UNITED STATES DISTRICT COURT
NORTHERN DISCTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
ARTHUR MYERS and HEATHER MYERS husband and wife 8601 East Hopi Drive Prescott Valley, Arizona 86314 Plaintiffs vs. ABBVIE, INC. 1 North Waukegan Road North Chicago, Illinois 60064 and ABBOTT LABORATORIES, INC. 100 Abbott Park Road Abbott Park, Illinois 60064 Defendants	COMPLAINT AND JURY DEMAND Civil Action No:._____

COMPLAINT AND DEMAND FOR JURY TRIAL

NOW COME the Plaintiffs, Arthur Myers and Heather Myers, husband and wife, by and through their undersigned attorneys who herein file this Civil Action Complaint and bring this civil action against the above-captioned Defendants based upon the predicate facts, causes of action, and demands for relief set forth in the Counts below. Plaintiffs aver the following:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiffs, Arthur Myers and Heather Myers, husband and wife ["Plaintiff-husband" and "Plaintiff-wife" and jointly, "Plaintiffs"], are adult citizens and residents of

Arizona, residing therein at 8601 East Hopi Drive, Prescott Valley, Yavapai County, Arizona 86314.

2. Defendant, AbbVie Inc. ["AbbVie"], is a corporation organized according to and existing under the laws of the State of Delaware, with headquarters and a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

3. Defendant, Abbot Laboratories, Inc. ["Abbott"], is a corporation organized according to and existing under the laws of the State of Illinois, with headquarters and a principal place of business at 100 Abbot Park Road, Abbott Park, Illinois 60064.

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

5. Venue is proper within this district pursuant to 28 U.S.C. §1391 because Defendants reside in this district and because a substantial part of the transactions and occurrences giving rise to Plaintiffs' claims and causes-of-action occurred within this district.

6. Venue is proper within this district pursuant to Case Management Order No. 12 in MDL 2545 *In re: Testosterone Replacement Therapy Products Liability Litigation*, that permits any plaintiff whose case would be subject to transfer to MDL 2545 to file his or her case directly in the MDL Proceedings.

ALLEGATIONS GIVING RISE LIABILITY

7. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

8. AndroGel is a testosterone-containing topical gel.

9. AndroGel provides a continuous transdermal delivery system for testosterone for 24 hours following a single application to the skin of the shoulders and/or upper arms in men.

10. AndroGel was originally approved by the FDA in 2000, and marketed by Unimed Pharma ["Solvay"] under a licensing agreement from Besins Healthcare.

11. In 2003, Solvay Pharmaceuticals acquired Unimed.

12. In 2010, the Solvay Pharmaceuticals division was sold to Abbott Laboratories.

13. In 2013, AbbVie assumed the exclusive rights to market AndroGel in the United States when it split off from Abbott Laboratories as an independent pharmaceutical company.

14. At all times material hereto, AndroGel was sequentially a pharmaceutical product manufactured, distributed, marketed, sold, and promoted by Abbott and AbbVie and their predecessors-in-interest, and these companies successively assumed legal responsibility and liability for the design, regulatory approval, warnings, labelling, marketing and promotional content, safety and effectiveness, and manufacturing quality of the AndroGel products.

15. The AndroGel product was approved by the FDA in 2000 for the treatment of male primary and secondary hypogonadism.

16. The AndroGel product reached the Plaintiff-husband, as a consumer and patient, from AbbVie, Abbott, and/or their predecessors-in-interest in an unaltered condition through the stream of interstate commerce.

17. Plaintiff-husband was within the market to which Abbott and AbbVie directed its product marketing, physician-detailing, consumer and physician advertising and marketing, and promotional sales strategies and initiatives with respect to the AndroGel product.

18. Abbott and AbbVie undertook a duty to provide accurate, reliable, and truthful information to patients and consumers, including the Plaintiff-husband, concerning AndroGel's safety and effectiveness profiles, clinical indications for use, and approved clinical uses.

19. In fact, AbbVie, along with other testosterone replacement therapy ["TRT"] manufacturers,[1] stated in the *Advisory Committee Industry Briefing Document Testosterone Replacement Therapy* (emphasis added) submitted to the FDA in advance of the September 17, 2014 Advisory Committee[2] hearing: "TRT Sponsors remain committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions."

20. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest made no changes to the AndroGel product labelling or Medication Guide to include the risks of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

[1]The "TRT Sponsors" include AbbVie, Auxilium Pharmaceuticals, Inc., Besins Healthcare, Clarus Therapeutics, Eli Lilly and Company, LillyEndo Pharmaceuticals, Lipocine, MonoSol Rx, TesoRx, Trimel Pharmaceuticals, Upsher Smith Laboratories, and Viramal.

[2]Joint Meeting for Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSARM AC).

e. other acute visceral and central venous and arterial thrombotic phenomena.

21. At all times material hereto, despite being "committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions," and undertaking a duty to provide such education, neither Abbott, AbbVie, nor their predecessors-in-interest made labelling or Medication Guide changes, or offered information to consumers and patients, concerning the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

22. Hypogonadism is a medical disorder characterized by low testosterone levels caused by a congenital or acquired injury to or infection or pathological conditions of the male reproductive organs (testes); or pathologic conditions of the hormonal axis which regulates testosterone production by the male reproductive organs.

23. Primary hypogonadism occurs under circumstances of congenital or acquired pathologic insults to and conditions of the testes in men.

24. Secondary hypogonadism occurs under circumstances of hypogonadotropism, including hypothalamic-pituitary diseases and disorders (e.g., space occupying lesions of the

pituitary fossa) and other conditions which cause suppression of gonadotropin-releasing hormone ["GnRH"].

25. GnRH is a trophic peptide hormone responsible for the release of follicle-stimulating hormone ["FSH"] and luteinizing hormone ["LH"] from the anterior pituitary gland.

26. GnRH is synthesized and released from neurons within the hypothalamus.

27. In men, LH binds to receptors on Leydig cells in the testes, and stimulates the synthesis and secretion of testosterone.

28. In men, FSH is critical for sperm production.

29. FSH supports the function of Sertoli cells, which in turn support sperm cell maturation.

30. At all times material hereto, and since the time that the AndroGel product was approved by the FDA, Abbott, AbbVie, and their predecessors-in-interest knew and understood the FDA-approved indications for clinical use of the AndroGel product.

31. Abbott, AbbVie, and their predecessors-in-interest exhibited these indications on, among other places, the Product Package Insert ["PPI"] as follows:

1 INDICATIONS AND USAGE

AndroGel 1% is an androgen indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations, but have gonadotropins in the normal or low range.

1 INDICATIONS AND USAGE

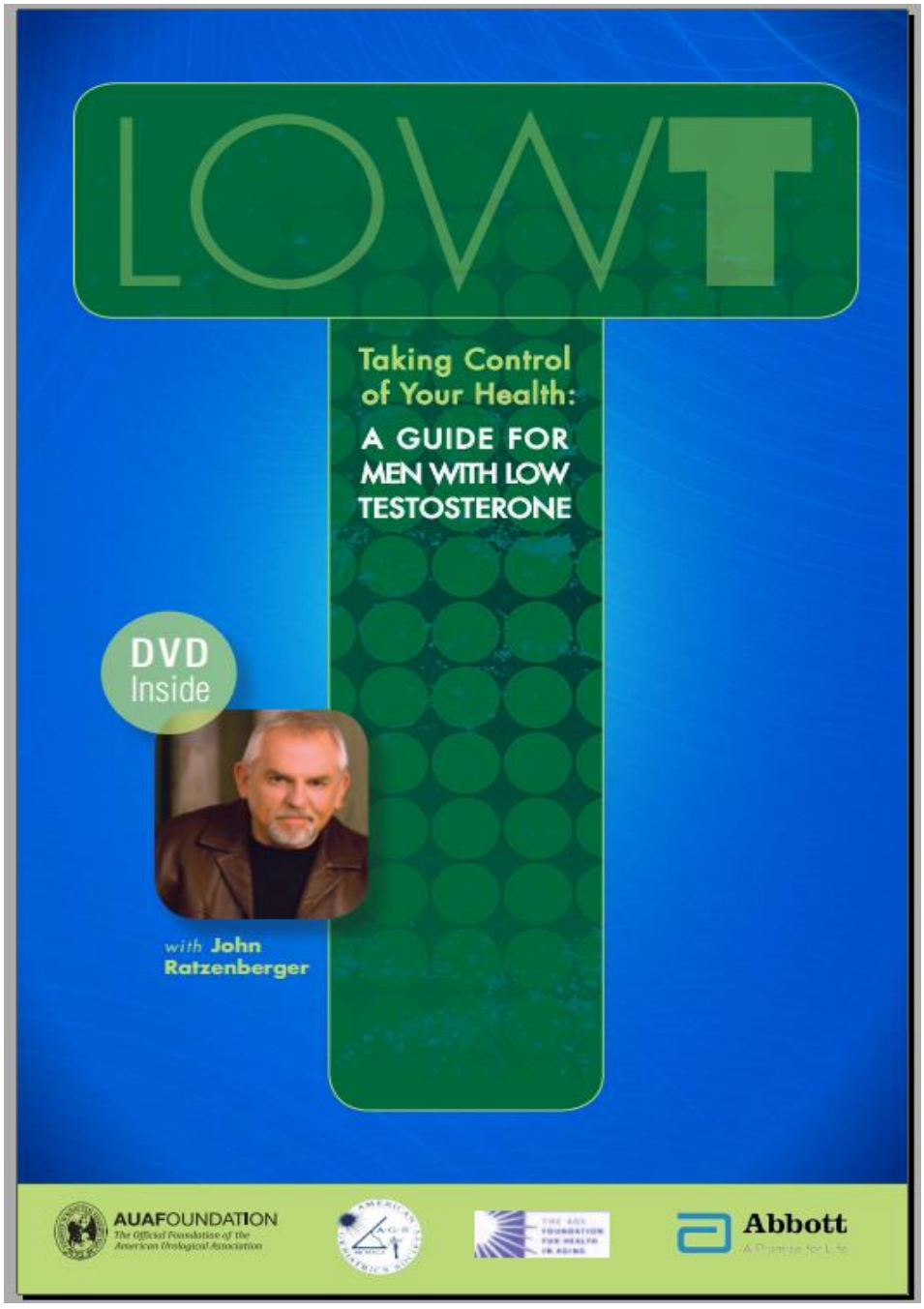
AndroGel 1.62% is an androgen indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations, but have gonadotropins in the normal or low range.

