UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

JEFFREY DABOVAL PEULER and JENNIFER PEULER GILLEN Individually and as the sole heirs of JOHN BENEDICT PEULER (Deceased)	Case No:
	Judge:
Plaintiffs	Magistrate:
Vs.	
AUXILIUM PHARMACEUTICALS, INC.	
Defendant	**JURY TRIAL REQUESTED**

COMPLAINT FOR DAMAGES

NOW INTO COURT, THROUGH UNDERSIGNED COUNSEL, COME **Plaintiffs, Jeffrey D. Peuler and Jennifer P. Gillen, individually and as sole heirs of their father, John B. Peuler (deceased),** and for his and their causes of action, hereby sue the **Defendant, Auxilium Pharmaceuticals, Inc**., and allege as follows:

INTRODUCTION

1. This case involves the prescription drug Testim®, which is manufactured, sold, distributed, and promoted by Defendant, Auxilium Pharmaceuticals, Inc. (hereinafter "Auxilium" or "Defendant"), as a testosterone replacement therapy.

2. Auxilium misrepresented that Testim® is a safe and effective treatment for hypogonadism or "low testosterone" when, in fact, this drug causes serious medical

problems, including life threatening cardiac events, strokes, and thrombolytic events.

3. Auxilium engaged in aggressive consumer and physician marketing and advertising campaigns for Testim®. Further, Defendant engaged in an aggressive "disease awareness" campaign to alert men that they might be suffering from "Low T."

4. Consumers of Testim® 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

5. **Plaintiffs, Jeffrey D. Peuler and Jennifer P. Gillen ("Plaintiffs"), are the sole heirs and survivors of their father, John B. Peuler**. At all times relevant hereto, all Plaintiffs were citizens of Louisiana and residents of Jefferson Parish. John B. Peuler suffered injury and died on or about March 22, 2013, due to his use of Testim®. John B. Peuler was sixty-one years of age at the time of his death.

6. **Defendant, Auxilium Pharmaceuticals, Inc.,** is a Delaware corporation which has its principal place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087. Plaintiffs aver that Auxilium conducted business and derived substantial revenue from sales of Testim® within the State of Louisiana.

7. At all times relevant to this Complaint, Auxilium was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related

entities, the prescription testosterone replacement therapy drug sold under the name Testim® throughout the United States, including the State of Louisiana.

JURISDICTION AND VENUE

8. Subject matter jurisdiction over this action arises under 28 U.S.C. § 1332. The parties are citizens of different states, and the amount in controversy between the parties exceeds the sum of $75,000.00, exclusive of interest and costs.

9. Venue is proper in the U.S. District Court for the Eastern District of Louisiana, pursuant to 28 U.S.C. § 1391, because, inter alia, John B. Peuler, was prescribed Testim®, ingested Testim®, and suffered injury and death due to heart attack at his residence located at 851 Wilshire Dr., Metairie, Louisiana 70005 in Jefferson Parish, Louisiana.

10. The U.S. District Court for the Eastern District of Louisiana has personal jurisdiction over Auxilium because Auxilium transacts business in Louisiana and the wrongs complained of herein arose in Louisiana.

11. This Court has supplemental jurisdiction over any corollary state claims pursuant to 28 U.S.C. § 1367.

SUMMARY OF THE CASE

12. This action is brought by the heirs of John B. Peuler (deceased), who was prescribed, supplied with, received, and applied the prescription testosterone replacement drug Testim® tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed,

marketed, labeled, promoted, packaged, advertised for sale, sold or otherwise placed in the stream of interstate commerce by Auxilium. This action seeks, among other relief, money damages for general and special damages sustained and to be sustained as a result of the wrongful death of John B. Peuler caused by or substantially contributed to by Defendant's conduct and product Testim®.

13. Defendant's wrongful acts, omissions, and fraudulent misrepresentations caused and/or were substantial factors in John B. Peuler's injuries, damages, and death.

14. At all times herein mentioned, Auxilium was authorized to do business within Louisiana, the state of residence of Plaintiffs and John B. Peuler.

15. At all times herein mentioned, the officers and directors of Auxilium 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, damages and losses suffered by all Plaintiffs herein.

16. John B. Peuler used Defendant's product, Testim®, as directed beginning on or about April 30, 2012, until the date of his death on or about March 22, 2013. This complaint is filed with the applicable statute of limitations period.

OVERVIEW

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

18. Auxilium coordinated massive advertising campaigns designed to convince men that they suffered from low testosterone. Auxilium orchestrated national disease awareness media blitzes that purported to educate male consumers about the signs of low testosterone. The marketing campaigns included online media and promotional literature placed in healthcare providers' offices and distributed to potential testosterone users.

