admit that the text of the articles referenced therein is only viewable by clicking on the title as set forth in the first sentence of paragraph 40. Deny the statement or implication that consumers are unable to understand the nature and implications of these materials as stated or implied in the second sentence of paragraph 40. Defendants admit that the study referred to in this paragraph are “interim results” and that the procedure used by the Defendants is different than the procedure used in the study referred to therein, as alleged in the third and fourth sentences of paragraph 40.
68. Defendants deny the allegations contained in paragraph 41 of the complaint and respectfully refer the Court to the website for a determination as to the import or intent of the references to these studies and the significance therein.
69. With respect to paragraph 42, Defendants deny that the standard in this case is “lack of competent reliable scientific evidence to substantiate these claims” and maintain that the studies referenced on the website and clinical experience are sufficient and adequate to justify Defendants’ use of the treatment and the representations made on the website.

#### **E. Orthopedic Conditions**

70. Defendants admit the allegations contained in paragraph 43 of the complaint.
71. Defendants admit the allegations contained in paragraph 44 of the complaint.
72. Defendants admit that as of the date of the filing of the complaint, Defendants’ website contains the quote set forth in paragraph 45 of the complaint.

73. Defendants admit the allegations contained in paragraph 46 of the complaint.

74. With respect to paragraph 47 of the complaint, Defendant deny the allegations and refers the Court to the website for the proper interpretation of the matters set forth therein.

75. Defendant deny that the appropriate or relevant standard in this case is “competent and reliable scientific evidence to substantiate these claims” and maintain that the studies and other information contained on the website as well as other materials justify the claim set forth on the website.

#### **F. Sports Related Injuries**

69. Defendants admit the allegations contained in paragraph 49 of the complaint.

70. Defendants admit the allegations contained in paragraph 50 of the complaint.

71. Defendants admit the allegations contained in paragraph 51 of the complaint.

72. Defendants deny the allegations contained in paragraph 52 of the complaint and refer the Court to the website materials referred to therein for an accurate and correct understanding of what is directly represented or represented by location.

73. Defendants deny that the appropriate or relevant standard in this case is “competent and reliable scientific evidence to substantiate these claims” as alleged in paragraph 54, and maintain that the studies and other information contained on the website, and clinical experience as well as other materials justify the claim set forth on the website.

#### **Defendants’ Alleged Misstatements Regarding FDA Approval of their Stem Cell Procedure**

74. Defendants admit the allegations set forth in paragraph 54 of the complaint and was true to the best of Defendants’ knowledge and belief until November 2018,

whereupon the statement was removed from the website, at the specific request of the Plaintiff. Defendants did so voluntarily.

75. Defendants admit the allegations contained in paragraph 55 of the complaint.

76. Defendants admit the allegations contained in paragraph 56 of the complaint.

**Defendants' Alleged Misleading References to the Existing Scientific Literature and its Participation in Clinical Studies**

77. Defendants deny the allegations contained in paragraph 57 the complaint, but admits that it does make reference to various scientific studies and articles on its website.

78. Defendants admit the allegations contained in paragraph 58.

79. With respect to paragraph 59 of the complaint, deny that this is that the standard to be employed is “sufficient substantiation of the claims” and further deny that the study referenced therein was ever intended to be the sole basis of the treatments employed by the Defendants or the claims made in the website. Defendants admit the remaining allegations set forth in paragraph 59.

80. Defendants deny the allegations contained in the first sentence of paragraph 60, except admit that the individuals and company referred to therein did conduct the study, and those individuals are defendants in the current lawsuit involving the FDA. Defendant respectfully refers the Court to the pleadings in that lawsuit for a true and correct understanding of the allegations set forth in that lawsuit. Defendants deny knowledge and information sufficient to form a belief about the truth or falsity of the second sentence in paragraph 60. With respect to the third sentence of paragraph 60, Defendants do not understand how a patient in a clinical study could be subject to

“placebo testing.” Deny the other allegations contained in the sentence. Defendants admit that the quoted statements in the last two sentences of paragraph 60 are in the referenced article, and refer the Court to the article cited therein for a true, correct and complete understanding of the matters set forth in these last two sentences of paragraph 60.