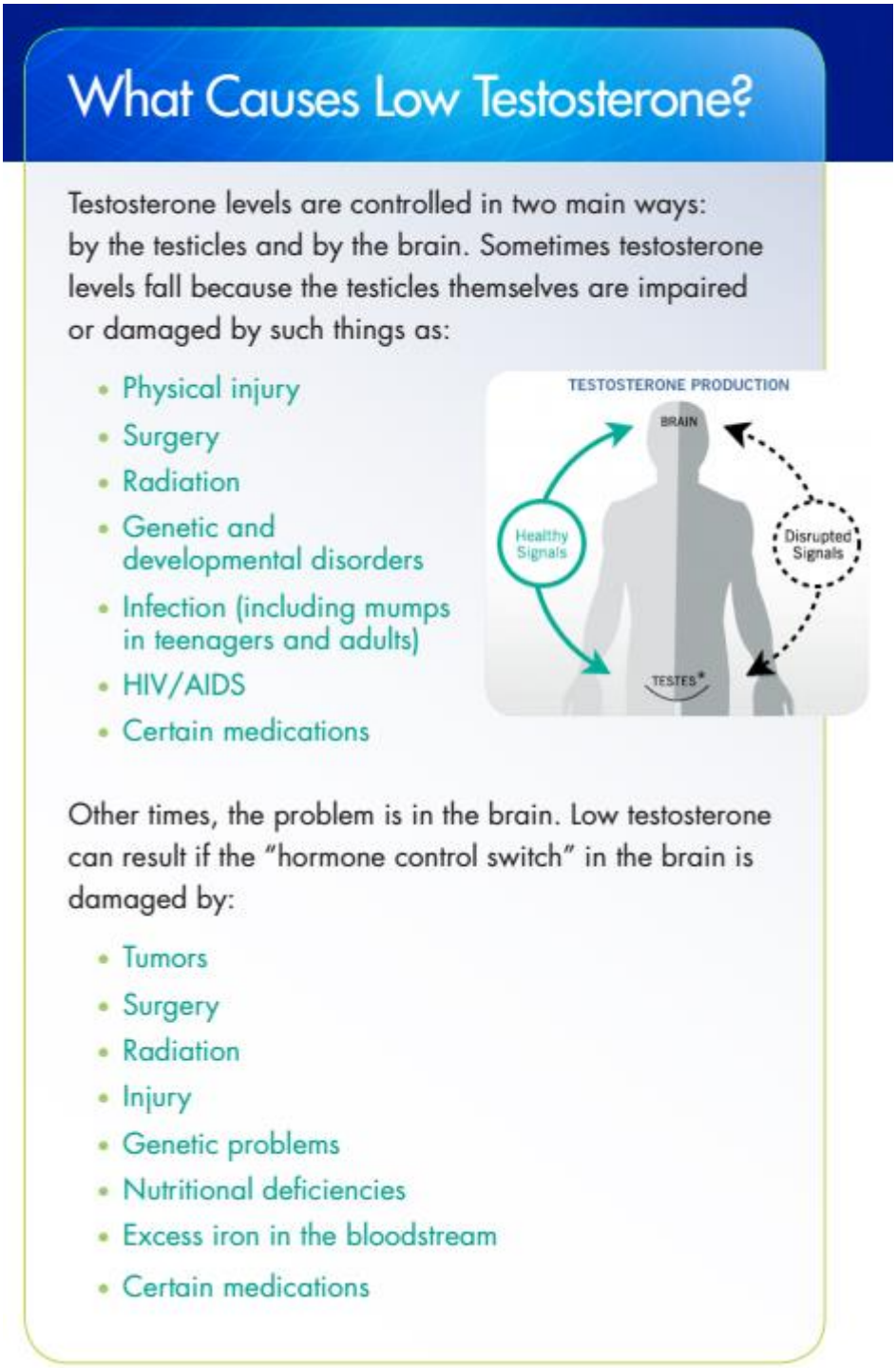
32. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest knew and understood the medical and pathologic conditions and diagnoses, as set forth in the

AndroGel PPI, which form and comprise the indications for clinical use of the AndroGel product.

33. In 2010, Abbott and the American Urological Association Foundation, the official foundation of the American Urological Association (AUA) published the pamphlet *Low T Taking Control of Your Health: A Guide for Men With Low Testosterone* for patients:



34. In the *Low T Taking Control of Your Health: A Guide for Men With Low Testosterone* pamphlet, the following causes of low testosterone or "Low T," which coincide with and track the "Indications and Usage" set forth on the AndroGel PPI and approved labelling, are listed:



35. The answers to the question "What causes Low Testosterone?" set forth in the *Low T Taking Control of Your Health: A Guide for Men With Low Testosterone* pamphlet track

the FDA-approved clinical uses for the AndroGel products, and is identical to the definitions of primary and secondary hypogonadism.

36. The *Low T Taking Control of Your Health: A Guide for Men With Low Testosterone* pamphlet does not discuss *normal* age-related declines in testosterone levels or age-related symptoms in men, which were the "off-label" clinical indications for use for which Abbott and AbbVie were promoting and marketing the AndroGel product.

37. The *Low T Taking Control of Your Health: A Guide for Men With Low Testosterone* pamphlet additional sets forth the "Symptoms of Low Testosterone" as follows:

38. At all times material hereto, and since the launch of the AndroGel products in 2000, Abbott, AbbVie and their predecessors-in-interest knew and understood that the AndroGel was not FDA-approved to treat:

a. tiredness or loss of energy;

b. low interest in sex;

c. loss of vitality;

d. problems getting or maintaining an erection;

e. depressed mood;

f. decreased sense of well-being;

g. muscle weakness;

h. reduced bone density;

i. low blood iron levels; or

j. small or soft testicles.

39. At all times material hereto, Abbott, AbbVie, and their predecessors-in interest knew and understood the meaning of the terms "off-label" use and "label expansion," and additionally knew and understood the FDA rules and regulations pertaining to these activities.

40. Abbott, AbbVie, and their predecessors-in-interest knew and understood that when testosterone deficiency conditions occur prior to puberty, androgen replacement therapy is required during the adolescent years for development of androgen-dependent secondary sexual characteristics. Prolonged androgen treatment is then required to maintain sexual characteristics in these males following puberty.

41. Abbott, AbbVie, and their predecessors-in-interest further knew and understood that androgen therapy may be indicated to stimulate puberty in males with delayed puberty, and that these male patients generally manifest a form of familial-pattern pubertal delay that is not secondary to a pathological disorder. Rather, in these male patients, puberty is expected to occur

spontaneously at a relatively late date. Brief treatment with conservative doses of testosterone may be indicated in these patients if they do not respond to psychological support.

42. The FDA-approved indications for clinical use of the AndroGel product do not and never have included the treatment of age-related declines in testosterone levels and age-related symptoms in men, including:

a. tiredness or loss of energy;

b. low interest in sex;

c. loss of vitality;

d. problems getting or maintaining an erection;

e. depressed mood;

f. decreased sense of well-being;

g. muscle weakness;

h. reduced bone density;

i. low blood iron levels; or

j. small or soft testicles.

43. Abbott, AbbVie, and their predecessors-in-interest marketed AndroGel in the United States through its own marketing, advertising, and branding teams; and through marketing firms, agencies, organizations, and/or other external pharmaceutical companies.

44. At all times material hereto, the marketing strategies of Abbott, AbbVie, and their predecessors-in-interest included the use of sales or drug detailing representatives [“reps”] and marketing and brand team personnel who performed on-line and in-person AndroGel product detailing to physicians; and promotional and detailing to healthcare providers and physicians at medical organization and professional medical society meetings and conventions via display

booths, sponsored meeting sessions, "satellite" sessions and meetings, and sponsored medical speakers.

45. Abbott, AbbVie, and their predecessors-in-interest drug detailing "reps" who provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the AndroGel product, as well as discount and/or rebate coupons to give to patients for the purchase of AndroGel.