19. The advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

20. Auxilium also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed and that conditions associated with normal aging could be caused by low testosterone levels.

21. While running disease awareness campaigns, Auxilium promotes its product, Testim®, as easy to use topical testosterone replacement therapies. Auxilium contrasts its products' at-home topical application with less convenient prescription testosterone

injections, which require frequent doctor visits.

22. Auxilium convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Auxilium's promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

23. What consumers received, however, were not safe drugs; instead, they received products which cause life threatening problems, including strokes and heart attacks.

24. Auxilium's 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 testosterone is safe for humans, even though Auxilium knew these to be false, and even though Auxilium had no reasonable grounds to believe them to be true

25. There have been a number of studies concluding that testosterone therapy causes a sudden increase in hematocrit, hemoglobin and estradiol, and associating its use with increased the risk of heart attacks and strokes. Defendant, Auxilium, knew or in the exercise of reasonable care should have known that its product, Testim®, was defectively designed, unreasonable dangerous in normal use, and highly likely to cause injury or death, but it failed to provide adequate warnings about these known risks.

FACTUAL ALLEGATIONS

26. The Food and Drug Administration approved Testim® on October 31, 2002, for the treatment of adult males who have low or no testosterone. After FDA approval, Testim® was widely advertised and marketed by Auxilium as a safe and effective testosterone replacement therapy.

27. Testim® is a hydro-alcoholic gel containing testosterone. Testim® is applied to the shoulders and upper arms. Testim® enters the body through transdermal absorption.

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

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

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

31. Testim® may produce undesirable side effects to patients who use the drugs, including but not limited to, myocardial infarction, stroke, and death.

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

33. In addition to the above, Testim® 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 testosterone. Patients taking testosterone may experience enlarged prostates and increased serum prostate-specific antigen levels.

34. Auxilium's marketing strategy beginning in 2000 has been to aggressively market and sell its products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Auxilium knew or should have known to result from use of its products.

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

36. Auxilium purposefully downplayed, understated, and outright ignored the health hazards and risks associated with using testosterone. Auxilium deceived potential testosterone 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.

37. As a result of Auxilium's advertising and marketing, and representations

about its products, men in the United States pervasively seek out prescriptions for testosterone. If John B. Peuler had known the risks and dangers associated with testosterone replacement therapy, he would not have taken testosterone and consequently would not have been subject to its serious side effects and ultimately death.

38. John B. Peuler was prescribed and used as directed Testim® for symptoms his doctor attributed to low testosterone as a result of Auxilium's advertisements, actions and inactions.

39. After taking daily doses of Testim® beginning on approximately April 30, 2012, John B. Peuler died on or about March 22, 2013, as the result of a heart attack.

40. Prior to using Testim®, John B. Peuler had no history of blood clots, diabetes, strokes, or significant cardiovascular problems.

41. Plaintiffs have and will sustain significant general and special damages and wrongful death and survival damages, including medical expenses, funeral expenses, lost wages, diminished economic horizons, loss of nurture guidance and support, loss of love, affection, and companionship, and other items of recoverable damages for which they seek maximum recovery as a matter of law.

42. Had Auxilium properly disclosed the risks associated with the use of its product Testim®, Plaintiff would have avoided the risk of cardiac injury and ultimately death by either not using testosterone replacement therapy 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.

FEDERAL REQUIREMENTS

43. Auxilium had an obligation to comply with the law in the manufacture, design, and sale of Testim®.

44. Upon information and belief, Auxilium violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*.

45. With respect to the testosterone replacement drug Testim®, Auxilium, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs, including, but not limited to, one or more of the following violations:

a. The prescription drug Testim® is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug Testim® is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from, or its quality or purity falls below, the standard set forth in the official compendium for Testim®, and such deviations are not plainly stated on its labels.

c. The prescription drug Testim® is misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

d. The prescription drug Testim® is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. §352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug Testim® is misbranded pursuant to 21 U.S.C. §352 because the labeling does not (i) bear adequate directions for use, and/or (ii) bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug Testim® is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage, manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The prescription drug Testim® does not contain adequate directions for use pursuant to 21 CFR §201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of:

(1) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used;

(2) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions;

(3) frequency of administration or application;

(4) duration or administration or application; and/or

(5) route or method of administration or application.

h. Auxilium violated 21 CFR §201.56 because the labeling was not informative and accurate.

