Weitz v Merck & Co.
2020 NY Slip Op 32275(U)
June 24, 2020
Supreme Court, New York County
Docket Number: 805322/15
Judge: Joan A. Madden

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: PART 11
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ADAM WEITZ,

Plaintiff, INDEX NO. 805322/15

-against-

MERCK & CO., MERCK SHARPE & DOHME CORP., ROBERT M. BERNSTEIN, M.D. and BERNSTEIN MEDICAL, P.C.,

Defendants.
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JOAN A. MADDEN, J.:

In this action for damages for medical malpractice and lack of informed consent, defendants Robert M. Bernstein, M.D. and Bernstein Medical, P.C. (collectively "Dr. Bernstein") move for summary judgment and plaintiff opposes.[1]

On January 10, 2013, plaintiff saw Dr. Bernstein for complaints of hair loss and Dr. Bernstein recommended the medication Propecia or its generic form finasteride. Plaintiff began taking Propecia/finasteride on August 10, 2014 and stopped September 5, 2014. Based on the affirmation of his expert, Dr. Marks, plaintiff alleges that Dr. Bernstein departed from the standard of care by advising him to take Propecia, given his early stage male pattern hair loss and relatively young age, since more conservative treatments were available; Dr. Bernstein failed to adequately warn him of the risks of taking Propecia/finasteride by downplaying the risk of persistent side effects and Post Finasteride Syndrome ("PFS"); and as a result of taking Propecia/finasteride, he developed PFS and is no longer able to work.

[1]Plaintiff discontinued the action as against the two other defendants, Merck & Co., and Merck Sharpe & Dohme Corp., the manufacturer of Propecia and finasteride.

When plaintiff first saw Dr. Bernstein on January 10, 2013, he was interested in hair transplant surgery. At the time he was 33 years old. Dr. Bernstein advised plaintiff that his hair loss was not advanced enough for surgery, and recommended that he take the drug Propecia/finasteride. Dr. Bernstein gave plaintiff an eight-page document entitled "Information on Finasteride and Propecia," and plaintiff signed a form acknowledging receipt of the document . Although Dr. Bernstein prescribed Propecia/finasteride that day, plaintiff did not start taking the medication until 19 months later, in August 2014.

In the meanwhile, in February 2013, plaintiff emailed Dr. Bernstein's office inquiring whether Dr. Bernstein recommended Propecia or the generic finasteride. On September 18, 2013, he sent an email requesting a prescription for 5 mg of finasteride (prescribed, dosage 1/4 of each 5 mg pill); later the same day he requested Propecia. In August 2014, plaintiff contacted Dr. Bernstein's office requesting a new prescription. Up until this time, he had not taken Propecia or finasteride, and he first began taking finasteride on August 10, 2014.

Plaintiff alleges that within the next two weeks, he began experiencing erectile dysfunction and loss of libido, and switched to the name brand Propecia; the sexual side effects continued, and included severe headaches, brain fog, major mood swings, extreme anxiety, social withdrawal and profuse sweating. He called Dr. Bernstein's office about the adverse side effects and saw Dr. Bernstein on September 5, 2014. Dr. Bernstein advised plaintiff to immediately stop taking finasteride; he also examined plaintiff's scalp and determined that the his hair loss had worsened since his last examination 20 months earlier and transplant surgery could be considered. Plaintiff alleges that a few weeks after discontinuing Propecia/finasteride, he suffered a "major system crash" involving major cognitive, sexual and physical symptoms that continue to this day.

On December 23, 2014 plaintiff sent Dr. Bernstein's office an email with a detailed list and time-line of his numerous symptoms since September 2014. On December 29, 2014, plaintiff sent Dr. Bernstein an email that his symptoms after taking Propecia have been "absolutely devastating" and he has become "almost completely non-functional." At some point around this time, Dr. Bernstein had a telephone conversation with plaintiff. Plaintiff alleges that by December 2015, his treating physicians identified Propecia/finasteride as the cause of his symptoms and diagnosed PFS, the "permanent sexual, mental and physical side effects after discontinuing finasteride."

Plaintiff commenced this action on October 26, 2015. The complaint assets three causes of action against the drug manufacturer, Merck & Co. and Merck Sharpe & Dohme Corp. (the "Merck defendants"), for negligence and failure to warn, strict products liability and breach of warranty; and three causes of action against Dr. Bernstein for medical malpractice, breach of fiduciary duty and fraud/intentional misrepresentation. On January 9, 2017, plaintiff filed a stipulation discontinuing the claims against the Merck defendants. Dr. Bernstein is now moving for summary judgment.