46. Abbott, AbbVie, and their predecessors-in-interest drug "reps" detailed and marketed AndroGel to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

47. Abbott, AbbVie, and their predecessors-in-interest denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

48. The AndroGel product was never approved by the FDA for "off-label" promotion for the treatment of "Low T" as an indication for clinical use.

49. Abbott, AbbVie, and their predecessors-in-interest engaged in "label expansion" in both their promotion of AndroGel use to physicians and in their marketing of AndroGel to consumers and patients.

50. Abbott, AbbVie, and their predecessors-in-interest marketed, promoted, and detailed AndroGel for "off-label" use for the purpose of "label expansion" to populations of men who were not appropriate candidates for testosterone treatment, and detailed and promoted the AndroGel product to physicians, and advertised the AndroGel product to consumers and patients, under the rubric that "Low T" was an indication for clinical use of the AndroGel product.

51. A manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an "off-label" purpose.

52. A manufacturer misbrands a drug if the labelling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

53. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

54. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

55. Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made, or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials.

56. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest knew and understood that they had not provided the FDA with data supporting the clinical use of the AndroGel product to treat age-related symptoms and:

a. tiredness or loss of energy;

b. low interest in sex;

c. loss of vitality;

d. problems getting or maintaining an erection;

e. depressed mood;

f. decreased sense of well-being;

g. muscle weakness;

h. reduced bone density;

i. low blood iron levels; or

j. small or soft testicles.

57. At all times material hereto, the marketing strategy of Abbott, AbbVie, and their predecessors-in-interest for the AndroGel products included the use of sales representative ["reps"] who performed detailing to physicians and mass promotional and detailing activities at professional medical organization and society meetings and conventions by way of display booths, sponsored speakers, sponsored presentations, and sponsored or recruited presenters.

58. The detailing "reps" of Abbott, AbbVie, and their predecessors-in-interest provided physicians with:

a. information concerning the clinical indications for use of the AndroGel product and medical literature;

b. product information and literature concerning testosterone, testosterone replacement therapy:

c. "Low T" and its treatment with AndroGel;

d. "detailing pieces" and literature for distribution to patients;

e. invitations to Abbott, AbbVie, and their predecessors-in-interest sponsored presentations and events; and

f. discount and/or rebate coupons or vouchers and information about discount and/or rebate plans with respect to the purchase of AndroGel for distribution to patients.

59. The sales "reps," promoters, and product detailers of Abbott, AbbVie, and their predecessors-in-interest marketed and promoted the testosterone-containing AndroGel product to physicians and healthcare providers as products approved and clinically indicated for the treatment of age-related declines in testosterone levels and age-related symptoms in men. These were not FDA-approved clinical uses for these testosterone-containing products, and this was known to the sales "reps," promoters, and product detailers.

60. Abbott, AbbVie, and their predecessors-in-interest marketed and promoted the testosterone-containing AndroGel product directly to consumers as products approved and clinically indicated for the treatment of age-related declines in testosterone levels and age-related symptoms in men. These were not FDA-approved clinical uses for these testosterone-containing products, and this was known to those marketing and promoting the AndroGel product directly to consumers and patients.

61. Abbott, AbbVie, and their predecessors-in-interest engaged in "off-label" promotion and misbranding of the testosterone-containing AndroGel product during their marketing and detailing of this product to physicians and healthcare providers.

62. Abbott, AbbVie, and their predecessors-in-interest engaged in "off-label" promotion and misbranding of the testosterone-containing AndroGel product during their marketing and detailing of this product to consumers and patients.

63. Abbott, AbbVie, and their predecessors-in-interest engaged in a direct-to-consumer marketing and promotional campaign through a variety of educational, advertising, and informational multimedia platforms, including Internet-based dedicated "Low T" and "AndroGel" websites and branded and unbranded television commercials.

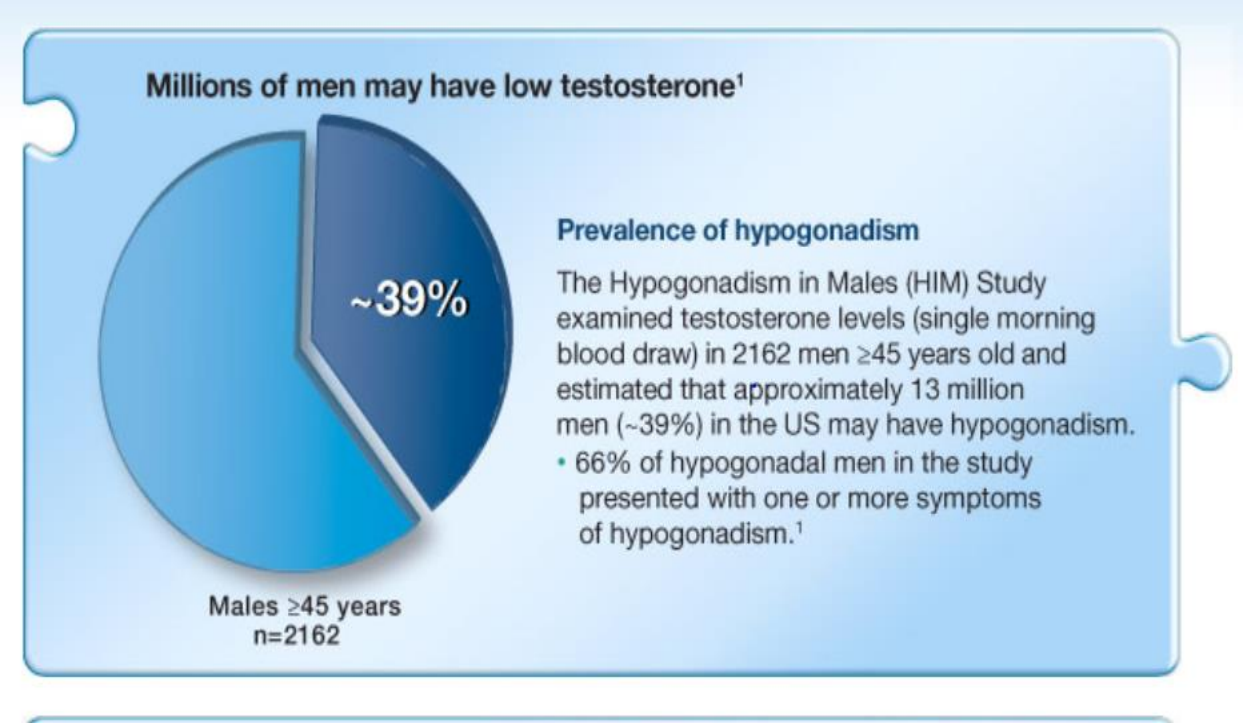
64. Abbott, AbbVie, and their predecessors-in-interest engaged in a direct-to-consumer marketing and promotional campaign through a variety of educational, advertising, and informational multimedia platforms, including Internet-based dedicated "Low T" and "AndroGel" websites, which contained misbranding of the AndroGel products.

65. Abbott, AbbVie, and their predecessors-in-interest materially misrepresented and mischaracterized to consumers the definition and clinical etiologies and characteristics of hypogonadism, which is a specific medical disease with well-defined etiologies and pathologic conditions.

66. Abbott, AbbVie, and their predecessors-in-interest engaged in deceptive trade practices.

67. Abbott and AbbVie, by way of example, cite the 2006 "the HIM Study"[3] on the AndroGel website as demonstrating that "Millions of men have low testosterone," and therefore hypogonadism:

[3]Mulligan, T., Frick, M.F., Zuraw, Q.C. *et al.* (2006). Prevalence of hypogonadism in males aged at least 45 years: the HIM study. *Int J Clin Pract* 60:762-769.



68. With respect to "the Him Study:" "The goal of this study was to estimate the prevalence of hypogonadism in men aged at least 45 years presenting (for any reason)[4] to primary care practices in the United States. A second objective was to correlate the presence of hypogonadism with select comorbid conditions and symptoms."[5]

69. The study, as cited on the AndroGel website, creates the false, deceptive, and misleading impression that 39% of men in the Unites States experience hypogonadism.

70. Further, the website fails to acknowledge that this study was performed by, and on behalf of, the predecessor-in-interest to Abbott and AbbVie, Solvay, and that several conflicts of interest existed with respect to this study:

[4]"Clinicians from a random sample of 2650 primary care practices throughout the United States were contacted and 130 practices agreed to participate. All men aged 45 years and older who were seen in a participating doctor's office between 8 AM and noon during a 2-week period, *regardless of the reason for their visit*, were invited to participate in the survey." *Id.* (emphasis added).
[5]*Id.*

CONFLICT OF INTEREST

Dr Thomas Mulligan has received funding from, and been a consultant for, Solvay Pharmaceuticals, Inc. He also does research for the Department of Veteran Affairs and Ascend Therapeutics and has been a consultant for GTx.

Myra Frick is an employee of Covance Periapproval Services, Inc. Covance conducted the study on behalf of Solvay Pharmaceuticals, Inc.

Dr Qing Zuraw is an employee of Covance Periapproval Services, Inc. Covance conducted the study on behalf of Solvay Pharmaceuticals, Inc.

Annette Stemhagen was formerly an employee of Covance Periapproval Services, Inc. Covance conducted the study on behalf of Solvay Pharmaceuticals, Inc.