i. The prescription drug Testim® is misbranded pursuant to 21 CFR §201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. Auxilium violated 21 CFR §201.57 by failing to provide information that is important to the safe and effective use of the drug, including the potential of Testim to cause cardiovascular disease and the need for regular and consistent monitoring to ensure that a potentially fatal cardiac condition has not developed.

k. Auxilium violated 21 CFR §201.57 because it failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Testim®.

l. Auxilium violated 21 CFR §201.57 because the safety considerations regarding the prescription drug Testim® are such that the drug should be reserved for certain situations, and the Defendant failed to state such information.

m. The prescription drug Testim® is mislabeled pursuant to 21 CFR §201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug Testim® is mislabeled pursuant to 21 CFR §201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. Auxilium violated 21 CFR §201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug Testim® and other drugs in the same pharmacologically active and chemically related class.

p. Auxilium violated 21 CFR §201.57 because the possibility that a patient could develop cardiovascular disease and other adverse reactions significantly more severe than the other reactions listed in the adverse reactions, and yet Auxilium failed to list the development of same before the other adverse reactions on the labeling of the prescription drug Testim®.

q. The prescription drug Testim® is mislabeled pursuant to 21 CFR §201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug Testim® violates 21 CFR §210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets

the requirements as to safety and meets the quality and purity characteristics that it purports or is represented to possess.

s. The prescription drug Testim® violates 21 CFR §210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug Testim® violates 21 CFR §211.165 because the test methods employed by Auxilium are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug Testim® violates 21 CFR §211.165 in that the prescription drug TESTIM® fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug Testim® violates 21 CFR §211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug Testim® were not followed.

w. The prescription drug Testim® violates 21 CFR §310.303 in that the prescription drug Testim® is not safe and effective for its intended use.

x. The Defendant violated 21 CFR §310.303 because Auxilium failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. Auxilium violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug Testim® as soon as possible or at least within 15 days of the initial receipt by the Defendant of the adverse drugs experience.

z. Auxilium violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug Testim®, and evaluating the cause of the adverse event.

aa. Auxilium violated 21 CFR §§310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. Auxilium violated 21 CFR §§310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional

information regarding serious, unexpected adverse drug experiences.

cc. Auxilium violated 21 CFR §§310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up."

dd. Auxilium violated 21 CFR §312.32 because it failed to review all information relevant to the safety of the prescription drug Testim® or otherwise received by the Defendant from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. Auxilium violated 21 CFR §314.80 by failing to provide periodic reports to the FDA containing

(1) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval,

(2) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or

(3) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. Auxilium violated 21 CFR §314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

46. Defendant failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as John B. Peuler, making Auxilium liable under Louisiana law.

CAUSES OF ACTION:

FIRST CAUSE OF ACTION:
Construction or Composition Defect under La. R.S. 9:2800.55

47. Plaintiffs repeat, reiterate, and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

48. At all times material to this action, Defendant was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Testim®.

49. At all times material to this action, Testim® was expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including John B. Peuler, without substantial change in the condition in which it was sold.

50. At all times material to this action, Testim® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Auxilium in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Testim® contained manufacturing defects which rendered the subject product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of Auxilium;

c. The subject product was not made in accordance with Auxilium's specifications or performance standards; and

d. The subject product's manufacturing defects existed before it left the control of Auxilium.

51. The subject product manufactured and/or supplied by Auxilium was defective in construction or composition in that, when it left Auxilium's hands, it deviated in a material way from Auxilium's manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula. In particular, the product is not safe, has numerous and serious side effects, and causes severe and permanent injuries including, but not limited to, developing cardiovascular disease, strokes, and myocardial infarctions. The product was unreasonably dangerous in construction or composition as provided by La. R.S. 9:2800.55.

SECOND CAUSE OF ACTION:
Design Defect under La. R.S. 9:2800.56

52. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

53. Testim® is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The subject product was unreasonably dangerous in design as provided by La. R.S. 9:2800.56.

54. At all times material to this action, Testim® was expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including John B. Peuler, without substantial change in the condition in which it was sold.

55. At all times material to this action, Testim® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Auxilium in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Testim® contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting John B. Peuler to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing cardiovascular disease, strokes, myocardial infarctions, and other serious injuries and side effects;

b. When placed in the stream of commerce, Testim® was defective in design and formulation, making the use of Testim® more dangerous than an ordinary consumer would expect, and more dangerous than

other risks associated with the other medications and similar drugs on the market to treat low testosterone ;

c. The design defects of Testim® existed before it left the control of Auxilium;

d. Testim® was insufficiently tested;

e. Testim® caused harmful side effects that outweighed any potential utility; and

f. Testim® was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including John B. Peuler, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Auxilium liable to Plaintiffs.