A defendant moving for summary judgment in a medical malpractice action must make a prima facie showing of entitlement to judgment as a matter of law by demonstrating that "in treating the plaintiff, there was no departure from good and accepted medical practice or that any departure was not the proximate cause of the injuries alleged." Roques v. Nobel, 73 AD3d 204, 206 (1st Dept 2010). To satisfy this burden, defendant must present expert opinion testimony that is supported by the facts in the record, addresses the essential allegations in the complaint or the bill of particulars, and is detailed, specific and factual in nature. Id; see Joyner–Pack v. Sykes, 54

AD3d 727, 729 (2ndept 2008). Expert opinion must be based on facts in the record or those personally known to the expert, and the opinion of defendant's expert should specify "in what way" the patient's treatment was proper and "elucidate the standard of care." Ocasio-Gary v. Lawrence Hospital, 69 AD3d 403, 404 (1st Dept 2010). Defendant's expert opinion must "explain 'what defendant did and why.'" Id (quoting Wasserman v. Carella, 307 AD2d 225, 226 [1st Dept 2003]).

"[T]o avert summary judgment, plaintiff must demonstrate that the defendant did in fact commit malpractice and that the malpractice was the proximate cause of the plaintiff's injuries." Roques v. Nobel, supra at 207. To meet this burden, "plaintiff must submit an affidavit from a medical doctor attesting that the defendant departed from accepted medical practice and that the departure was the proximate cause of the injuries alleged." Id. General and conclusory allegations of malpractice are insufficient to defeat summary judgment, and plaintiff's expert must specifically address the opinions rendered by defendant's expert. See Perez v. Riverdale Family Medical Practice, PC, 177 AD3d 554 (1st Dept 2019); DiLorenzo v. Zaso 148 AD3d 1111 (2nd Dept 2017); Giampa v. Shelton, 67 AD3d 439 (1st Dept 2009); Browder v. New York City Health and Hospitals Corp, 37 AD3d 375 (1st Dept 2007). If the expert's ultimate assertions are speculative or not supported by an evidentiary foundation, the opinion has no probative force. See Diaz v. New York Downtown Hospital, 99 NY2d 542, 544 (2002); accord Rivera v. New York Pain Care Center, 154 AD3d 421 (1st Dept 2017). However, if the parties submit conflicting expert opinions that are adequately supported by the record, summary judgment must be denied. See Frye v. Montefiore Medical Center, 70 AD3d 15 (1st Dept 2009); Cruz v. St. Barnabas Hospital, 50 AD3d 382 (1st Dept 2008).

In support of summary judgment, Dr. Bernstein submits the expert affirmation of Dr. Frederic Pereira, a board certified dermatologist, who reviewed the bills of particulars, plaintiff's expert disclosure, the parties' depositions, Dr. Bernstein's medical records, and the medical records of non-party Dr. Alan Jacobs. Dr. Pereira opines that Dr. Bernstein did not negligently or improperly prescribe Propecia/finasteride, and did not fail to apprise plaintiff of the risks of the medication nor induce him to take the medication.

Dr. Pereira bases his opinion on plaintiff's age and early stage of hair loss, opining that it was well within the standard of care to prescribe Propecia/finasteride, as it is an extremely effective medical treatment for hair loss; carries a low risk of side effects; to this day is recommended as the first course of treatment by the American Hair Loss Association for patients suffering from male pattern baldness; and in 2013, Propecia was widely prescribed to treat hair loss and still is today. In support of his opinion, he provides a detailed medical explanation of the discovery of Propecia/finasteride as a medication to treat hair loss, and the science behind how it works in effectively treating hair loss in men.[2] He also notes that clinical studies in balding men showed that finasteride reduced scalp DHT levels and improved hair growth; in 1997, the FDA

[2]According to Dr. Pereira, medicine has recently made tremendous strides in the medical treatment of men's hair loss primarily through the discovery that 5-alpha-reductase inhibitors such as Propecia were effective in promoting hair growth in male pattern baldness. In the 1990's, researchers discovered that endogenous androgens alter scalp hair follicles, resulting in miniaturized rather than cosmetically significant hair, which leads to a progressive decline in visible scalp density, resulting in thinning and eventually baldness. Dihydrotestosterone (DHT), a metabolic of testosterone produced by the enzyme 5-alpha-reductase, has been detected in scalp follicles, and balding scalps have increased Type 2 5-alpha-reductase activity and DHT levels. Together, these findings provided a rationale for the use of Type 2 5-alpha-reductase inhibitors in the treatment of men with hair loss, and finasteride, a specific and potent inhibitor of human Type 2 5-alpha-reductase, was known to decrease the formation of DHT from testosterone. Finasteride was originally developed to treat benign prostatic hyperplasia (BPH) and was later evaluated as a treatment for hair loss in men.