71. The AndroGel website does not identify these conflicts of interest to consumers or patients.

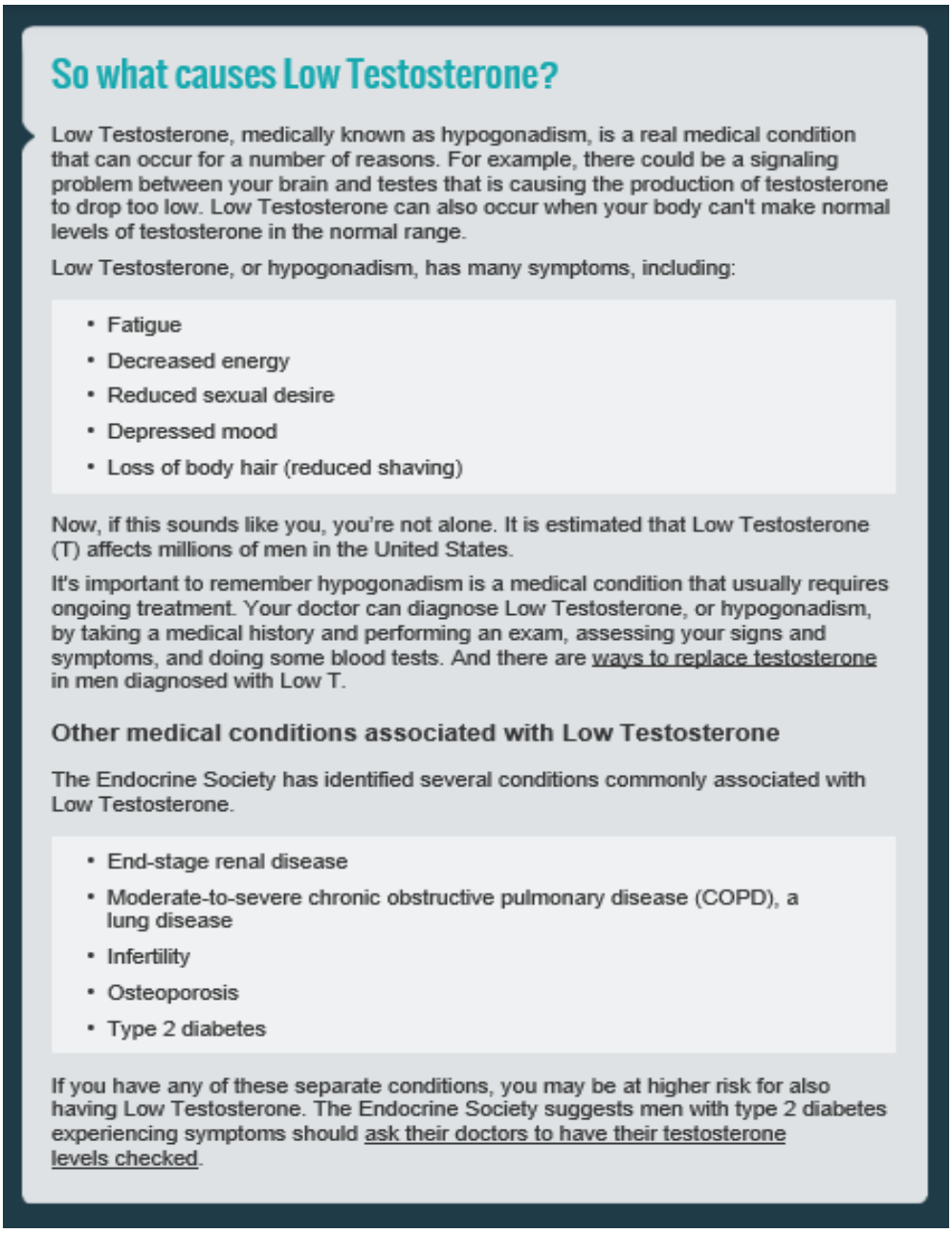
72. The AndroGel website creates the false, misleading, and deceptive impression that "the Him Study" was an independently performed assessment of hypogonadism, and significantly misstates the prevalence of hypogonadism.

73. "The Him Study" is scientifically flawed in its design and conclusion, and is a self-serving exercise by Abbott, AbbVie, and their predecessors-in-interest to create the false and misleading impression amongst consumers and patients of a widespread epidemic of hypogonadism in men age 45 years or older.

74. Abbott, AbbVie, and their predecessors-in-interest materially misrepresented and mischaracterized to consumers and patients the meaning of the term hypogonadism, and provided misinformation concerning hypogonadism and "Low T" with the intent of confuse, deceive, and otherwise mislead consumers and patients to believe that "Low T," age-related

declines in serum testosterone levels in men, and age-related symptoms in men are synonymous entities and pathologic conditions or diseases.

75. Abbott, AbbVie, and their predecessors-in-interest materially misrepresented and mischaracterized to consumers and patients the meaning of the term hypogonadism with the intent of confuse, deceive, and otherwise mislead consumers and patients to believe that "Low T," age-related declines in serum testosterone levels in men, and age-related symptoms in men are synonymous entities and pathologic conditions or diseases suitable for treatment with the AndroGel products.



So what causes Low Testosterone?

Low Testosterone, medically known as hypogonadism, is a real medical condition that can occur for a number of reasons. For example, there could be a signaling problem between your brain and testes that is causing the production of testosterone to drop too low. Low Testosterone can also occur when your body can't make normal levels of testosterone in the normal range.

Low Testosterone, or hypogonadism, has many symptoms, including:

- Fatigue
- Decreased energy
- Reduced sexual desire
- Depressed mood
- Loss of body hair (reduced shaving)

Now, if this sounds like you, you're not alone. It is estimated that Low Testosterone (T) affects millions of men in the United States.

It's important to remember hypogonadism is a medical condition that usually requires ongoing treatment. Your doctor can diagnose Low Testosterone, or hypogonadism, by taking a medical history and performing an exam, assessing your signs and symptoms, and doing some blood tests. And there are ways to replace testosterone in men diagnosed with Low T.

Other medical conditions associated with Low Testosterone

The Endocrine Society has identified several conditions commonly associated with Low Testosterone.

- End-stage renal disease
- Moderate-to-severe chronic obstructive pulmonary disease (COPD), a lung disease
- Infertility
- Osteoporosis
- Type 2 diabetes

If you have any of these separate conditions, you may be at higher risk for also having Low Testosterone. The Endocrine Society suggests men with type 2 diabetes experiencing symptoms should ask their doctors to have their testosterone levels checked.

76. Throughout their marketing and promotional campaigns to consumers, Abbott, AbbVie, and their predecessors-in-interest misrepresented and mischaracterized the *normal* physiologic declines in testosterone levels in aging men and age-related symptoms in men as being synonymous with or an indication of the medical diagnosis of hypogonadism; and knowingly, falsely, deceptively, and inaccurately designated this contrived and medically unfounded form of "hypogonadism" as being "Low T."

77. Testosterone replacement therapy is not a treatment for end-stage renal disease, moderate to severe chronic obstructive pulmonary disease, infertility, osteoporosis, or type 2 diabetes mellitus. This representation is knowingly false, misleading, and deceptive.

78. Throughout their marketing and promotional campaigns to consumers and patients, Abbott and AbbVie misrepresented and mischaracterized the *normal* physiologic declines in testosterone levels in aging men and age-related symptoms in men as being synonymous with or an indication of the medical diagnosis of hypogonadism; and knowingly, falsely, deceptively, and inaccurately marketed and promoted the Androgen product as an approved treatment for "Low T."

79. The FDA-approved the AndroGel product for the treatment of primary and secondary hypogonadism.

80. Abbott, AbbVie, and their predecessors-in-interest engaged in "off-label" marketing, promotional, and detailing campaigns which encouraged and drove "off-label" prescription and clinical use of the AndroGel product with respect to the clinical indications for use of AndroGel and the populations and subpopulations of patients suitable for treatment with AndroGel product and for whom the product should be prescribed.

81. Abbott, AbbVie, and their predecessors-in-interest knowingly, falsely, deceptively, and inaccurately educated and detailed physicians that AndroGel was FDA-approved for the treatment of "Low T," and thereby engaged in "off-label" promotion and "label expansion," and enlisted and offered something of value to "thought leaders," "key opinion leaders," and sponsored speakers. These individuals assisted in the perpetuation of the "off-label" usage of the AndroGel product through authored medical journal articles, speaking engagements, presentations at medical society meetings, including the American Urological

Association, the Endocrine Society, and the American Andrology, and through their participation in the drafting of Clinical Practice Guidelines by these societies.

82. In 2010, Abbott Laboratories held an approximately 70% market share in the testosterone replacement therapy space with its AndroGel 1% and 1.62% products. These products were FDA-approved for the treatment of primary and secondary hypogonadism.