81. With respect to paragraph 61, Defendants admit that the website currently provides consumers with reference articles and studies, but deny the remaining allegations and refer to the Court to the website and the reference articles and studies listed therein for a true accurate and complete representation of the matters asserted.
82. Defendants deny the sufficient substantiation standard applies, and denies that the published studies and clinical experience do not justify the claims made on the website.
83. Admit the allegations in paragraph 63 of the complaint.
84. Admit that some of the studies were not double-blind, but deny that double-blind studies are necessary with respect to testing of stem cell therapies. Deny knowledge or information sufficient to form a belief as to the veracity of the other allegations in paragraph 64 the complaint, at this time.
85. Admit the allegations in paragraph 65 of the complaint.
86. Admit the allegations in paragraph 66 of the complaint.
87. Admit the allegations in paragraph 67 of the complaint
88. Deny the allegations in paragraph 68 of the complaint.
89. With respect to paragraph 69, deny the allegations in the first sentence. Admit that most clinical studies are not patient funded, as set forth in the second sentence of paragraph 69. Deny the third sentence of paragraph 69, insofar as a treatment can be

both medical treatment as well as clinical research, which could benefit future patients.

90. Admit the allegations in paragraph 70 of the complaint.
91. Deny the allegations in paragraph 71.
92. Deny the allegations in paragraph 72 of the complaint. The database listed references a study and article written by the two principal investigators who maintain the data base and it is not Defendant Singer, nor does it refer to the Defendant entities, but rather the CSN group. That is adequate disclosure that Defendants did not treat all 5,000 database/study participants.

#### **Defendant's Alleged Misleading Reference to Scientific Organizations**

93. Defendants admit the allegations in paragraph 73 of the complaint.
94. Defendants deny the allegations in paragraph 74 of the complaint.
95. Admits that these organizations have not endorsed Defendants' treatment as alleged in the first sentence of paragraph 75 of the complaint. Admit that Defendant Singer claims to be a member of these organizations as stated within the second sentence of paragraph 25, but denies this fact is not disclose the website.

#### **Defendant's Alleged Misuse of Endorsements and Testimonials**

96. Defendants admit the allegations contained in paragraph 76 of the complaint.
97. With respect to paragraph 77 of the complaint, the Defendants admit that the FTC has published guidelines concerning endorsements and testimonials and refer the Court to the guidelines cited therein. Deny that the guidelines apply to the Plaintiff's burden or standard of proof on the causes of action in this case is based on these FTC guidelines.
98. With respect to paragraph 78 of the complaint, deny the allegations, except that

refers the Court to the guidelines for true and accurate recitation of the requirements therein. Deny that the FTC guidelines apply to Plaintiff's case.

99. Deny the allegations in the paragraph 79 of the complaint, and refer the Court to the guidelines for correct analysis of the requirements set forth therein.
100. Admit the allegations in paragraph 80 of the complaint.
101. Admit the allegations of paragraph 81 of the complaint.
102. Deny the allegations in paragraph 82 except admits the references to what is listed on the website are accurate.
103. Deny that the standard used in this case is "competent and reliable scientific evidence to substantiate the direct implied claims" because set forth in paragraph 83 the complaint. Defendants maintain that there is sufficient evidence and clinical experience to support the use of stem cell treatments, and the information contained on the website.
104. Deny the allegations in paragraph 84 of the complaint.
105. Defendants admit that there was no such disclosure as set forth in paragraph 85, because these individuals did not receive a fee so there was no fee to disclose. (The individuals did however receive a discount on the treatment.)
106. Defendants admit the allegations in page 86 of the complaint.
107. Defendants admit the allegations in paragraph 87 the complaint, however the website discloses in several places that results achieved in the testimonials may not be what another patient might experience.
108. Defendants deny that the standard in this case is "competent and reliable scientific evidence to support the claims" as set forth in paragraph 88 of the complaint. Defendants maintained that there is ample scientific evidence and clinical experience to

support the use of the treatment.

**Alleged Additional False Claims on the PASC Website**

109. Defendants deny the allegations in paragraph 89 of the complaint.
110. Defendants admit the allegations in paragraph 90 of the complaint.
111. Defendants admit the allegations in paragraph 9 of the complaint.
112. Defendants admit the allegations in paragraph 92 of the complaint.
113. Defendants admit the allegations in paragraph 93 of the complaint.
114. Defendants deny the allegations in paragraph 90 for the complaint and respectfully refer the Court to the pleadings in that case refer to therein for a true and accurate representation of the allegations made by the FDA against those Defendants.
115. Defendants admit the allegations in paragraph 95 of the complaint.
116. Defendants admit the allegations in paragraph 96 of the complaint.
117. Defendants admit the allegations n paragraph 97 of the complaint.
118. Defendants admit the allegations in paragraph 98 of the complaint.
119. With respect to paragraph 99, Defendants admit that the allegation accurately states the FDA's position in the lawsuit referenced therein.
120. Defendants denies the allegations in paragraph 99 of the complaint.
121. Defendants deny the allegations in paragraph 100 of the complaint.
122. Defendants deny the allegations in paragraph 101 of the complaint.
123. Defendants deny the allegations in paragraph 102 of the complaint.