56. In addition, at the time the subject product left the control of Auxilium, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of John B. Peuler's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of John B. Peuler's injuries without substantially impairing the product's utility.

THIRD CAUSE OF ACTION:
Inadequate Warning under La. R.S. 9:2800.57

57. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

58. Testim® was defective and unreasonably dangerous when it left the possession of Auxilium in that it contained warnings insufficient to alert consumers, including John B. Peuler, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing cardiovascular disease, strokes, myocardial infarcts, and other serious injuries, side effects, and death; notwithstanding Auxilium's knowledge of an increased risk of these injuries and side effects over other forms of treatment for low testosterone. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as provided pursuant to La. R.S. 9:2800.57.

59. The subject product manufactured and supplied by Auxilium was defective due to inadequate post-marketing warning or instruction because, after Auxilium knew or should have known of the risk of serious bodily harm from the use of the subject product, Auxilium failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and

instructions, or recall, while knowing that the product could cause serious injury and/or death.

60. John B. Peuler was prescribed and used the subject product for its intended purpose.

61. John B. Peuler could not have discovered any defect in the subject product through the exercise of reasonable care.

62. Auxilium, as manufacturers and/or distributors of the subject prescription product, is held to the level of knowledge of an expert in the field.

63. Auxilium, the manufacturer and/or distributor of the subject prescription product, is held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

64. The warnings that were given by Auxilium were not accurate, clear, and/or were ambiguous.

65. The warnings that were given by Auxilium failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, developing serious injuries, side effects and death.

66. John B. Peuler, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Auxilium.

67. Auxilium had a continuing duty to warn John B. Peuler of the dangers associated with the subject product.

68. Had John B. Peuler received adequate warnings regarding the risks of the subject product, he would not have used it.

FOURTH CAUSE OF ACTION:
Breach of Express Warranty under La. R.S. 9:2800.58

69. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

70. Auxilium expressly represented to John B. Peuler, other consumers, and the medical community that Testim® was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

71. Testim® does not conform to Auxilium's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including, but not limited to, developing cardiovascular disease and other serious injuries and side effects.

72. At the time of the making of the express warranties, Auxilium knew, or in the exercise of reasonable care should have known, of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to an expressed warranty of Auxilium as provided by La. R.S. 9:2800.58.

73. At the time of the making of the express warranties, Auxilium knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

74. At all relevant times Testim® did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

75. John B. Peuler, other consumers, and the medical community relied upon Auxilium's express warranties.

FIFTH CAUSE OF ACTION:
Redhibition

76. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

77. The subject product contains a vice or defect which renders it useless or its use so dangerous that buyers would not have purchased it.

78. Auxilium sold and promoted Testim®, which Auxilium placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The subject product sold and promoted by Auxilium, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is

unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have bought the subject product had he known of the defect. Pursuant to La. C.C. art. 2520, Plaintiffs are entitled to obtain a rescission of the sale of the subject product.

79. The subject product alternatively possesses a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiffs are entitled to a reduction of the purchase price.

80. Auxilium is liable as a bad faith seller for selling a defective product with knowledge of the defect, and thus, is liable to Plaintiffs for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product and attorneys' fees. As the manufacturer of the subject product, under Louisiana law, Auxilium is deemed to know that Testim® possessed a redhibitory defect. La. C.C. art. 2545.

SIXTH CAUSE OF ACTION:
Breach of Warranty of Fitness for Ordinary Use

81. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if stated herein.

82. In addition to warranting against redhibitory defects, Auxilium warrants, as a matter of law, that the subject product is reasonably fit for its ordinary and intended use. La. C.C. art. 2524.

83. The subject product is not safe, has numerous and serious side effects and causes severe and permanent injuries including, but not limited to, developing cardiovascular disease and other serious injuries and side effects. As a result, Testim® is unfit and inherently dangerous for ordinary use.

84. As a direct and proximate result of Defendant's actions, John B. Peuler died. Plaintiffs, Jeffrey D. Peuler and Jennifer P. Gillen, have and will sustain significant injuries, damages, and losses, including, but not limited to: medical and related expenses, funeral expenses, loss of income and support, and diminished economic horizons. Plaintiffs have also suffered and will continue to suffer other losses and damages, including, but not limited to: diminished capacity for the enjoyment of life, a diminished quality of life, grief, loss of love and affection, nurture, and parental guidance.