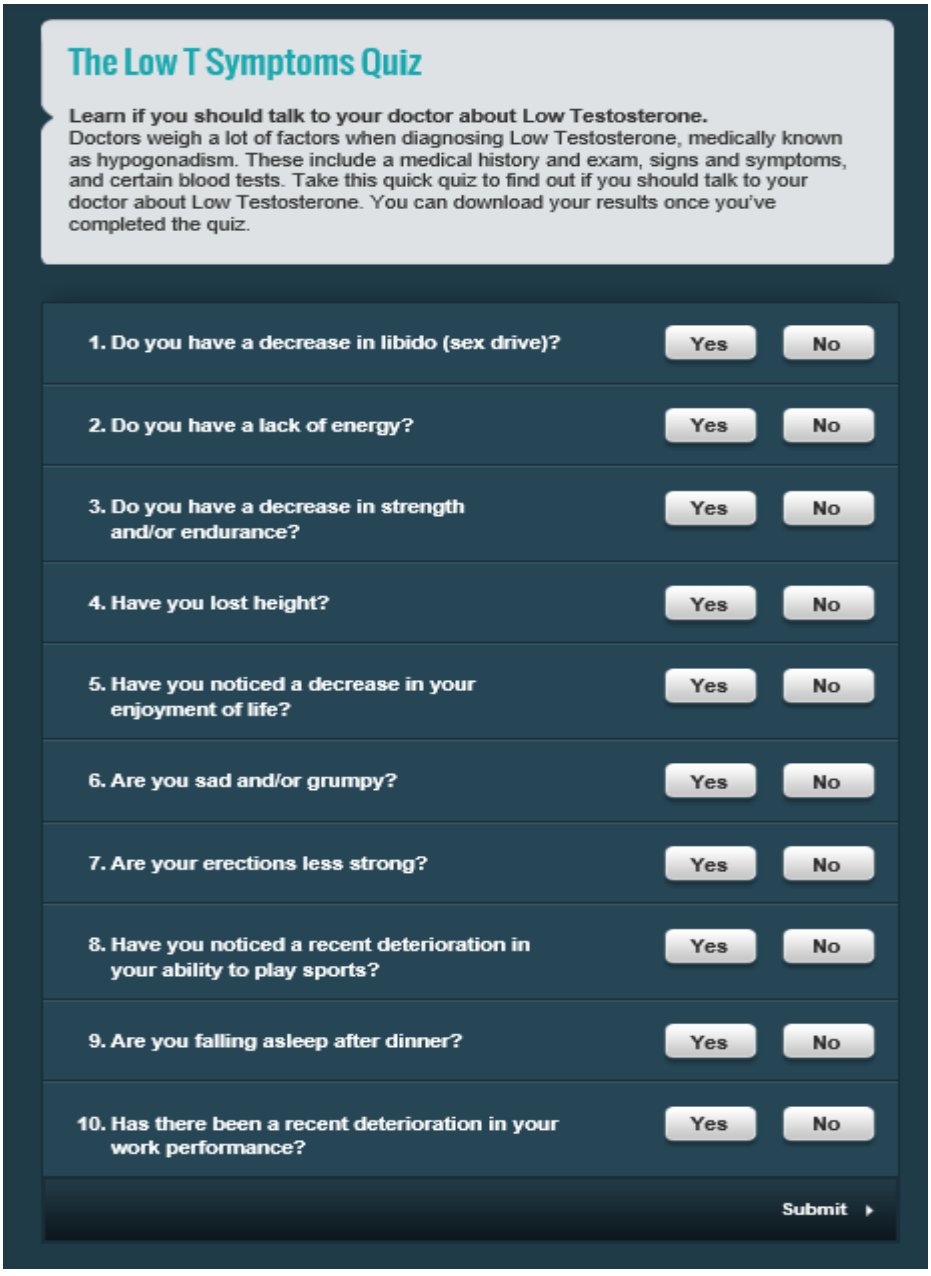
83. Abbott and AbbVie made materially false and misleading statements about the nature of "Low T," and created the impression among consumers and patients that testosterone-replacement therapy in general, and the AndroGel product line in particular, were approved treatments for age-related declines in testosterone levels and age-related symptoms in men:

84. "Low T" is not "a real medical condition."

85. Hypogonadism (primary and secondary) is a "real medical condition," not "Low T," and is the FDA-approved clinical indications for AndroGel product administration.

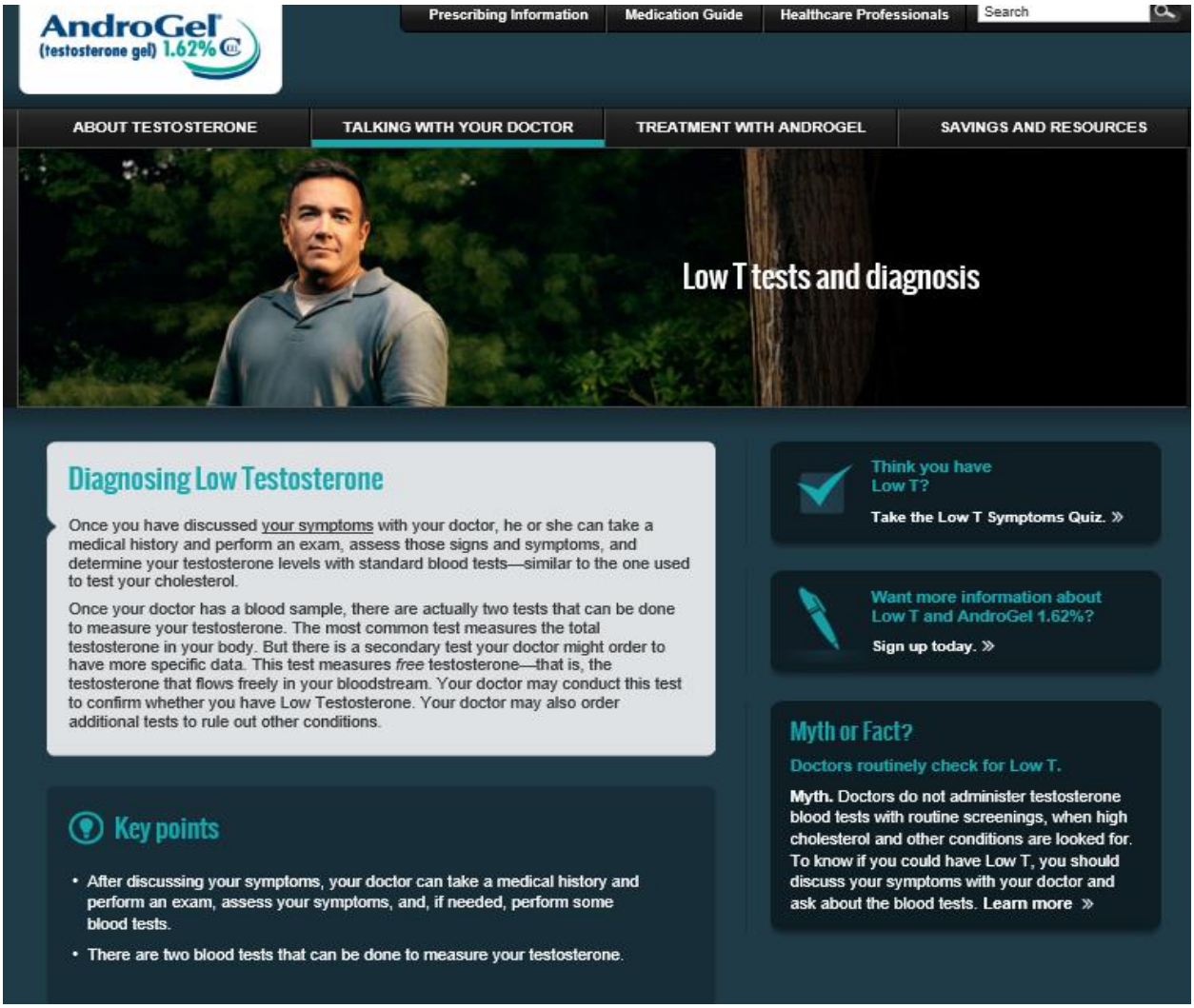
86. "Low T" is not a disease, and does not have an assigned ICD code designator.

87. Abbott, AbbVie, and their predecessors-in-interest were encouraging men to self-diagnose and self-assess themselves for the signs and symptoms of "Low T," a pharmaceutical industry created "disease," by way of an interactive medical history and screening questionnaire:



88. In this manner, Abbott, AbbVie, and their predecessors-in-interest provided consumers and patients with a means to self-assess and self-diagnose for the signs and symptoms of this pharmaceutical industry created disease, "Low T," prior to engaging or interfacing with a physician or other healthcare provider. Abbott, AbbVie, and their predecessors-in-interest designed this questionnaire to ensure that these patients would then request further evaluation for and treatment of "Low T" with AndroGel.

89. Abbott, AbbVie, and their predecessors-in-interest engaged in, promoted, and marketed "patient-directed medical care," in which patients were and continue to be encouraged to self-diagnose their "Low T" condition, and then seek out and direct their medical therapy from physicians. Abbott, AbbVie, and their predecessors-in-interest also referred patients to physicians upon patient request. These physicians were known to be high-prescribers of the AndroGel product.



90. Consumers and patients were encouraged to render their own self-diagnosis of "Low T," and to then seek medical treatment with the self-diagnosis and self-assessment of "Low T" already in hand. Abbott, AbbVie, and their predecessors-in-interest provided patients with scripted discussion guides with respect to their interactions with physicians concerning "Low T."

91. The self-diagnosis of "Low T" by consumers and patients was therefore made according to diagnostic criteria posited by Abbott, AbbVie, and their predecessors-in-interest.