**Alleged Individual Liability of Defendant Dr. Singer**

124. Defendants deny the allegations in paragraph 103 of the complaint.
125. Defendants admit the allegations contained in paragraph 104 the complaint.



- 126. Defendants admit the allegations in paragraph 105 of the complaint.
- 127. Defendants admit the allegations in paragraph 106 of the complaint.
- 128. Defendants admit the allegations contained in paragraph 107 of the complaint.
- 129. With respect to paragraph 108 of the complaint, Defendants admit that Dr. Singer has appeared in the referenced YouTube and that statements were made but deny that the statements were “unsubstantiated.”
- 130. Defendants admit the allegations in paragraph 109 of the complaint.
- 131. Defendants deny the allegations in paragraph 110 of the complaint.
- 132. Defendants admit the allegations in paragraph 111 of the complaint.
- 133. Defendants admit the allegations contained in paragraph 112 of the complaint.

**FIRST CAUSE OF ACTION**

**VIOLATION OF EXECUTIVE LAW 63(12) FRAUD**

- 134. Defendants deny the allegations in paragraph 113 of the complaint.
- 135. Defendants admit the allegations in paragraph 114 of the complaint.
- 136. Defendants admit the allegations n paragraph 115 of the complaint.
- 137. Defendants deny each and every allegation in paragraph 116 of the complaint.
- 138. Defendants deny the allegations in paragraph 117 of the complaint.

**SECOND CAUSE OF ACTION**

**EXEUCTIVE LAW 63(12) GBL 349**

- 139. Defendants deny the allegations in paragraph 118 of the complaint.
- 140. Defendants admit the allegations in paragraph 119 of the complaint.

- 141. Defendants admit the allegations in paragraph 120 of the complaint.
- 142. Defendants deny each and every allegation in paragraph 121 of the complaint.
- 143. Defendants deny the allegations in paragraph 122 of the complaint.

**THIRD CAUSE OF ACTION**

**GBL 349(b)**

- 144. Defendants deny the allegations in paragraph 123 of the complaint.
- 145. Defendants admit the allegations in paragraph 124 of the complaint.
- 146. Defendants admit the allegations in paragraph 125 of the complaint.
- 147. Defendants deny each and every allegation contained in paragraph 126 of the complaint.
- 148. Defendants deny the allegations in paragraph 127 of the complaint.

**FOURTH CAUSE OF ACTION**

**EXECUTIVE LAW 63(12) GBL 350**

- 149. Defendants deny the allegations in paragraph 128 of the complaint.
- 150. Defendants admit the allegations in paragraph 129 of the complaint.
- 151. Defendants admit the allegations in paragraph 130 of the complaint.
- 152. Defendants deny each and every allegation in paragraph 132 of the complaint.
- 153. Defendants deny the allegations in paragraph 132 of the complaint,

**AND AS FOR A FIRST DECLARATORY JUDGMENT COUNTERCLAIM****THE FTC'S SUBSTANTIATION STANDARD DOES NOT APPLY IN DETERMINING WHETHER PLAINTIFF HAS MET ITS BURDEN OF PROOF ON THE CAUSES OF ACTION IN THIS CASE**

154. Contrary to the position taken or implied in the complaint, the standard which the Court should use in determining whether Plaintiff has met its burden of proof in proving false advertising, deceptive trade practices and statutory fraud is not federal FTC law and does not involve the concept of adequate substantiation as used by the FTC as a term of art under federal law.
155. Defendants seek a declaratory judgment under CPLR 3001 that FTC law and guidelines have no application in determining the standard/elements/requirements which Plaintiff must prove to establish any of its claims in this case or any case involving a physician or a medical clinic.

**AND AS FOR A SECOND DECLARATORY JUDGMENT COUNTERCLAIM****FIRST AMENDMENT RIGHT TO RECEIVE AND PROVIDE ANY AVAILABLE INFORMATION OR EVIDENCE ABOUT DEFENDANTS' STEM CELL PROCEDURES**

156. Defendants website is not just proposing a commercial transaction. It is an informational platform advocating the benefits of Regenerative Medicine. Consumers, including prospective patients have a First Amendment right to receive any and all information about stem cell therapies, including all published studies, regardless of the studies' conclusion, and the right to receive information about patients treated with these therapies by way of testimonials. Defendants have a First Amendment right to provide such information to consumers and prospective patients.

