IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WILLIAM LOHAN,	§	
	§	
Plaintiff,	§	
	§	
vs.	§	Case No.
	§	
ENDO PHARMACEUTICALS, INC.	§	
	§	
Defendant.	§	
	§	
	§	
	§	JURY TRIAL DEMANDED

COMPLAINT

Plaintiff, William Lohan ("Plaintiff"), residing in New Hanover County, North Carolina, by and through his undersigned counsel, hereby sues Defendant Endo Pharmaceuticals, Inc. ("Defendant") and alleges as follows:

INTRODUCTION

1. This case involves the prescription drug Fortesta, which is manufactured, sold, distributed and promoted by Defendant as a testosterone replacement therapy.

2. Defendant misrepresented that Fortesta is a safe and effective treatment for hypogonadism or "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thrombolytic events.

3. Fortesta causes the hematocrit level to increase, thereby thickening the blood. This effect, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thrombolytic events.

4. Defendant failed to adequately warn physicians about the risks associated with Fortesta and the monitoring required to ensure the safety of patients using Fortesta.

5. Defendant engaged in aggressive, direct-to-consumer and physician marketing and advertising campaigns for Fortesta. Further, Defendant engaged in an aggressive unbranded "disease awareness" campaign to alert men that they might be suffering from "low T."

6. Defendant published a quiz on the website for Fortesta titled "Could it be Low T?", encouraging men as young as 35 to take the quiz to find out whether their symptoms are caused by low testosterone levels. According to the "Could it be Low T?" quiz, the symptoms of "Low T" include feeling tired, a loss of body hair, and needing to shave less. See, http://www.gettestedforlowt.com/.

7. As a result, diagnoses of Low T have increased exponentially. This has directly related to Fortesta's net sales increasing by 154% in 2013 as compared to 2012. Defendant attributed the sales increase to "improved formulary access to this product." *Available at: http://biz.yahoo.com/e/130806/endp10-q.html*.

8. However, consumers of Fortesta were misled as to the drug's safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thrombolytic events.

PARTIES

9. Plaintiff is a natural person and a citizen of the State of North Carolina.

10. Defendant Endo Pharmaceuticals, Inc., formerly Endo Laboratories, LLC., and a subsidiary of Endo Pharmaceuticals Holdings, Inc., is a corporation organized and existing under the laws of Delaware with its principal place of business at 100 Endo Boulevard, Chaddes Ford, Pennsylvania 19317.

11. At all times herein mentioned, Defendant, in interstate commerce and in this judicial district, advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public a certain pharmaceutical product, Fortesta.

JURISDICTION AND VENUE

12. This Court has jurisdiction over Defendant and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy between Plaintiff and Defendant exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendant have significant contacts with this district by virtue of doing business within this judicial district.

13. Venue is proper pursuant to the order issued by the United States Judicial Panel on Multidistrict litigation on June 6, 2014, establishing MDL No. 2545 consolidating for pre-trial purposes all cases involving injuries arising from the use of testosterone replacement therapies before the honorable Matthew F. Kennelly in the Northern District of Illinois.

GENERAL ALLEGATIONS

14. This action is for damages brought on behalf of Plaintiff who was prescribed and supplied with, received and who has taken and applied the prescription drug Fortesta, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendant. This action seeks, among other relief, general and special damages and equitable relief in order to enable Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

15. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

16. At all times herein mentioned, the Defendant was engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Fortesta for the use and application by Plaintiff.

17. At all times herein mentioned, Defendant was authorized to do business within the state of residence of Plaintiff and in the state of Illinois.

18. At all times herein mentioned, the officers and directors of Defendant participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

19. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful case of Plaintiff's injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when Plaintiff's injuries were discovered their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendant herein misrepresented and continue to

misrepresent to the public and to the medical profession that the drug Fortesta is safe and free from serious side effects, and Defendant have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

OVERVIEW

20. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone.

21. In 1999, hypogonadism was estimated to affect approximately "one million American men." This number increased to “four to five million American men.” By 2003, the number increased to “up to 20 million American men.”

22. A study published in the Journal of the American Medical Association (“JAMA”) in August 2013 entitled “Trends in Androgen Prescribing in the United States, 2001-2011” indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

23. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of Fortesta is safe for human use, even though Defendant knew these to be false, and even though Defendant had no reasonable grounds to believe them to be true.

24. There have been a number of studies suggesting that testosterone in men increases the risk of heart attacks and strokes.

25. In 2010, a study published in the New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group were suffered adverse events.

26. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" which indicated that testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

27. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men" which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a previous diagnosis of heart disease.