92. Abbott, AbbVie, and their predecessors-in-interest engaged in a mass program of consumer-based self-diagnostic "Low T" quizzes and self-assessment questionnaires which

screened for signs and symptoms which Abbott, AbbVie, and their predecessors-in-interest knew and understood were not approved indications for AndroGel treatment; namely, age-related declines in testosterone levels and age-related symptoms in men.

93. Abbott, AbbVie, and their predecessors-in-interest engaged in a mass program of consumer-based self-diagnostic "Low T" quizzes and self-assessment questionnaires which screened for signs and symptoms which Abbott, AbbVie, and their predecessors-in-interest knew and understood were not approved indications for Androgel treatment; namely, age-related declines in testosterone levels and age-related symptoms in men.

94. Abbott and/or AbbVie and/or their predecessors-in-interest established "The Restoration Program" for the AndroGel product line to establish and maintain a "patient-pharmaceutical company" relationship with users and potential users of the AndroGel products, and to further provide "educational emails" to consumers and patients.

95. Abbott, AbbVie, and their predecessors-in-interest sent "refill reminders" and "helpful information on Low T" and "facts about AndroGel" directly to patients, without an intermediary physician, and established lines of communication directly with patients concerning Protected Health Information (PHI) independent of the involvement of healthcare providers.

96. Abbott, AbbVie, and their predecessors-in-interest assumed and stepped into roles coterminous with but separate and apart from healthcare providers, including:

a. offering consumers and patients extensive medical information concerning a "disease," including its signs, symptoms, etiology, and associated co-morbidities;

b. advising patients concerning the treatment and/or treatment options for that "disease;"

c. providing assistance in the diagnosis of the "disease" by taking a detailed history of patient signs and symptoms, and recommending or directing laboratory testing for the "disease;"

d. providing physician referrals;

e. providing prescription refill reminders;

f. providing information about specific drug therapy for the "disease, including adverse effects of the therapy;" and

g. soliciting Protected Health Information (PHI) and data concerning the health status of patients, including prior or current medical conditions.

97. Abbott, AbbVie, and their predecessors-in-interest specifically detailed and promoted the use of the AndroGel products to prescribing physicians for clinical use in patients

with "Low T," which Abbott, AbbVie, and their predecessors-in-interest knowingly, deceptively, and falsely claimed was included in and fell under the clinical definition of hypogonadism.

98. In fact, Abbott, AbbVie, and their predecessors-in-interest challenged the competency of physicians to recognize, diagnose, and treat "Low T," and informed consumers and patients that it was a "myth" that "Doctors routinely check for Low T."

99. Abbott, AbbVie, and their predecessors-in-interest challenged the competency of physicians to recognize, diagnose, and treat "Low T," and therefore encouraged patients to demand tests for testosterone levels and treatment for "Low T" because "physicians do not administer testosterone blood tests with routine screenings."

100. Abbott, AbbVie, and their predecessors-in-interest knew and understood that "doctors do not administer testosterone blood tests with routine screenings" because these blood tests are not indicated in the diagnosis of age-related symptoms in men.

101. Abbott, AbbVie, and their predecessors-in-interest knew and understood that "doctors do not administer testosterone blood tests with routine screenings" because these blood tests are not indicated absent one of the medical diagnoses or conditions specifically set forth on the AndroGel PPI.

102. Abbott, AbbVie, and their predecessors-in-interest assumed and undertook a duty of care when they chose to educate and inform consumers about "Low T;" when they chose to provide consumers with the means for self-diagnostic assessment and screening for "Low T;" and when they offered differential diagnoses for signs and symptoms which Abbott, AbbVie, and their predecessors-in-interest claimed were consistent with or indicative of "Low T."

103. The duty of care of Abbott, AbbVie, and their predecessors-in-interest included the obligation to provide truthful, accurate, and incomplete information about "Low T," including information that "Low T" is not an indication for clinical use of testosterone-containing preparations in general, and the AndroGel product in particular.

104. Abbott, AbbVie, and their predecessors-in-interest expressly and impliedly warranted to consumers that the AndroGel product was an FDA-approved treatment for "Low T" and age-related symptoms; that AndroGel had a favorable clinical safety and effectiveness profile for the treatment of "Low T" and age-related symptoms; and that AndroGel was an appropriate treatment for this particular purpose. This was a "basis of the bargain" upon which consumers, including the Plaintiff-husband, justifiably relied in their choice to accept treatment with, purchase, and administer the AndroGel product.

105. Abbott, AbbVie, and their predecessors-in-interest expressly and impliedly warranted to consumers that the AndroGel product line was an FDA-approved treatment for "Low T" and age-related symptoms; that AndroGel had a favorable clinical safety and effectiveness profile for the treatment of "Low T" and age-related symptoms; and that AndroGel was an appropriate treatment for this particular purpose. This was a "basis of the bargain" upon which consumers, including the Plaintiff-husband, relied in their choice to accept treatment with, purchase, and administer an AndroGel product.

106. The duty of care to consumers and patients of Abbott, AbbVie, and their predecessors-in-interest included providing accurate, true, complete, full, and correct information concerning hypogonadism and its diagnostic criteria; the FDA-approved indications for the clinic use of the AndroGel product line; the clinical safety and effectiveness profiles of AndroGel; and the full and complete panoply of warnings about the adverse effects of AndroGel, including the risks of serious adverse life- and limb-threatening cardiovascular and cerebrovascular events, including:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

107. Abbott, AbbVie, and their predecessors-in-interest knowingly, falsely, deceptively, and inaccurately designated the age-related physiologic decrease in men's testosterone levels and the age-related symptoms which men experience with senescence as a form of acquired hypogonadism with the intent to deceive or otherwise encourage physicians to prescribe AndroGel for "off-label" indications for clinical use; to engage in "label expansion" of the AndroGel product in order to increase revenues and profits through market expansion; and to drive increasing consumer demand for AndroGel prescriptions.

108. Abbott, AbbVie, and their predecessors-in-interest knowingly, falsely, deceptively, and inaccurately misstated the clinical effectiveness profile of AndroGel to physicians, to include statements concerning the effectiveness of treatment of the age-related symptoms. There was no evidence to support this clinical use of the AndroGel products, and no approval by the FDA to warrant promotion of these indications of clinical use for the AndroGel.

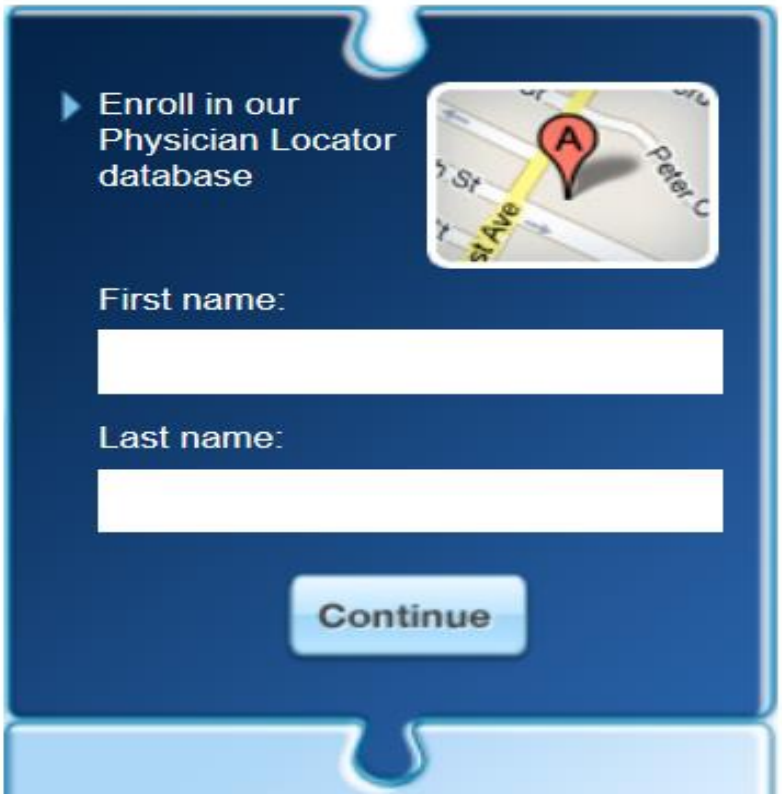
109. Abbott, AbbVie, and their predecessors-in-interest knowingly, falsely, deceptively, and inaccurately designated the physiologic declines in men's testosterone levels and age-related symptoms men experience as a form of "acquired hypogonadism," with the intent to confuse, mislead, and deceive consumers and patients, and to foster the belief among consumers and patients, including the Plaintiff-husband, that they harbored a "disease" that was appropriately and effectively treated with an AndroGel product.

110. Consumers, including the Plaintiff-husband, required truthful, accurate, full, complete, and correct information concerning the FDA-approved indications for clinical use of the AndroGel product and AndroGel therapy, and the clinical safety and effectiveness profiles of the AndroGel product.

111. Consumers and patients, including the Plaintiff-husband, were never informed by Abbott, AbbVie, or their predecessors-in-interest that AndroGel was being promoted, marketed, detailed, and endorsed for "off-label" clinical uses.

112. Abbott, AbbVie, and their predecessors-in-interest maintained a list of the top AndroGel prescribing physicians, and directed consumers and patients to these physicians via a physician-finder service.

113. Abbott, AbbVie, and their predecessors-in-interest actively enrolled AndroGel prescribing physicians into a "Physician Locator database," and directed and referred patients to the top-prescribing physicians of the AndroGel products.