157. Defendants seek a declaratory judgment under CPLR 3001 declaring that the information contained on Defendants website, consisting of published studies and other information about the program about stem cell treatments offered by Defendants is fully protected by the First Amendment and not subject to restriction under the FTC adequate substantiation standard, or FTC testimonial standards which govern commercial speech.

**AND AS FOR A THIRD DECLARATORY JUDGMENT COUNTERCLAIM**

**PATIENT INFORMED CONSENT DOCUMENTS ARE CONSIDERED IN DETERMINING THE NET EFFECT IN THE FALSE ADVERTISING, DECEPTIVE TRADE PRACTICES AND STATUTORY FRAUD ANALYSIS**

158. There is no possible danger or harm to any consumer by virtue of representations on Defendants' website, because Defendants have no contact with consumers unless they present to the clinic as a prospective patient. There is no possible harm to a prospective patient unless he/she becomes a patient. All clinic patients receive written and verbal informed consent about the nature, potential risks and benefits of the treatment and possible side effects. The consent documents have been approved by a duly registered Institutional Review Board.

159. Based on the foregoing, in this lawsuit, the finder of fact must take into consideration the informed consent process and documents in evaluating whether there has been a violation of any of the causes of action set forth in the complaint, and that includes conversations with a spouse/relative accompanying the patient, if any.

160. Defendants seek a declaratory judgment under CPLR 3001 mandating Defendants and all other medical providers who are accused of the violations set forth in the

complaint are entitled to have their informed consent documents and process considered in evaluating whether the Plaintiff has met its burden of proof.

**AND AS FOR A FOURTH DECLARATORY JUDGMENT COUNTERCLAIM**

**THERE IS A CONSTITUTIONAL RIGHT TO RECEIVE THIS TREATMENT AND TO RECEIVE ALL AVAILABLE INFORMATION WITHOUT GOVERNMENT FILTERING ON THE STATED ASSERTION THAT CONSUMER WHO BECOME PATIENTS ARE NOT SMART OR SOPHISTICATED ENOUGH TO UNDERSTAND DEFENDANTS' WEBSITE CONTENT**

161. New York citizens have a privacy right to control their own bodies. *Schloendorff v. NY Hospital*, 211 NY 125, 105 NE.102 1914 (J. Cardoza) (overruled on other grounds *Bing. V. Thunig* 2 NYS 656, 143 NE2d 3, (1957) and that right includes the right to receive unconventional, non-FDA approved treatment, and that patients can assume the risk of such treatment if provided with proper informed consent. *Schneider v Revici* 817 F.2d 987 (2<sup>nd</sup> Cir. 1987). *See also*, NY Education law 230 (9). There would be not practical or effective right unless physicians were free to provide such treatment to patients. Notwithstanding anything to the contrary under federal law, New Yorkers have a right to receive treatment consisting of their own body materials, such as that provided by the Defendants herein.
162. Defendants seek a declaratory judgement under CPLR 3001 declaring that Defendants have a right to provide treatment to patients consisting of their own body parts, and the right and obligation to provide all pertinent information to satisfy their professional obligations to provide informed consent.

WHEREFORE Defendants respectfully request that after a trial of this action, the Court dismiss the Plaintiff's case and enter judgment on Defendant's Counterclaims as follow:

1. Declaring that the Federal Trade Commission's guideline documents concerning adequate substantiation of claims do not apply to claims under the New York General Business law Sections 349 and 350 or under Executive law Section 63 (12) to the states burden of proof in establishing such claims.
2. Declaring that consumers have a First Amendment right to receive all relevant available information about autologous stem cell treatments from physicians providing such treatments irrespective of FTC guidance documents.
3. Declaring that New York patients have a right to receive autologous stem cell treatment based on New York constitutional and privacy rights and that Defendants have the right to provide the treatment and all pertinent information about it, and that such information is required as part of proper informed consent, as set forth in the Third and Fourth Counterclaims, and for such other as the Court deems just and proper.