28. Two days later, on January 31, 2014, the FDA issued a Drug Safety Communication to physicians advising that the FDA was investigating the risk of stroke, heart attack and death in men using testosterone products based on the recent studies suggesting an increased risk of cardiovascular events among men using these products.

29. And on April 11, 2014, the European Medicines Agency announced that in light of the recent studies regarding the increased risk of cardiovascular events in patients using testosterone products, its Pharmacovigilance Risk Assessment Committee would be reviewing all data on the benefit-risk balance of testosterone-containing medicines to determine whether the marketing authorizations for these products should be maintained, varied, suspended or withdrawn across the European Union.

FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

30. Defendant Endo is engaged in the business of manufacturing, design, distributing, marketing, and/or selling prescription drugs including Fortesta.

31. The FDA approved Fortesta on December 29, 2010.

32. Fortesta is a clear, colorless and odorless gel comes in a small canister with a pump that delivers 10 mg of testosterone with each pump and is applied once-a-day directly to the inner thighs.

33. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

34. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

35. In men, testosterone levels normally begin a gradual decline after the age of thirty.

36. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.

37. Fortesta may produce undesirable side effects to patients who use the drug, including but not limited to, myocardial infarction, stroke, and death.

38. In some patient populations, Fortesta use may increase the incidence of myocardial infarctions and death by over 500%.

39. In addition to the above, Fortesta has been linked to several severe and life changing medical disorders in both users and those who come into physical contact with users or

the unwashed clothes of someone who applied Fortesta. Patients taking Fortesta may experience enlarged prostates and increased serum prostate-specific antigen levels.

40. Secondary exposure to Fortesta can cause side effects in others. In 2009 the FDA issued a black box warning for Fortesta prescriptions, advising patients of reported virilization in children who were secondarily exposed to the gel. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with Fortesta.

41. Defendant successfully marketed Fortesta by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low-T."

42. Endo's advertising program, sought to create the image and belief by consumers and their physicians that the use of Fortesta was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendant knew or should have known these to be false, and even though the Defendant had no reasonable grounds to believe them to be true.

43. Defendant purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Fortesta. Defendant deceived potential Fortesta users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

44. Defendant concealed material relevant information from potential Fortesta users and minimized user and prescriber concern regarding the safety of Fortesta.

45. In particular, in the warnings Defendant give in their commercials, online and print advertisements, Defendant fail to mention any potential cardiac or stroke side effects and falsely represents that Endo adequately tested Fortesta for all likely side effects. Defendant also fail to warn and instruct regarding the importance of adequate monitoring of hematocrit levels.

46. As a result of Defendant' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Fortesta. If Plaintiff in this action had known the risks and dangers associated with Fortesta, Plaintiff would not have taken Fortesta and consequently would not have been subject to its serious side effects.

SPECIFIC FACTUAL ALLEGATIONS

47. Plaintiff was prescribed Fortesta and used it as directed from approximately July 6, 2011 to December 5, 2012.

48. Plaintiff was 50 years of age when he was prescribed and used testosterone for symptoms he attributed to low testosterone after viewing Defendant' advertisements.

49. Plaintiff was very healthy prior to taking testosterone. In keeping with his healthy and proactive lifestyle, Plaintiff agreed to initiate testosterone treatment. He relied on claims made by Defendant that testosterone had been clinically shown to safely and effectively raise testosterone levels.

50. Plaintiff was diagnosed with myocardial infarction on or about August 28, 2011. As a result, for the rest of his life he must undergo regular testing, adhere to a restrictive diet, and take medication. Due to his myocardial infarction he is now at markedly increased risk of additional cardiovascular disease, cerebrovascular accidents, and death.

51. Had Defendant properly disclosed the risks associated with testosterone, Plaintiff would have avoided the risk of myocardial infarction by either not using testosterone at all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs were adversely affecting his health.

52. As alleged herein, as a direct, proximate, and legal result of Defendant' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug testosterone, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to myocardial infarction. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

53. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

54. The Fortesta manufactured and/or supplied by Defendant was defective due to inadequate warnings or instructions because Defendant knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks. The Fortesta manufactured and/or supplied by Defendant was defective due to inadequate post-marketing warnings or instructions because, after Defendant knew or should have known of the risk of serious bodily harm from the use of Fortesta, Defendant failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

55. As a direct and proximate result of Plaintiff's reasonably anticipated use of Fortesta as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendant, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

SECOND CAUSE OF ACTION
NEGLIGENCE

56. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though set forth herein.

