UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Steven Rossello **902 S. Loop 499** **Apt 204** **Harlingen, Texas 78550** **and** **Justin Herrman** **1125 Red Margin, Unit 101** **Las Vegas, NV 89183** **Plaintiffs,** **Vs.** **Merck & Co., Inc** **One Merck Drive** **P.O. Box 100** **Whitehouse Station, New Jersey 08889** **and** **Merck Sharpe & Dohme Corp.** **One Merck Drive** **P.O. Box 100** **Whitehouse Station, New Jersey 08889** **Defendants.**	:	**NO.:** **JURY TRIAL DEMAND**

COMPLAINT

Plaintiffs Steven Rossello and Justin Herrman ("plaintiffs"), by and through their counsel, Sherman, Silverstein, Kohl, Rose & Podolsky, P.A., by way of complaint against Merck & Co., Inc. and Merck Sharpe & Dohme Corp. (collectively, "Merck") hereby say, state, and aver as follows:

Parties

1. Plaintiff Steven Rossello is an individual and citizen of Texas with a principal

address of 902 S. Loop 499, Apt 204, Harlingen, Texas 78550

2. Plaintiff Justin Herrman is an individual of Nevada with a principal address of 1125 Red Margin, Unit 101, Las Vegas, NV 89183.

3. The defendant Merck & Co., Inc. is believed to be a New Jersey corporation with its corporate headquarters at One Merck Drive, Whitehouse Station, New Jersey 08889.

4. The defendant Merck Sharpe & Dohme Corp. is also believed to be a New Jersey Corporation and has its corporate headquarters at One Merck Drive, Whitehouse Station, New Jersey 08889. Merck Sharpe & Dohme Corp. owns the registered trademarks for Propecia and Proscar.

Jurisdiction

5. This Court's jurisdiction is based upon diversity of citizenship as set forth in 28 U.S.C. §1332 in that plaintiffs are citizens of the State of Texas and Nevada and defendants are citizens of the State of New Jersey. The amount in controversy for each plaintiff is in excess of Seventy Five Thousand Dollars ($75,000.00).

6. Venue is proper in this district because defendants are located and regularly conduct business in the State of New Jersey.

I. STATEMENT OF FACTS

7. This action concerns the prescription drugs Propecia and Proscar which are prescribed as a cosmetic treatment for male pattern hair loss also known as androgenic alopecia.

8. Propecia is the brand name of the 1 milligram tablet of finasteride; Proscar is the brand name of the 5 milligram tablet of finasteride.

9. The active ingredient in Propecia and Proscar is finasteride. Finasteride has a number of serious side effects, including cognitive impairment, the development of depression, and various forms of sexual dysfunction such as erectile dysfunction, reduced ejaculate

volume, low sex drive, reduced sexual sensation and infertility.

10. Plaintiff Steven Rossello was initially prescribed Propecia in 2006 by his physician for cosmetic purposes to treat male pattern hair loss; he later took Proscar from September 2010 to December 2010.

11. Plaintiff Justin Herrman was initially prescribed Propecia by his physician in 2003 for cosmetic purposes to treat male pattern hair loss.

12. Male pattern hair loss is a common condition thought to be caused by a combination of genetic factors and a hormone, called dihydrotestosterone (DHT). DHT is believed to contribute to shortening the growth phase of and to thinning of the hair.

13. Merck claims finasteride is a type II 5-Alpha reductase inhibitor that prevents the conversion of androgen testosterone to DHT in the scalp leading to a reduction of hair loss.

14. Merck knew or should have known that DHT is a hormone critical to male sexual performance and functioning.

15. Merck promotes the use of Propecia for treatment of male pattern hair loss as a safe treatment with little risk. In its product labeling, Merck represents the side effects in a limited number of users may be sexual dysfunction such as decreased libido, erectile dysfunction, ejaculation disorder and decreased ejaculate volume but that these side effects resolve after discontinued use of the drug.