approved finasteride as a treatment for hair loss; finasteride is marketed as Proscar (finasteride 5 mg) and Propecia (finasteride 1 mg); and in 2013, finasteride and minoxidil were two of a handful of FDA approved drugs for treating male pattern hair loss.

Dr. Pereira points to Dr. Bernstein's testimony that he classified plaintiff's hair loss as Class III, the earliest stage of male pattern hair loss. Dr. Pereira states that patterned hair loss is the most common cause of hair loss in both men and women; the Hamilton-Norwood classification system used by Dr. Bernstein is most commonly used to stage hair loss in men; and Class III indicates a progression to the adult or mature hairline that sit's a finger breath (1.5 cm) above the upper brow crease, with some temporal recession, which does not represent balding.

Pointing to Dr. Bernstein's testimony as to his examination of plaintiff in January 2013, plaintiff's young age and the pattern of his hair loss, Dr. Pereira opines that Dr. Bernstein appropriately recommended Propecia/finasteride as a first course of treatment, since plaintiff's hair loss was not yet advanced enough to warrant a costly and possibly ineffective hair transplant procedure; Propecia/finasteride is extremely effective in preventing and even reversing hair loss; and Propecia/finasteride was a more conservative, efficacious and appropriate method of treatment than hair transplant surgery. Dr. Pereira states that based on clinical studies, the consensus in the medical community was that Propecia/finasteride had a low incidence of reversible side effects, and was a more conservative approach well within the standards of good and accepted dermatological practice.

As to plaintiff's claim that Dr. Bernstein departed from the standard of care by recommending Propecia/finasteride as a first course of treatment before considering surgery, Dr. Pereira notes Dr. Bernstein testified that he neither required nor insisted that plaintiff take

Propecia/finasteride for one year before he would consider surgery, and it was plaintiff's choice to take the medication, as plaintiff testified that he could have, had he chosen, seen other physicians about hair transplant surgery, rather than taking Propecia/finasteride. In support of the foregoing, Dr. Periera points to the record which indicates that plaintiff did not consult any other physicians about such surgery but waited for approximately 19 months after his visit with Dr. Bernstein before finally deciding to take Propecia/finasteride.

Dr. Pereira also opines that it cannot be said that Dr. Bernstein departed from the standard of care by prescribing Propecia in January 2013 on the ground that it caused plaintiff to develop PFS, since PFS was not recognized syndrome at that time (and still is not today) which dermatologists had to consider when prescribing Propecia/finasteride. He opines that some years ago, anecdotal reports of a number of symptoms allegedly caused by finasteride began to emerge, and the term "post-finasteride syndrome" was used to describe these symptoms, which at that time had occurred in small, uncontrolled studies and was otherwise self-reported by patients to their physicians. Dr. Pereira states that in September 2016, three years after Dr. Bernstein prescribed finasteride to plaintiff, one of the first articles was published on the validity of PFS and concluded that the documented persistent adverse sexual side effects associated with 5-alpha-reductace inhibitors such as Propecia, "were only documented in low-quality studies with strong bias selection as participants were part of an Internet Blog,"[3] He states that to this day the National Institute of Health does not officially recognize PFS.

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[3]The article is entitled "Investigation of the Plausibility of 5-Alpha-Reductase Inhibitor Syndrome," and was written by researchers affiliated with the University of Miami School of Medicine and New York University School of Medicine, among others.