114. In this manner, Abbott, AbbVie, and their predecessors-in-interest assumed a role and undertook a duty traditionally reserved for healthcare providers: The referral of patients for medical evaluation and treatment, including the selection of the physician receiving the patient referral.

115. Physician referrals are something of value, and create an income stream for physicians receiving these referrals from Abbott, AbbVie, and their predecessors-in-interest.

116. Patient referrals create and income stream for physicians receiving these referrals.

117. Abbott, AbbVie, and their predecessors-in-interest selected physicians to whom to make consumer and patient referrals based upon the prescribing habits of those physicians with respect to the AndroGel product, and rewards physicians who are high-prescribers of the AndroGel product with further referrals. This constitutes an indirect transfer of something of value from the pharmaceutical company to a physician.

118. Abbott, AbbVie, and their predecessors-in-interest expressly and impliedly warranted to consumers that the AndroGel product was an FDA-approved treatment for "Low T" and age-related symptoms; that AndroGel had a favorable clinical safety and effectiveness profile for the treatment of "Low T" and age-related symptoms; and that AndroGel was an appropriate treatment for this particular purpose. This was a "basis of the bargain" upon which consumers, including the Plaintiff-husband, justifiably relied in their choice to accept treatment with, purchase, and administer an AndroGel product.

119. Neither Abbott, AbbVie, nor their predecessors-in-interest informed consumers about the risks of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

120. Abbott, AbbVie, and their predecessors-in-interest knowingly encouraged and drove the demand for laboratory testing for testosterone levels premonitory to the clinical diagnosis and treatment of "Low T," with actual knowledge that "Low T" and age-related symptoms in men are not indications for treatment with an AndroGel product.

121. Abbott, AbbVie, and their predecessors-in-interest failed to disclose to physicians that the FDA had not approved the use of AndroGel product for the treatment of age-related declines in testosterone levels in men or age-related symptoms in men, and that the FDA knew of no data supporting these indications for use.

122. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest made false and misleading statements and claims to physicians regarding the clinical safety and effectiveness profiles of AndroGel and its spectrum of FDA-approved indications for use.

123. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest promoted and marketed AndroGel products to physicians and healthcare providers, and failed to warn of the known risks of serious adverse life- and limb-threatening cardiovascular and cerebrovascular injuries causally related to the use of AndroGel.

124. Abbott, AbbVie, and their predecessors-in-interest knew and understood that there were no prospective, randomized, long-term-use clinical trials which demonstrated either the clinical safety or effectiveness of testosterone therapy for age-related declines in testosterone levels or age-related symptoms in men, and that the FDA had not approved these as indications for AndroGel use.

125. Neither Abbott, AbbVie, nor their predecessors-in-interest ever informed the FDA that it was engaging in "label expansion" through its physician marketing, and promotional and

detailing activities to include the use of the AndroGel product "off-label" to treat "Low T" or age-related declines in testosterone levels or to age-related symptoms in men.

126. This "label expansion" for AndroGel by Abbott, AbbVie, and their predecessors-in-interest exceeded the FDA-approved clinical uses to treat of primary and secondary hypogonadism.

127. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest owed a duty to prescribing physicians to inform these physicians of the approved uses for the AndroGel product, and to warn prescribing physicians that the FDA had not approved AndroGel product for the treatment of age-related declines in testosterone levels and age-related symptoms in men.

128. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest had a duty to warn physicians that AndroGel was being promoted for "off-label" indications for clinical use, and that there was no appropriately developed, controlled, suitably powered, and independent data to support this use.

129. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest knowingly deceived physicians, including the Plaintiff-husband's prescribing physician, concerning the FDA-approved uses for the AndroGel product and the clinical indications for AndroGel therapy.

130. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest knowingly deceived physicians, including the Plaintiff-husband's prescribing physician, concerning the clinical safety and effectiveness profiles of the AndroGel product.

131. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest intentionally sought to simultaneously deceive, mislead and confuse consumers, on the one hand,

concerning the approved clinical indications for use of the AndroGel products, the products' safety and effectiveness profiles, and the definitions of hypogonadism; and on the other hand, the physicians prescribing AndroGel, to whom the product was knowingly, willfully, and deceptively being detailed and promoted for "off-label" use. These activities were undertaken to promote and increase "off-label" prescription and clinical use of the AndroGel products.

132. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest disseminated and provided information during the promotion and detailing of the AndroGel products to physicians and healthcare providers, including the Plaintiff-husband's prescribing physician, which failed to disclose the correct and accurate FDA-approved indications for use of the AndroGel product line.

133. The information provided to healthcare providers was false, misleading, and deceptive, and failed to warn that the product was being promoted for "off-label" clinical indications for use and that safety and effectiveness profiles were lack in the patient populations and subpopulations for which Abbott, AbbVie, and their predecessors-in-interest were advocating product use.

134. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest had, undertook, and assumed a continuing duty to correct the known misinformation which had been disseminated to physicians, healthcare providers, patients, and consumers concerning the FDA-approved indications for clinical use of the AndroGel product; the lack of clinical safety and effectiveness profiles for AndroGel; and the relationship of AndroGel to heart attacks, strokes, deep vein thrombosis, pulmonary emboli, sudden cardiac death, and risk factors for these disease states. Abbott, AbbVie, and their predecessors-in-interest failed in these duties.

135. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest misbranded the AndroGel product on an on-going and continuous basis, and failed to warn that the AndroGel product line was not approved for the treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

136. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest sought to conflate the diagnosis of hypogonadism with the diagnosis of "Low T."

137. Abbott, AbbVie, and their predecessors-in-interest sales "reps" and promotional and marketing teams detailed the AndroGel product line to physicians, including the Plaintiff-husband's physician, as an appropriate FDA-approved treatment for "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

138. The treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms with AndroGel product created a manifest and unreasonable public health hazard, including a hazard to the Plaintiff-husband, because patients with "Low T" should not have been exposed to treatment with AndroGel product.

139. Abbott, AbbVie, and their predecessors-in-interest knew and understood that consumers and patients would rely upon the educational and medical information that they provided through its multi-platform marketing, promotional, and awareness campaigns concerning the AndroGel product line and its indications for clinical use; and further knew that consumers and patients would make treatment choices and decisions about their use of the AndroGel product in justifiable reliance upon this information.

140. As marketed, detailed, and promoted to physicians, Abbott, AbbVie, and their predecessors-in-interest failed to warn physicians that AndroGel caused or increased the risk of harm of serious life- and limb-threatening cardiovascular and cerebrovascular injuries, including:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

141. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the AndroGel product to cause, or increase the harm of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

142. At all times material hereto, and presently, neither Abbott, AbbVie, nor their predecessors-in-interest have warned physicians, consumers, or patients of the risks of serious

adverse life- and limb-threatening cardiovascular and cerebrovascular events caused by or increased in the risk of harm by the AndroGel product.

143. AndroGel should not have been designed for the treatment of age-related declines in testosterone levels and age-related symptoms in men; or the treatment of "Low T;" and should not have been promoted for, prescribed for, or used for these clinical purposes.

144. Safer pharmaceutical and non-pharmaceutical alternatives to AndroGel treatment of "Low T" or age-related declines in testosterone levels in men or age-related symptoms in men existed which were FDA-approved and/or of known safety and effectiveness for the treatment of these conditions.

145. AndroGel was negligently designed for the treatment of "Low T."

146. The Plaintiff-husband relied to his detriment upon the fraudulent representations, misrepresentations, misinformation, and express and implied warranties made by or provided by Abbott, AbbVie, or their predecessors-in-interest with respect to the AndroGel product.

147. The Plaintiff-husband would not have sought, accepted, or continued treatment for "Low T," or administered AndroGel, or continued with or otherwise undergone testosterone replacement therapy, had he been provided with adequate, true, accurate, and correct information by Abbott, AbbVie, or their predecessors-in-interest about the risks of serious adverse life- and limb-threatening cardiovascular and cerebrovascular events causally associated with the of increased in their risk of harm by the use of AndroGel, and the fact that "Low T" was not an FDA-approved indication for use for the AndroGel product line.

148. The Plaintiff-husband would not have sought or continued treatment for "Low T," or administered AndroGel, had he been provided with adequate, true, accurate, and correct

information by Abbott, AbbVie, or their predecessors-in-interest that there was no proven clinical profile of safety or effectiveness for the use of AndroGel to treat "Low T."

149. Abbott, AbbVie, or their predecessors-in-interest further assumed a duty traditionally undertaken by physicians and health care providers to assist patients in tracking their symptoms and "disease" treatment progress. Abbott and/or AbbVie offered the "6 Month Tracker Progress" as a component of "The Restoration Program" on the AndroGel website:

6-Month Progress Tracker

The RESTORATION PROGRAM

Use these charts to help you keep track of your progress over the next 6 months. You can download the file to your desktop and print out the chart to write in your answers.

Simply insert an "X" for the weeks you experience symptoms in each area. Use the spaces at the bottom of the page to help you keep track of upcoming appointment dates and your lab results. Share the results of the Progress Tracker with your doctor.