Dated: April 22, 2019  
New York, New York

Respectfully submitted,

S/Richard A. Jaffe

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# EXHIBIT “A”

## Partial List of Safety Studies of Stem Cells

### in General

<https://www.regenexx.com/webres/File/PDF/2016-Safety-Report.pdf>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5040903/>

<https://www.jocmr.org/index.php/JOCMR/article/view/3187>

<https://www.ncbi.nlm.nih.gov/m/pubmed/29038672/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5880231/pdf/can-12-822.pdf>

<https://journals.sagepub.com/doi/pdf/10.1177/0748806817691152>

<https://www.ncbi.nlm.nih.gov/m/pubmed/15323455/>

<https://www.telegraph.co.uk/science/2016/08/10/hope-of-cure-for-arthritis-ms-and-diabetes-as-stanford-makes-ste/>

<https://stemcellres.biomedcentral.com/track/pdf/10.1186>

### Autoimmune

<https://www.nejm.org/doi/full/10.1056/NEJMoa1703327>

<https://stemcellres.biomedcentral.com/track/pdf/10.1186/s13287-018-1053-4>

### Neurology

<https://www.neurologylive.com/journals/neurologylive/2018/october-2018/phase-iii-study-brings-hope-to-als>

<https://www.ncbi.nlm.nih.gov/m/pubmed/26395626/>

<https://www.nature.com/articles/d41586-019-00656-2>

<https://www.nature.com/articles/d41586-018-05856-w>

<https://www.ncbi.nlm.nih.gov/m/pubmed/21864075/>

[https://www.thelancet.com/pdfs/journals/laneur/PIIS1474-4422\(11\)70305-2.pdf](https://www.thelancet.com/pdfs/journals/laneur/PIIS1474-4422(11)70305-2.pdf)

<http://www.hoajonline.com/journals/pdf/2055-091X-2-8.pdf>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2679713/>

<https://www.ncbi.nlm.nih.gov/m/pubmed/25934946/>

[https://www.ebiomedicine.com/article/S2352-3964\(18\)30051-3/pdf](https://www.ebiomedicine.com/article/S2352-3964(18)30051-3/pdf)

[https://www.nature.com/articles/d41586-019-00178-x?error=cookies\\_not\\_supported&code=16756f75-1b1d-41b2-8e0b-de8a2b45f05e](https://www.nature.com/articles/d41586-019-00178-x?error=cookies_not_supported&code=16756f75-1b1d-41b2-8e0b-de8a2b45f05e)

<https://clinicaltrials.gov/ct2/show/NCT02017912>

## Eye

<http://sci.amegroups.com/article/view/19760/19702>

<https://directorsblog.nih.gov/2019/01/29/moving-closer-to-a-stem-cell-based-treatment-for-amd/>

<https://www.reviewofophthalmology.com/article/stem-cell-therapy-in-retinal-disease>

## Vascular Disease

<https://stemcellres.biomedcentral.com/track/pdf/10.1186/s13287-019-1214-0>

<http://circres.ahajournals.org/content/95/7/671.full>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4012944/>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3688296/>

<http://bmb.oxfordjournals.org/content/98/1/187.long>

<http://www.stemcellsportal.com/content/2015-0118>

<http://www.futuremedicine.com/doi/pdf/10.2217/rme.11.35>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3294273/>



<http://www.ncbi.nlm.nih.gov/pubmed/27335447>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3580848/>

<http://onlinelibrary.wiley.com/doi/10.1634/stemcells.2008-0428/full>

<https://www.ncbi.nlm.nih.gov/pubmed/21132470>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3369878/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3604746/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2833273/>

<https://www.ncbi.nlm.nih.gov/pubmed/17463327>

#### Gastroenterology

[https://www.gastrojournal.org/article/S0016-5085\(17\)36726-](https://www.gastrojournal.org/article/S0016-5085(17)36726-4/fulltext?referrer=https%3A%2F%2Fwww.gastrojournal.org%2Farticle%2FS0016-5085%2817%2936726-4%2Ffulltext)

[4/fulltext?referrer=https%3A%2F%2Fwww.gastrojournal.org%2Farticle%2FS0016-5085%2817%2936726-4%2Ffulltext](https://www.gastrojournal.org/article/S0016-5085(17)36726-4/fulltext?referrer=https%3A%2F%2Fwww.gastrojournal.org%2Farticle%2FS0016-5085%2817%2936726-4%2Ffulltext)

<https://clinicaltrials.gov/ct2/show/NCT01287936>

#### Stroke

<https://med.stanford.edu/news/all-news/2016/06/stem-cells-shown-safe-beneficial-for-chronic-stroke-patients.html>

<http://www.strokecenter.org/trials/clinicalstudies/ex-vivo-cultured-adult-allogenic-mscs-in-ischemic-cerebral-stroke/description>