SEVENTH CAUSE OF ACTION:
Breach of Implied Warranty of Merchantability and Fitness

85. Plaintiffs repeat, reiterate and re-allege each and every allegation of this Complaint as detailed above, with the same force and effect as if stated herein.

86. At all relevant times, Auxilium knew of the use for which Testim® was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

87. Auxilium was aware that consumers, including John B. Peuler, would use Testim® for treatment or prevention of male hypogonadism/ low testosterone.

88. John B. Peuler and the medical community reasonably relied upon the judgment and sensibility of Auxilium to sell Testim® only if it was indeed of merchantable quality and safe and fit for its intended use.

89. Auxilium breached the implied warranty to consumers, including John B. Peuler, as Testim® was not of merchantable quality or safe and fit for its intended use.

90. Consumers, including John B. Peuler and the medical community, reasonably relied upon Auxilium's implied warranty for Testim®.

91. Testim® reached consumers, including John B. Peuler, without substantial change in the condition in which it was manufactured and sold by Auxilium.

EIGHTH CAUSE OF ACTION:
Fraud

92. Plaintiffs adopt by reference each and every paragraph of the Complaint applicable to all counts of this Complaint, and each and every count of this Complaint as if stated herein.

93. Auxilium, from the time it first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed Testim® until the present, willfully deceived John B. Peuler and his family by concealing from them, John B. Peuler's physicians, and the general public the true facts concerning Testim®, which Auxilium had a duty to disclose.

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

95. Auxilium concealed and suppressed the true facts concerning Testim® with the intent to defraud, in that Auxilium knew that John B. Peuler's physicians would not prescribe Testim®, and John B. Peuler would not have used Testim®, if they were aware of the true facts concerning its dangers.

96. As a result of Auxilium's fraudulent and deceitful conduct, Plaintiffs suffered injuries and damages as alleged herein.

NINTH CAUSE OF ACTION:
Negligent Misrepresentation

97. Plaintiffs adopt by reference each and every paragraph of the Complaint

applicable to all counts of this Complaint, and each and every count of this Complaint as if stated herein.

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

99. Auxilium made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by Auxilium, by sales representatives and other authorized agents of Auxilium, 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.

100. The representations by the Defendant were in fact false, in that Testim® is not safe, fit and effective for human consumption, using Testim® is hazardous to health, and Testim® has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by John B. Peuler.

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

102. In reliance of the misrepresentations by Auxilium, and each of them, John B. Peuler was induced to purchase and use Testim®. If John B. Peuler had known of the true facts and the facts concealed by Auxilium, John B. Peuler would not have used Testim®. The reliance of John B. Peuler upon Auxilium's misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

103. As a result of the foregoing negligent misrepresentations by Auxilium, John B. Peuler, suffered injuries and death as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, Jeffrey D. Peuler and Jennifer P. Gillen, individually and as the sole heirs of their deceased father, John B. Peuler, pray for judgment against the Defendant, Auxilium Pharmaceuticals, Inc., for all elements and items of general and special damages recoverable at law or in equity in amounts which are reasonable in the premises, including but not limited to:

a. Actual damages to Plaintiffs incidental to John B. Peuler's purchase and use of Testim® in an amount to be determined at trial;

b. Wrongful death and survival damages as allowed by law;

c. Pre-Judgment and post-judgment interest to Plaintiffs;

d. All costs and expenses of this litigation;

e. Reasonable attorneys' fees and costs to Plaintiffs as provided by law; and

f. Restitution, disgorgement of profits, and other equitable relief;

g. Injunctive relief; and

h. Such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs are entitled to and hereby request a jury trial on all issues so triable in this action.

Respectfully submitted,

Domengeaux Wright Roy & Edwards, LLC

James P. Roy

JAMES P. ROY (La. Bar No. 11,511) (T.A.)
ELWOOD C. STEVENS, JR. (La. Bar No. 12,459)
JOHN P. ROY (La. Bar No. 32,048)
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Email: ElwoodS@wrightroy.com
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ATTORNEYS FOR PLAINTIFFS:
Jeffrey D. Peuler and Jennifer P. Gillen, Individually and as sole heirs of John B. Peuler (deceased)

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

DEFENDANTS

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ❒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

❒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ❒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

Jeffrey Daboval Peuler and Jennifer Peuler Gillen, Individually and as sole heirs of John Benedict Peuler (Deceased)

Plaintiff(s)

v.

Auxilium Pharmaceuticals, Inc.

Defendant(s)

Civil Action No. 2:14-cv-00658

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Auxilium Pharmaceuticals, Inc.
640 Lee Road
Chesterbrook, PA 19087

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:14-cv-00658

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: