

IN THE CIRCUIT COURT OF THE
11TH JUDICIAL CIRCUIT IN AND FOR
MIAMI-DADE COUNTY, FLORIDA

PATSY BADE,

Plaintiff,

CIRCUIT CIVIL DIVISION

CASE NO.: 2015-021463 CA 30

v.

SHAREEN GREENBAUM, M.D.,
HOLLYWOOD EYE INSTITUTE, P.A.,

Defendants.

AMENDED COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

The Plaintiff Patsy Bade sues the Defendants Shareen Greenbaum, M.D., and Hollywood Eye Institute, P.A., and alleges as follows:

1. This case arises out of negligent preoperative clearance of the Plaintiff by the Defendant Dr. Greenbaum and the subsequent provision of stem cell therapy to Plaintiff. As alleged in detail below, Dr. Greenbaum negligently allowed the Plaintiff participate in and be subjected to a so-called clinical trial wherein a “stem cell” medical product was injected directly into Plaintiff’s eyes, causing her to suffer permanent blindness.

JURISDICTIONAL STATEMENT AND IDENTIFICATION OF THE PARTIES

2. This is an action for damages in excess of this Court’s minimum jurisdictional limits, exclusive of interest and costs.

3. Venue is proper in Broward County, Florida, where one or more of the Defendants reside and the events giving rise to this lawsuit occurred.

4. Plaintiff Patsy Bade resides in Sarasota County, Florida.

5. Defendant Shareen Greenbaum, M.D. is a medical doctor, specializing in ophthalmology. She lives in Weston, Florida, and practices medicine in Hollywood and Sunrise, Florida.

6. Defendant Hollywood Eye Institute, P.A. ("Hollywood Eye") is the Florida professional association through which Dr. Greenbaum operates her medical practice.

COMPLIANCE WITH CONDITIONS PRECEDENT
AND FLORIDA STATUTE SECTION 766.106(2)

7. Notice of Intention to Initiate Litigation against the Defendants named in this Complaint was given and acknowledged in accordance with the requirements of Fla. Stat. 766.106(2). The Plaintiff has complied with all of the requirements of the Department of Health, Agency for Health Care Administration. A copy of the Complaint will be sent to that entity at the time the Complaint is filed. This action is properly brought within two years of when the alleged negligent incident occurred or within two years from the date the alleged negligent incident could have been discovered with the exercise of due diligence. Any and all conditions precedent to the filing of this lawsuit have been complied with.

CERTIFICATE OF COUNSEL

8. Through counsel's signature below, it is hereby certified, pursuant to Florida Statute section 766.203, that counsel for the Plaintiff, before filing this action, made a reasonable investigation as permitted by the circumstances to determine that there are grounds for a good faith

belief that there was negligence in the care and treatment of Patsy Bade. Such reasonable investigation has given rise to a good faith belief that grounds exist for an action against the named Defendant.

FACTS GIVING RISE TO THE ACTIONS

A. U.S. Stem Cell Claims to Provide Effective Stem Cell Therapy.

9. A Florida corporation called U.S. Stem Cell, Inc., formerly known as “Biohart,” operates a “stem cell” therapy business, which it advertises including research and clinical trials.

10. U.S. Stem Cell, Inc. claims to harvest stem cells by using liposuction to collect adipose tissue from patients and by processing that tissue to isolate stem cells. U.S. Stem Cell, Inc. through its agents, officers and employees, then injects the stem cells via needle into various parts of patients’ bodies.

11. U.S. Stem Cell, Inc. claims that this stem cell therapy is cutting edge therapy and can be used to treat a myriad of ailments and diseases, including macular degeneration.

12. Despite these representations of fact, no scientific evidence or peer-reviewed literature shows that U.S. Stem Cell, Inc.’s stem cell therapies provide any medical benefit for macular degeneration.

13. U.S. Stem Cell, Inc. administers its services at a clinic called “U.S. Stem Cell Clinic,” located at the Sawgrass Mall in Sunrise, Florida.

14. A woman named Kristin Comella, an aerobics instructor at the YMCA in Weston, Florida, serves as U.S. Stem Cell, Inc.’s chief scientific

officer. Ms. Comella is not a physician, and, at all times relevant to this lawsuit, she did not have any degree in medicine or cell biology. Nonetheless, Ms. Comella touted herself as an expert in adipose stem cell research and actively participated in U.S. Stem Cell, Inc.'s stem cell procedures.

15. Also working for U.S. Stem Cell Clinic during the times relevant to this lawsuit, was a registered nurse practitioner, Alejandro Perez. Mr. Perez was permitted to conduct procedures at the clinic that should have been performed by a medical doctor. Mr. Perez, who was supposedly trained as a doctor in Cuba, was routinely introduced as a physician to prospective U.S. Stem Cell Clinic patients.

B. Defendant Dr. Greenbaum Agrees to Lead a Clinical Trial, Without Any Experience of Formal Training.

16. Dr. Greenbaum first became aware of U.S. Stem Cell, Inc. through Ms. Comella. Dr. Greenbaum routinely exercises at the local YMCA, where she met Ms. Comella and the two developed a close friendship.