As to plaintiff's allegation that Dr. Bernstein departed from the standard of care when he discussed the risks and benefits of Propecia/finasteride with plaintiff, Dr. Pereira opines that Dr. Bernstein's discussion complied with the standard of care and that he specifically mentioned anecdotal reports of PFS when the standard of care did not require him to do so. Dr. Pereira relies, in part, on the eight-page informational document detailing the risks and benefits of Propecia/finasteride, which Dr. Bernstein gave to plaintiff, and the fact that plaintiff signed a consent form acknowledging receipt of this document and testified that he read the document. Dr. Pereira points out that this informational document includes sections on label changes for finasteride which mention the persistence of erectile dysfunction, libido disorders, ejaculation disorder, orgasm disorder, decreased libido, male infertility, and poor semen quality after discontinuance of the medication; and expressly states that "[d]espite the fact that clear causal links between finasteride (Propecia and Proscar) and sexual adverse events have NOT been established, the cases suggest a broader range of adverse effects than previous reports in patients taking these drugs" (emphasis in original). He notes that this document lists other possible adverse side effects including testicular pain, depression, cognitive changes and brain fog, which are the side effects plaintiff alleges he was never apprised of; explicitly mentions PFS as a syndrome characterized by persistent adverse side effects after discontinuation of the medication; and correctly states that the reports of PFS were anecdotal, i.e. lacking a scientific basis.

Pointing to Dr. Bernstein's records and plaintiff's two examinations before trial, Dr. Pereira opines that Dr. Bernstein did not mislead plaintiff with respect to the possible side effects persisting after discontinuation of Propecia/finasteride, as in 2013-2014, reports of PFS were only anecdotal and the ordinary standard of care at that time did not require the patient to be informed of

the risk of PFS. In addition, Dr. Pereira points out that the informational document given to plaintiff included statistics as to the various side effects and mentioned that cases reported where side effects did not desist upon discontinuing the drug.

Finally, Dr. Pereira opines that no part of Dr. Bernstein's care or treatment was a cause of or a contributing factor to his alleged injuries, as even assuming *arguendo,* that PFS is a legitimate condition that plaintiff suffers from, and that his PFS was caused by Propecia/finasteride, Dr. Bernstein cannot be shown to have departed from the standard of care as it existed on January 10, 2013, since it was well within the standard of care to prescribe Propecia/finasteride to young men with early stage hair loss. He further opines that the standard of care is the same today (as of February 6, 2019, the date of his affirmation).

Based on the foregoing expert opinions of Dr. Pereira, Dr. Bernstein has made a prima facie showing for summary judgment, and the burden shifts to plaintiff.

In opposition, plaintiff submits the expert affirmation of Dr. Donald Marks, which is insufficient to raise an issue of fact so as to defeat summary judgment.

Dr. Marks, a board certified internist, states that he reviewed the parties' depositions and exhibits; his affirmation references only the parties' testimony and plaintiff's amended bill of particulars. Significantly, although Dr. Bernstein's medical records were marked as exhibits during his deposition, Dr. Marks does not specifically reference those records. Moreover, Dr. Marks did not review any of the other medical records annexed to plaintiff's opposition papers, which include records from at least ten different physicians who treated or examined plaintiff from November 2014 through January 2019.

Dr. Marks opines that Dr. Bernstein's treatment violated the standard of care given the circumstances of plaintiff's early stage male pattern hair loss and relatively young age, since more conservative treatments were available, specifically treatment with Rogaine or a Follicular Unit Extraction.[4] He opines that Dr. Bernstein also deviated from the standard of care in recommending Propecia/finasteride when plaintiff sought treatment from Dr. Bernstein for the purpose of having hair transplant surgery; and by downplaying the warnings of persistent side effects and PFS associated with Propecia/finasteride. He opines that Dr. Bernstein failed to adequately disclose the risks, benefits and alternative treatments which a reasonable medical practitioner under similar circumstances would have disclosed, and that a reasonably prudent person in plaintiff's position would not have commenced treatment with Propecia/finasteride.

Dr. Marks also opines that is more likely than not that plaintiff's symptoms and PFS are temporally and causally related to his use of Propecia/finasteride. He opines that Dr. Bernstein's departures in recommending Propecia/finasteride, and in failing to adequately warn of the risks of persistent side effects and PFS, caused plaintiff to suffer PFS and undergo "unnecessary physical and emotional pain and suffering." He further opines that while the prescribing of Propecia/finasteride to plaintiff "may not have been contraindicated," treatment with Propecia/finasteride should have been a "last resort afer the exhaustion of more conservative

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[4]Dr. Marks provides no explanation or details regarding a Follicular Unit Extraction procedure. Dr. Bernstein, however, testified that it is "newer" hair transplant surgical procedure that does not leave a scar on the back of the head and allows the patient to wear his hair shorter. The transcript of his deposition indicates that he testified that "in 2003" this procedure "wasn't very good." It is unclear whether this was a typographical error in the transcript or whether Dr. Bernstein misstated the year and intended to say "2013," the year he treated plaintiff.