<https://clinicaltrials.gov/ct2/show/NCT01287936>

#### Diabetes

<https://www.ucsf.edu/news/2019/02/413186/functional-insulin-producing-cells-grown-lab>

## Spinal cord

[https://www.technologynetworks.com/cell-science/news/japan-approves-stem-cell-therapy-for-spinal-cord-injuries-315803?utm\\_campaign=NEWSLETTER\\_TN\\_Stem%20Cell%20Research&utm\\_source=hs\\_email&utm\\_medium=email&utm\\_content=70295424&hsenc=p2ANqtz--hiJdEMelNR97MdydtAscNTPN43VOAgwNmp3b80-lmt0WVa-OPQZjEQ2fb22N310P1dt5tUfx5JP7a43uFxrDR6jTLeA&hsmi=70295424](https://www.technologynetworks.com/cell-science/news/japan-approves-stem-cell-therapy-for-spinal-cord-injuries-315803?utm_campaign=NEWSLETTER_TN_Stem%20Cell%20Research&utm_source=hs_email&utm_medium=email&utm_content=70295424&hsenc=p2ANqtz--hiJdEMelNR97MdydtAscNTPN43VOAgwNmp3b80-lmt0WVa-OPQZjEQ2fb22N310P1dt5tUfx5JP7a43uFxrDR6jTLeA&hsmi=70295424)  
<https://stemcellsjournals.onlinelibrary.wiley.com/doi/full/10.1002/sctm.18->

## Orthopedics

<https://journals.sagepub.com/doi/pdf/10.1177/0363546516662455>  
<https://stemcellsjournals.onlinelibrary.wiley.com/doi/full/10.1002/sctm.18-0183>  
<https://clinicaltrials.gov/ct2/show/NCT03014401>  
<https://www.findmecure.com/clinicaltrials/show/nct02290886>  
<https://clinicaltrials.gov/ct2/show/NCT03752827>  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4880954/>  
<https://stemcellsjournals.onlinelibrary.wiley.com/doi/full/10.1002/stem.1634>  
<https://clinicaltrials.gov/ct2/show/NCT03503305>  
<https://translational-medicine.biomedcentral.com/track/pdf/10.1186/s12967-018-1736-8>  
<https://stemcellportal.com/article-scans/successful-first-human-clinical-trial-adipose-derived-stem-cell-therapy-rotator-cuff>  
<https://link.springer.com/article/10.1007/s00402-018-2991-0>

<https://www.ncbi.nlm.nih.gov/m/pubmed/29511819/>

<https://www.ncbi.nlm.nih.gov/m/pubmed/29233163/?i=3&from=/29511819/related>

<https://www.ncbi.nlm.nih.gov/m/pubmed/30835956/?i=2&from=/30762487/related>

<https://www.futuremedicine.com/doi/pdf/10.2217/rme-2018-0161>

#### Osteoarthritis

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4880954/>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4830073/>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4736810/>

<https://jmedicalcasereports.biomedcentral.com/articles/10.1186/1752-1947-5-296>

[http://www.aimjournal.ir/pdf/files/62\\_june2015\\_003.pdf](http://www.aimjournal.ir/pdf/files/62_june2015_003.pdf)

<http://onlinelibrary.wiley.com/doi/10.1002/stem.1634/full>

<http://onlinelibrary.wiley.com/doi/10.1002/art.21994/full>

[http://orthopaedics.gu.se/digitalAssets/1477/1477218\\_article-menisk.pdf](http://orthopaedics.gu.se/digitalAssets/1477/1477218_article-menisk.pdf)

<https://www.ncbi.nlm.nih.gov/pubmed/24449146?dopt=Abstract>

<https://clinicaltrials.gov/ct2/results?term=arthritis>

#### Rheumatoid Arthritis (RA)

<http://www.ncbi.nlm.nih.gov/pubmed/26205964>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4071294/>

<http://arthritis-research.biomedcentral.com/articles/10.1186/s13075-015-0634-1>

<http://arthritis-research.biomedcentral.com/articles/10.1186/ar2514>

<https://www.ncbi.nlm.nih.gov/pubmed/23941289?dopt=Abstract>

COPD

<https://www.ncbi.nlm.nih.gov/m/pubmed/23172272/>

<https://clinicaltrials.gov/ct2/results?term=emphysema>

Urology

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4874275/pdf/gox-4-e631.pdf>

<https://stemcellres.biomedcentral.com/articles/10.1186/s13287-018-0990-2>