16. Merck's October 6, 2010, product monograph for Propecia states "Resolution of these adverse reactions occurred in men who discontinued therapy with PROPECIA and in most who continued therapy."

17. In 2006, the Swedish Medical Products Agency began investigating reports of persistent sexual dysfunction side effects which continue in men despite discontinuing

finasteride.

18. In 2008, Merck changed the label in Sweden to include the following warning:

> In addition, the following have been reported in post-marketing use: persistence of erectile dysfunction after discontinuation of treatment with PROPECIA.

19. In August 2009, the Swedish Medical Products Agency concluded that Propecia could lead to permanent erectile dysfunction.

20. Merck changed the product label in other European countries to include a warning of permanent erectile dysfunction as an adverse reaction. In the United Kingdom, Merck included the following warning:

> In addition, the following have been reported in postmarketing use; persistence of erectile dysfunction after discontinuation of treatment with PROPECIA; male breast cancer (see 4.4 Special warnings and precautions for use)

21. In Italy, Merck revised the label in March 2010, to include a warning of persistent erectile dysfunction after discontinuation of treatment.

22. Though Merck revised the product monograph in the United States for finasteride on October 6, 2010, these revisions did not include an updated warning regarding the persistence of sexual dysfunction after discontinuation of use.

23. The Federal Drug Agency (FDA) approved Propecia in December 1997 for the treatment of male pattern hair loss.

24. As a result of the use of finasteride, the FDA has received numerous complaints of side effects related to sexual dysfunction.

25. Physicians who treat men's health issues in the United States and Europe have publically expressed their concerns about patients who have permanent sexual, mental and physical side effects after discontinuing finasteride. These physicians have posted information

on their websites and have spoken at medical symposiums about the problem of permanent sexual dysfunction from the use of finasteride.

26. For example, Dr. John Crisler, a physician at a men's health clinic in Michigan, stated:

> I am just totally against finasteride. I have had so many patients that have come to me where that medication has destroyed their life.
>
> ...They take finasteride for even as short as a week and it destroys their lives. And they become depressed, weak, impotent and the problem is when they go off the drug their symptoms remain.

27. Dr. Alan Jacobs, a neuroendocrinologist in New York has started a blog addressing issues related to hormones, behavior and the brain at http://alanjacobsmd.typepad.corn/alan-jacobsmds-blog/. In one of his posts in April 2010 titled "A Neuroendocrine Approach To Finasteride Side Effects In Men," he states:

> I have recently seen an increasing number of men who have developed significant degrees of clinical hypogonadism - low sex drive, erectile dysfunction, reduced sexual sensations and listlessness, fatigue and/or "brain fog" - while either taking finasteride or after stopping the medication, even long after stopping it.
>
> Finasteride certainly helps men fight hair loss and prostate enlargement. However, a considerable number of men have intolerable and sometimes persistent side effects from the medicine. A systematic neuroendocrine approach to this problem should shed light on the cause in a majority of cases and bring relief.

28. Dr. Andrew Rynne, a physician in Kildare, Ireland, who is a specialist in treating sexual dysfunction, has also spoken out about the risk of using finasteride. On the website for his clinic, he has posted this entry titled "Male Pattern Baldness and Propecia" where he writes about the problems he has seen in his patients who have taken Propecia:

> I want to shout this from the rooftops. However, I will shout it into cyberspace instead. I want the ear of every young man on this

planet who may be experiencing testosterone driven male pattern balding. Please listen to me. Do NOT under any circumstances even for one minute consider taking the testosterone-suppressing drug Proscar or Propecia or Finasteride to give it its chemical name. The consequences of using this drug for male pattern balding can be life shattering.

Here's what the manufacturers Merck say on their Patient's Product Information leaflet about Propecia:

"In clinical studies for Propecia, a small number of men experienced certain sexual side effects, such as less desire for sex, difficulty in achieving an erection, decrease in the amount semen produced. Each of these side effects occurred in less than 2% of men and went away in men who stopped taking Propecia because of them."