57. At all times herein mentioned, Defendant had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Fortesta.

58. At all times herein mentioned, Defendant negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold Fortesta and failed to adequately test and warn of the risks and dangers of Fortesta.

59. Despite the fact that Defendant knew or should have known that Fortesta caused unreasonable, dangerous side effects, Defendant continued to market Fortesta to consumers including Plaintiff, when there were safer alternative methods of treating loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions Fortesta's advertising claims are caused by low testosterone.

60. Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendant' failure to exercise ordinary care as described above.

61. Defendant' negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

THIRD CAUSE OF ACTION
FOR BREACH OF IMPLIED WARRANTY

62. Plaintiff incorporates by reference here each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

63. Prior to the time that the aforementioned products were used by Plaintiff, Defendant impliedly warranted to Plaintiff and Plaintiff's agents and physicians that Fortesta was of merchantable quality and safe and fit for the use for which it was intended.

64. Plaintiff was and is unskilled in the research, design and manufacture of the products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendant in using Fortesta.

65. Fortesta was neither safe for its intended use nor of merchantable quality, as warranted by Defendant, in that Fortesta has dangerous propensities when used as intended and will cause severe injuries to users.

66. As a result of the abovementioned breach of implied warranties by Defendant, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION
FOR BREACH OF EXPRESS WARRANTY

67. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth here.

68. At all times mentioned, Defendant expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendant or

their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Fortesta is safe, effective, fit and proper for its intended use. Plaintiff purchased Fortesta relying upon these warranties.

69. In utilizing Fortesta, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendant. These warranties and representations were false in that Fortesta is unsafe and unfit for its intended uses.

70. As a result of the abovementioned breach of express warranties by Defendant, Plaintiff suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION
FRAUD

71. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

72. Defendant, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Fortesta, and up to the present, willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning Fortesta, which the Defendant had a duty to disclose.

73. At all times herein mentioned, Defendant conducted a sales and marketing campaign to promote the sale of Fortesta and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Fortesta. Defendant knew of the foregoing, that Fortesta is not safe, fit and effective for human consumption, that using Fortesta is hazardous to health, and that Fortesta has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

74. Defendant concealed and suppressed the true facts concerning Fortesta with the intent to defraud Plaintiff, in that Defendant knew that Plaintiff physicians would not prescribe Fortesta, and Plaintiff would not have used Fortesta, if they were aware of the true facts concerning its dangers.

75. As a result of Defendant' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

76. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

77. From the time Fortesta was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendant made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that Fortesta was safe, fit and effective for human consumption. At all times mentioned, Defendant conducted a sales and marketing campaign to promote the sale of Fortesta and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

78. The Defendant made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendant, by sales representatives and other authorized agents of Defendant, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

79. The representations by the Defendant were in fact false, in that Fortesta is not safe, fit and effective for human consumption, using Fortesta is hazardous to health, and Fortesta

has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

80. The foregoing representations by Defendant, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of Fortesta.

81. In reliance of the misrepresentations by the Defendant, and each of them, Plaintiff was induced to purchase and use Fortesta. If Plaintiff had known of the true facts and the facts concealed by the Defendant, Plaintiff would not have used Fortesta. The reliance of Plaintiff upon Defendant' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

82. As a result of the foregoing negligent misrepresentations by Defendant, Plaintiff suffered injuries and damages as alleged herein.

PUNITIVE DAMAGES ALLEGATIONS

83. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth herein.

84. The acts, conduct, and omissions of Defendant, as alleged throughout this Complaint were willful and malicious. Defendant committed these acts with a conscious disregard for the rights of Plaintiff and other Fortesta users and for the primary purpose of increasing Defendant' profits from the sale and distribution of Fortesta. Defendant' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendant in an amount appropriate to punish and make an example of Defendant.

85. Prior to the manufacturing, sale, and distribution of Fortesta, Defendant knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical,

mental, and emotional injuries. Further, Defendant, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendant unreasonably subjected consumers of said drugs to risk of injury or death from using Fortesta.

86. Despite its knowledge, Defendant, acting through its officers, directors and managing agents for the purpose of enhancing Defendant' profits, knowingly and deliberately failed to remedy the known defects in Fortesta and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Fortesta. Defendant and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Fortesta knowing these actions would expose persons to serious danger in order to advance Defendant' pecuniary interest and monetary profits.

87. Defendant' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendant with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendant as follows:

(a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for testosterone;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendant the seriousness of their conduct and to deter similar conduct in the future;

(h) For attorneys' fees, expenses, and costs of this action; and

(i) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: September 10, 2014

Respectfully submitted,

/s/ Rachel Abrams
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