17. Because of their friendship, Ms. Comella asked Dr. Greenbaum if she would be interested in being the principal investigator in a clinical trial of a treatment for Age Related Macular Degeneration ("AMD"), a progressive condition for which there is no known medical treatment.

18. Dr. Greenbaum had little or no experience in conducting medical research or clinical trials and had no experience with stem cells. Ms. Comella knew this, but advised that experience was not necessary. Dr.

Greenbaum initially refused the offer, but later agreed to participate in the AMD clinical trial.

19. In preparation to oversee the AMD clinical trial, in October 2013, Dr. Greenbaum took a course taught by Ms. Comella on how to harvest and use adipose derived stem cells. Ms. Comella agreed to defer the normal \$7,500 cost of the course in exchange for Dr. Greenbaum's work on the AMD clinical trial.

20. By December 2013, U.S. Stem Cell, Inc. was representing that Dr. Greenbaum was the principal investigator for the AMD clinical trial.

21. Dr. Greenbaum believed that the U.S. Stem Cell, Inc. clinical trial on AMD would be legitimate – that information would be gathered and shared, there would be follow up exams of the patients, and with the goal of identifying a quality treatment to help patients afflicted with AMD.

22. The AMD clinical trial was listed as an ongoing clinical trial on the United States National Institute of Health's clinical trial website, which is the central repository for ongoing clinical trials throughout the world.

C. Defendant Dr. Greenbaum Begins Performing Stem Cell Therapy Surgeries and Realizes the Clinical Trial to be a Scam.

23. Over the next year, Dr. Greenbaum participated in approximately 6 separate stem cell treatments on different patients.

24. U.S. Stem Cell, Inc. charged the clinical trial participants thousands of dollars to receive the treatment and paid Dr. Greenbaum fees to perform her functions.

25. On each of the patients, Dr. Greenbaum conducted a pre-

procedure exam in her office to determine whether the patient had the appropriate AMD diagnosis. If the patient was an eligible candidate and met inclusion criteria, Dr. Greenbaum would then perform the “stem cell” treatment, which entailed a mini liposuction procedure to extract the patient’s adipose tissue or fat and to then another procedure to inject adipose derived stem cells directly into the globe of the patient’s eye.

26. Ms. Comella was present and participated in the operations. Once the adipose tissue or fat was removed from the patient, Ms. Comella performed or oversaw the “stem cell” extraction and isolation process. She then returned to the operating room to monitor and direct the injection of the material into the patient.

27. Thus, Dr. Greenbaum and Ms. Comella both had direct patient contact and communication during the clinical trial procedures.

28. Over the course of the year, Dr. Greenbaum witnessed the inappropriate manner in which U.S. Stem Cell, Inc. was conducting the AMD trial. She saw or overheard U.S. Stem Cell, Inc. employees and representatives lie or make misrepresentations to patients about the trial. Additionally, Dr. Greenbaum knew that no follow up on the patients was performed to determine whether the treatment was effective or even harmful. And, she also determined that there was no gathering or sharing of information regarding the treatment. In short, U.S. Stem Cell, Inc. was operating a business for profit, under the guise of a clinical research trial.

29. Notwithstanding the failures regarding the AMD clinical trial,

Dr. Greenbaum did nothing until the spring of 2015, when she finally advised her good friend, Ms. Comella, that she would no longer participate.

30. Ms. Comella became extremely upset and ultimately convinced Dr. Greenbaum to at least perform the pre procedure exams for the already scheduled procedures. Dr. Greenbaum agreed to continue working for U.S. Stem Cell, Inc. on these terms, notwithstanding that she knew the aforementioned information and the AMD clinical trial to be a scam.

D. Dr. Greenbaum Clears Ms. Bade to Participate in the AMD Clinical Trial.

31. Ms. Bade discovered U.S. Stem Cell, Inc.'s AMD clinical trial one day while browsing the U.S. Health clinical trials website.

32. Ms. Bade had been diagnosed with AMD years before and had experienced some progression. At this point, she could not read small print without the help of a magnifying glass and was having trouble driving at night. But, even with these limitations, Ms. Bade was living entirely independently.

33. Ms. Bade phoned U.S. Stem Cell, Inc., spoke several times to Kristin Comella, and made plans to travel to Sunrise, Florida to undergo the procedure.

34. A short time later, Ms. Bade inquired of U.S. Stem Cell, Inc. whether the steroid medication she used to relieve knee pain would complicate her scheduled stem cell therapy surgery. The U.S. Stem Cell, Inc. representative told her that it would not, but that for an additional fee (\$1,500), a U.S. Stem Cell, Inc. physician could also inject stem cells into

her knee to treat her pain. Ms. Bade was persuaded to pay the extra amount and undergo this knee procedure as well.

35. On June 15, 2015, Dr. Greenbaum saw Ms. Bade for the pre procedure exam in her office.

36. During this visit, Dr. Greenbaum examined Ms. Bade and cleared her for the AMD clinical trial, which Dr. Greenbaum knew would be conducted the following day at U.S. Stem Cell Clinic in Sunrise, Florida.