Also, both Dr. Bernstein and plaintiff testified that Dr. Bernstein recommended that he use Rogaine (the brand name of the over-the counter topical medication minoxidil) together with Propecia/finasteride.

treatments in light of his early stage male pattern hair loss and relatively young age."

As noted above, as support for his opinions, Dr. Marks references only the parties' deposition testimony and plaintiff's amended bill of particulars; he does not reference Dr. Bernstein's medical records nor any other medical records. Not only are his opinions conclusory and unsupported by competent evidence, he also fails to address or refute most, if not all, of the opinions of defendant's expert, Dr. Pereira. See Diaz v. New York Downtown Hospital, suprs; Perez v. Riverdale Family Medical Practice, PC, supra; Rivera v. New York Pain Care Center, supra; DiLorenzo v. Zaso, supra; Giampa v. Shelton, supra; Browder v. New York City Health and Hospitals Corp, supra.

Dr. Marks opines that Dr. Bernstein violated the standard of care, since, based on plaintiff's young age and early stage hair loss, more conservative treatments should have been pursued, specifically the use of the over-the-counter hair loss medication Rogaine and an unexplained procedure referred to as Follicular Unit Extraction. However, that conclusory opinion is contradicted by his admission that Propecia/finasteride "may not have been contraindicated." Dr. Marks fails to refute Dr. Pereira's opinions that the prescribing of Propecia/finasteride was within the standard of case; is an extremely effective medical treatment for hair loss that carries a low risk of side effects; in January 2013, Propecia was widely prescribed for the treatment of hair loss; and it is still recommended by the American Hair Loss Association as the first course of treatment for patients suffering from male pattern baldness.

Dr. Marks' opinion that Dr. Bernstein failed to adequately inform plaintiff of the risks of taking Propecia/finasteride by downplaying or misrepresenting the risks of persistent side effects and PFS, ignores the eight-page informational document that plaintiff admittedly received from Dr.

Bernstein and plaintiff's testimony that he read such document. Dr. Marks fails to refute Dr. Pereira's opinions that this document complied with Dr. Bernstein's obligation to advise plaintiff of the risks and benefits of Propecia, detailed the possible adverse side effects and specifically mentioned anecdotal reports of PFS as a syndrome characterized by persistent adverse side effects after discontinuation of the drug. Dr. Marks likewise fails to refute Dr. Pereira's opinions that the standard of care in 2013-2014 did not require Dr. Bernstein to inform plaintiff as to risk of PFS; PFS was not a recognized syndrome in 2013 and still is not today; the National Institute of Health does not officially recognize PFS; and Dr. Bernstein actually mentioned anecdotal reports of PFS to plaintiff.

Moreover, Dr. Marks overlooks the undisputed record which shows that 19 months elapsed between January 2013, when Dr. Bernstein recommended that plaintiff take Propecia/finasteride and August 2014, when plaintiff first took the medication. The length of this delay raises a reasonable inference that plaintiff was aware of and had concerns about the potential side effects of Propecia/finasteride. Notably, plaintiff testified that he remembered Dr. Bernstein talking to him about the sexual side effects; and when he was asked whether the "fear of side effects" have anything to do with his not taking the medication, he answered that he was "concerned" about what Dr. Bernstein told him about the side effects. He also testified that "I sat on it [taking Propecia/finasteride] because something in my body just said I don't need to do this, why do I need to go on this medication."

Thus, since Dr. Marks offers only conclusory and unsupported opinions and fails to specifically address the opinions rendered by defendant's expert, his affirmation is insufficient to raise an issue of fact. See Diaz v. New York Downtown Hospital, suprs; Perez v. Riverdale

Family Medical Practice, PC, supra; DiLorenzo v. Zaso, supra; Giampa v. Shelton, supra. Dr. Bernstein, therefore, is entitled to judgment as a matter of law dismissing the complaint.

Accordingly, it is

ORDERED the motion for summary judgment by defendants Robert Mr. Bernstein, M.D. and Bernstein Medical, P.C., is granted, and the Clerk is directed to enter judgment accordingly, dismissing the complaint as against such defendants.[5]

DATED: June 24, 2020

ENTER:

Joan Madden

Digitally signed by Joan Madden
DN: C=US, OU=NY County Supreme Court, O=NYS Courts, CN=Joan Madden, E=jmadden@nycourts.gov
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J.S.C.

[5]As noted above, the action was previously discontinued as to the other two defendants, Merck & Co., and Merck Sharpe & Dohme Corp.