What jumps out at you here is that figure 2%. However, even if you accept this figure as true, and personally I do not accept it, but even if you do, to the uninitiated it might seem like a low figure. But for 2% of men on Proscar to. experience serious side effects like erectile dysfunction, loss of libido and reduced volume of semen this is actually a very high and significant figure.

Remember you are dealing here with a naturally occurring normal male phenomenon called 'Male Pattern Baldness'. This is not an illness or a disease. This is a healthy normal occurrence. If in an attempt to "cure" it, you are getting a 2% rate of serious side effects, then that quite frankly is unacceptable.

But here is the real lie that Merck is giving you in its Patient's Leaflet. Do you see that bit there about "went away in men who stopped taking Propecia — " That is simply not true and Merck know full well that it is not true. They know it is not true because I and hundreds of other doctors and thousands of patients have told them that these side effects do not always go away when you stop taking Propecia. We continue to be ignored of course. Merck in a multi-billion multinational company. In some cases men who have taken Proscar, even for a few months, have unwittingly condemned themselves to a lifetime of Sexual Anhedonia, the most horrible and cruel or all sexual dysfunctions.

I have spoken to several young men in my clinic in Kildare who continue to suffer from sexual anaesthesia and for whom all sexual pleasure and feelings have been obliterated for all time. I have felt their suffering and shared their devastation. If you would like to learn more about this subject then visit them on

> www.propeciahelp.com. Please spread the word around. Taking Propecia for balding can have utterly disastrous consequences.

29. Merck posts information about Propecia on its website, www.propecia.com. Under the tab "Possible Side Effects," Merck represents:

> A small number of men had sexual side effects, with each occurring in less than 2% of men. These include less desire for sex, difficulty in achieving an erection, and a decrease in the amount of semen. These side effects went away in men who stopped taking PROPECIA because of them. In addition, these side effects decreased to 0.3% of men or less by the fifth year of treatment.

30. This statement is deceptive and misleading in that it fails to advise potential users of the drug that numerous men have reported suffering persistent sexual side effects even after discontinuing use.

31. Neither the plaintiffs, nor their physicians, had received an adequate warning from the defendants about the risk of injury. To the contrary, the defendants continue to market and promote their product without providing clear and adequate warning.

32. Plaintiffs would not have taken finasteride had they or their physicians been adequately warned of the risks.

COUNT I

NEGLIGENCE AND FAILURE TO WARN

33. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

34. As the manufacturer, marketer, developer, distributor, and labeler of Propecia and Proscar, Merck owed users of the drugs a duty of care.

35. Specifically, Merck owed a duty to plaintiffs to exercise reasonable care when designing, testing, manufacturing, marketing, labeling, promoting, distributing, and selling

Propecia and Proscar.

36. Merck breached this duty and acted negligently by:

a. failing to test Propecia and Proscar properly and thoroughly before releasing the drug to the market;

b. failing to adequately disclose the serious side effects of Propecia and Proscar;

c. failing to conduct an adequate and timely analysis of adverse event reports;

d. failing to provide adequate warnings of the potential long term effects of ingesting Propecia and Proscar on the package inserts and labels;

e. marketing Propecia and Proscar in such a way as to give no reason to suspect that Propecia and Proscar had potentially harmful and serious adverse effects;

f. failing to design and implement an appropriate post marketing surveillance system to monitor and quickly identify adverse risks;

g. placing Propecia and Proscar on the market when they knew or should have known that the potential risks of these drugs outweighed their potential benefits.

37. As a direct and proximate result of this negligence, plaintiffs have suffered and will continue to suffer loss and damage.

38. As a direct and proximate cause of ingesting finasteride, each of the plaintiffs has suffered serious sexual dysfunction, resulting in emotional distress and anxiety, some or all of which may be permanent.

39. Defendants' action and inactions were wanton and willful, or were conducted with reckless disregard of the harm to users of their drug.

WHEREFORE, Plaintiffs individually demand judgment against Defendants, individually and severally, in an amount in excess of $100,000.00, punitive damages plus interest and allowable costs of suit.

COUNT II

Strict Products Liability

40. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

41. At all times relevant to the Complaint, Merck manufactured, distributed, produced and sold finasteride throughout the United States and the world and does substantial and continuing business in the State of New Jersey.

42. For years, Merck has claimed that finasteride does not cause permanent sexual dysfunction.

43. Contrary to these claims, for years Merck was aware that individuals who took finasteride suffered damaging permanent side effects including sexual dysfunction.

44. Merck failed to inform the FDA and the public at large of these reports.

45. Merck is liable for causing injuries to plaintiffs for the following reasons:

a. selling a product it knew or should have known was in a defective condition;

b. selling a product which it knew or should have known was unreasonably dangerous to the user;

c. selling a product which it knew or should have known was not safe;

d. supplying warnings with the product that it knew or should have known were inadequate;

e. providing instructions to be followed with regard to the prescribing of this product that it knew or should have known were not accurate and truthful;

f. selling a product wherein it was foreseeable that someone would be injured upon ingesting the medication in question;

g. selling a product which it knew or should have known was not safe for its intended use;

h. selling a product which it knew or should have known was lacking of one or more elements necessary to make it safe for its intended use;

i. manufacturing a product which it knew or should have known was defective and which could cause injury to the user;

j. designing a product which it knew or should have known was defective and which could cause injury to the user;

k. distributing a product which it knew or should have known was defective and could cause injuries to a user;

l. failing to see that ultimate users were advised of the dangers of said product;

m. failing to exercise reasonable care in the design of this product;

n. failing to exercise reasonable care in the marketing of this product;

o. failing to adequately and properly test said product;

p. failing to use reasonable care under the circumstances;

q. delivering a product which it knew or should have known was defective and could cause injury to the user;

r. producing a product which it knew or should have known was defective and could cause injury to the user;

s. producing a product with component parts that defendant knew or should have known increased the risk of harm to the user;

t. supplying a product which it knew or should have known was defective and could cause injury to the user;

u. engaging in other acts regarding the manufacturing, designing, preparing, producing, distributing, advising and selling finasteride as will be learned in discovery.

46. Defendants' action and inactions were wanton and willful, or were conducted with reckless disregard of the harm to users of their drug.

47. As a direct and proximate cause of ingesting finasteride, each of the plaintiffs has suffered serious sexual dysfunction, resulting in emotional distress and anxiety, some or all of which may be permanent.

WHEREFORE, Plaintiffs individually demand judgment against Defendants, individually and severally, in an amount in excess of $100,000.00, punitive damages plus interest and allowable costs of suit.

COUNT III

Breach of Warranty

48. Plaintiffs incorporate by reference the above paragraphs as if fully set forth at length herein.

49. At all times relevant to the Complaint, Merck was and is in the business of designing, manufacturing, distributing and selling drugs, including but not limited to the drug finasteride

50. Prior to plaintiffs taking finasteride, Merck impliedly warranted that the drug was of merchantable quality and was fit for the purpose for which it was intended.

51. At the time any and all finasteride ingested by plaintiffs last left the possession, custody or control of Merck, the said finasteride was not of merchantable quality and was not fit for the purpose for which it was intended, in breach of the above-mentioned implied warranties.

52. As a direct and proximate cause of ingesting finasteride, each of the plaintiffs has suffered serious sexual dysfunction, and resulting in emotional distress and anxiety, some or all of which may be permanent.

WHEREFORE, Plaintiffs individually demand judgment against Defendants, individually and severally, in an amount in excess of $100,000.00, punitive damages plus interest and allowable costs of suit.

SHERMAN, SILVERSTEIN, KOHL ROSE & PODOLSKY

DATED: **February 2, 2011**

By: _____

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Attorneys for Plaintiffs,
Steven Rossello and
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JURY TRIAL DEMAND

Please take notice that the plaintiff demands a trial by jury as to all issues in the above matter.

SHERMAN, SILVERSTEIN, KOHL ROSE & PODOLSKY

DATED: **February 2, 2011**

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