37. Dr. Greenbaum assured Ms. Bade that she was a candidate for the procedure and that it was safe for her to proceed.

38. At no point did Dr. Greenbaum warn Ms. Bade that the AMD clinical trial was not operating as represented or of her concerns about the trial which caused her to stop acting as the chief investigator. In short, Dr. Greenbaum did nothing to communicate her concerns about the clinical trial, nor did she do anything to dissuade Ms. Bade from going forward with this procedure.

39. Pursuant to Dr. Greenbaum's orders, the following day, on June 16, 2015, Ms. Bade arrived at U.S. Stem Cell's clinic at Sawgrass Mills. There, Ms. Bade was introduced to Mr. Alejandro Perez and told that he was the **DOCTOR** who would be performing the stem cell therapy surgeries on her eye and knee.

40. Mr. Perez, a nurse, then proceeded with the surgery on Ms. Bade, with Ms. Comella participating as well. Specifically, Ms. Comella isolated the stem cells from Ms. Bade's adipose tissue and then directed the

injection of these cells into Ms. Bade's eyes and knees.

41. Following the surgery, Ms. Bade's vision worsened drastically and she is now legally blind.

42. As a direct and proximate cause of Dr. Greenbaum's negligence, Ms. Bade suffered permanent damage, as alleged in more detail below.

COUNT I

CLAIM AGAINST DEFENDANT SHAREEN GREENBAUM, M.D.

PROFESSIONAL NEGLIGENCE

43. The Plaintiff adopts and realleges paragraphs 1 through 42 and further alleges:

44. The Defendant Shareen Greenbaum, M.D. held herself out to the public in general and Ms. Bade in particular as a healthcare provider capable of and who undertook the corresponding duty to Ms. Bade of providing healthcare services to Ms. Bade in accordance with that level of care and skill that is recognized as acceptable and appropriate by reasonably prudent similar healthcare providers under the same or similar circumstances.

45. Notwithstanding the duties undertaken, Defendant Dr. Greenbaum breached her duties by

- a. Negligently clearing Ms. Bade to undergo the U.S. Stem Cell, Inc.'s stem cell therapy procedure to treat her macular degeneration;
- b. Negligently advising Ms. Bade on a stem cell procedure, about which Dr. Greenbaum lacked expertise and experience;

- c. Negligently representing to Ms. Bade that U.S. Stem Cell, Inc.'s stem cell therapy was capable of treating the progression of macular degeneration;
- d. Negligently failing to warn Ms. Bade of the serious and dangerous side effects and risk of injury of the U.S. Stem Cell, Inc.'s stem cell therapy;
- e. Negligently allowing Ms. Bade to undergo the stem cell therapy when Dr. Greenbaum knew or should have known that U.S. Stem Cell, Inc. was not operating a legitimate clinical trial and that the stem cell therapy it was selling to Ms. Bade would not provide any benefit for her macular degeneration;
- f. Negligently allowing Ms. Bade to undergo a stem cell therapy procedure that Dr. Greenbaum knew or should have known would not be performed by a qualified medical professional; and
- g. Negligently allowing Ms. Bade to go forward with the stem cell therapy when she did not meet the criteria for inclusion in the clinical trial.

46. As a direct and proximate cause of the negligence of Defendant Dr. Greenbaum, Ms. Bade underwent the U.S. Stem Cell, Inc. stem cell therapy procedure and sustained serious permanent damages as alleged in detail below.

COUNT II

CLAIM AGAINST HOLLYWOOD EYE INSTITUTE, P.A.

VICARIOUS LIABILITY FOR THE NEGLIGENCE OF SHAREEN GREENBAUM, M.D.

The Plaintiff adopts and realleges paragraphs 1 through 42, and further alleges:

45. At all times material to this cause of action, Dr. Greenbaum was the principal, agent, servant, or employee of Hollywood Eye

Institute, P.A., her professional association, and was acting within the course and scope of her employment or agency and under its control.

46. Therefore, Defendant Hollywood Eye Institute, P.A. is vicariously liable for the negligence of Dr. Greenbaum, as set forth in Count I.

DAMAGES CLAIMED BY PATSY BADE

47. The Plaintiff Patsy Bade, as a direct and proximate result of the Defendants alleged above, has in the past and will in the future continue to suffer the following damages:

- a. Bodily injury;
- b. Pain and suffering;
- c. Disability;
- d. Disfigurement;
- e. Loss of the capacity for the enjoyment of life;
- f. Aggravation of pre-existing conditions;
- g. Medical and hospital care and expenses;
- h. Loss of earnings;
- i. Loss of earning capacity in the future;
- j. Rehabilitation expenses; and
- k. Mental distress;

WHEREFORE, Plaintiff Patsy Bade demands judgment against Defendants for damages in an amount in excess of the jurisdictional limits of

this Court exclusive of interest and costs, and all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

The Plaintiff demands trial by jury of all issues triable as of right.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the foregoing document was electronically filed with the Clerk of Court on this 19th day of July, 2016 and electronically served on all counsel on the attached Service List.

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