Month 1

Symptoms	Week 1	Week 2	Week 3	Week 4
Decreased sex drive				
Sexual dysfunction (weak erections, fewer erections)				
Loss of body hair or reduced shaving				
Decreased muscle mass				
Increased body fat				
Fatigue or decreased energy				
Depressed mood				

Month 2

Symptoms	Week 1	Week 2	Week 3	Week 4
Decreased sex drive				
Sexual dysfunction (weak erections, fewer erections)				
Loss of body hair or reduced shaving				
Decreased muscle mass				
Increased body fat				
Fatigue or decreased energy				
Depressed mood				

	1st visit	2nd visit	3rd visit	Additional appointments	
Doctor's visits (mm/dd/yy)					
Your testosterone level					

Month 3

Symptoms	Week 1	Week 2	Week 3	Week 4
Decreased sex drive				
Sexual dysfunction (weak erections, fewer erections)				
Loss of body hair or reduced shaving				
Decreased muscle mass				
Increased body fat				
Fatigue or decreased energy				
Depressed mood				

Month 4

Symptoms	Week 1	Week 2	Week 3	Week 4
Decreased sex drive				
Sexual dysfunction (weak erections, fewer erections)				
Loss of body hair or reduced shaving				
Decreased muscle mass				
Increased body fat				
Fatigue or decreased energy				
Depressed mood				

	1st visit	2nd visit	3rd visit	Additional appointments	
Doctor's visits (mm/dd/yy)					
Your testosterone level					

Month 5

Symptoms	Week 1	Week 2	Week 3	Week 4
Decreased sex drive				
Sexual dysfunction (weak erections, fewer erections)				
Loss of body hair or reduced shaving				
Decreased muscle mass				
Increased body fat				
Fatigue or decreased energy				
Depressed mood				

Month 6

Symptoms	Week 1	Week 2	Week 3	Week 4
Decreased sex drive				
Sexual dysfunction (weak erections, fewer erections)				
Loss of body hair or reduced shaving				
Decreased muscle mass				
Increased body fat				
Fatigue or decreased energy				
Depressed mood				

	1st visit	2nd visit	3rd visit	Additional appointments	
Doctor's visits (mm/dd/yy)					
Your testosterone level					

150. The symptoms listed on the "6-Month Symptom Tracker" were not indications for treatment with the AndroGel product; and knowingly, deceptively, and intentionally created a false belief among patients that AndroGel was an appropriate treatment for these conditions.

151. Abbott, AbbVie, and their predecessors-in-interest failed to warn physicians of the hazards and dangers of the AndroGel product to cause, or increase the risk of harm of serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

152. Abbott, AbbVie, and their predecessors-in-interest failed to warn consumers and patients of the hazards and dangers of the AndroGel products to cause or increase the risk of harm of serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

153. The AndroGel website advises consumers:

1. What is the most important information I should know about AndroGel 1.62%?

1. Early signs and symptoms of puberty have happened in young children who were accidentally exposed to testosterone through contact with men using AndroGel 1.62%.

Signs and symptoms of early puberty in a child may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

AndroGel 1.62% can transfer from your body to others.

2. Women and children should avoid contact with the unwashed or unclothed area where AndroGel 1.62% has been applied to your skin.

Stop using AndroGel 1.62% and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have occurred through accidental exposure to AndroGel 1.62%.

Signs and symptoms of exposure to AndroGel 1.62% in children may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

Signs and symptoms of exposure to AndroGel 1.62% in women may include:

- changes in body hair
- a large increase in acne

To lower the risk of transfer of AndroGel 1.62% from your body to others, you should follow these important instructions:

- Apply AndroGel 1.62% **only** to your shoulders and upper arms that will be covered by a short-sleeve t-shirt.
- Wash your hands **right away** with soap and water after applying AndroGel 1.62%.
- After the gel has dried, **cover the application area with clothing**. Keep the area covered until you have washed the application area well or have showered.
- **If you expect to have skin-to-skin contact with another person, first wash the application area well with soap and water.**
- **If a woman or child makes contact with the AndroGel 1.62% application area, that area on the woman or child should be washed well with soap and water right away.**

6. What are the possible side effects of AndroGel 1.62%?

See "What is the most important information I should know about AndroGel 1.62%?"

AndroGel 1.62% can cause serious side effects including:

- **If you already have enlargement of your prostate gland your signs and symptoms can get worse while using AndroGel 1.62%.** This can include:
  - increased urination at night
  - trouble starting your urine stream
  - having to pass urine many times during the day
  - having an urge that you have to go to the bathroom right away
  - having a urine accident
  - being unable to pass urine or weak urine flow
- **Possible increased risk of prostate cancer.** Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you use AndroGel 1.62%.
- **In large doses AndroGel 1.62% may lower your sperm count.**
- **Swelling of your ankles, feet, or body, with or without heart failure.**
- **Enlarged or painful breasts.**
- **Have problems breathing while you sleep (sleep apnea).**
- **Blood clots in the legs.** This can include pain, swelling, or redness of your legs.

Call your healthcare provider right away if you have any of the serious side effects listed above.

The most common side effects of AndroGel 1.62% include:

- increased prostate specific antigen (a test used to screen for prostate cancer)
- mood swings
- hypertension
- increased red blood cell count
- skin irritation where AndroGel 1.62% is applied

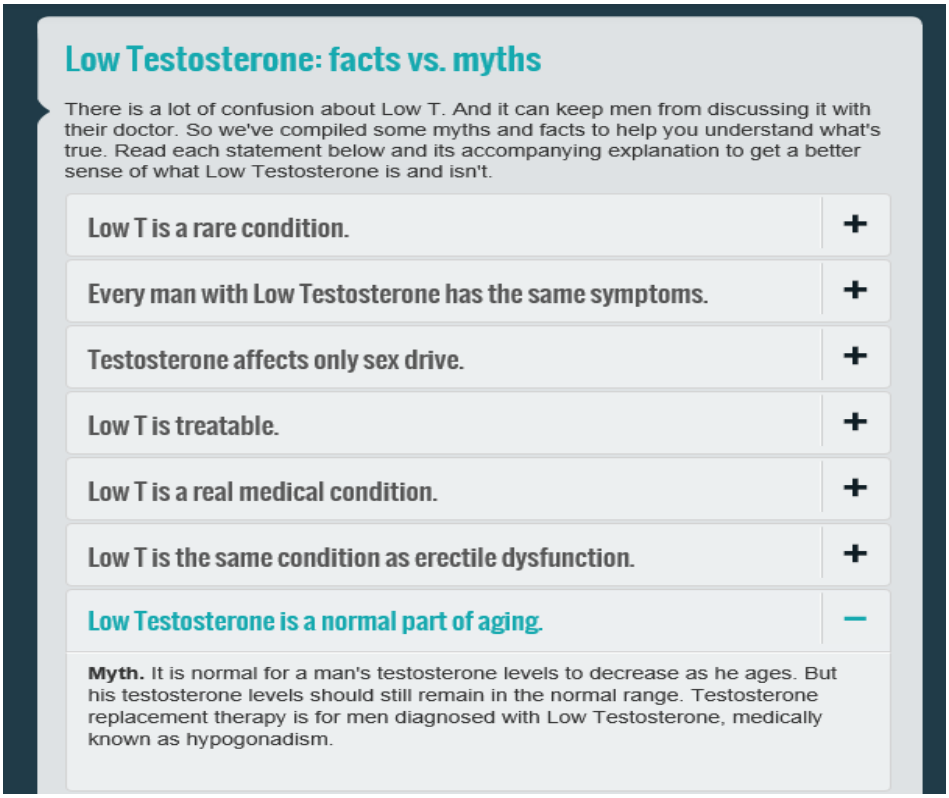
Other side effects include more erections than are normal for you or erections that last a long time.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of AndroGel 1.62%. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

154. Abbott and AbbVie misrepresented the nature of the decline in testosterone levels in normal older men, and claimed that the decrease in testosterone levels with aging remains within the normal range:



ALLEGATIONS AS TO THE SUBJECT TESTOSTERONE REPLACEMENT THERAPY PRODUCTS

155. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

156. The foregoing general allegations as to testosterone replacement therapy set forth in the subsequent paragraphs are applicable to all claims set forth herein.

157. The FDA scheduled a Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee for September 17, 2014 to "discuss the appropriate indicated population for testosterone replacement therapy and the potential for adverse cardiovascular outcomes associated with this use."[6]

[6]FDA (July 17, 2014). *September 17, 2014 Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting Announcement* at http://www.fda.gov/advisorycommittees/calendar/ucm404905.htm.

158. On January 31, 2014, the FDA announced an investigation into the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products.[7]

159. The FDA's announcement was based on two published studies which highlighted enhanced cardiovascular risks among men prescribed testosterone therapy:[8]

a. R. Vigen, C.I. O'Donnell, A.E. Barón, *et al.* (November 6, 2013). Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels. *JAMA* 310(7): 1829-1836 ["Vigen Study"], and

b. W.D. Finkle, S. Greenland, G.K. Ridgeway *et al*. Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men. *PlosOne* 9(1):1-7 ["Finkle Study"].

160. In 2010, S. Basaria, A.D. Coviello, T.G. Travison et al. published an article in the *New England Journal of Medicine* entitled "Adverse Events Associated with Testosterone Administration."[9] ["Basaria Paper"].

161. The clinical study reported in the Basaria Paper was prematurely discontinued because the Data and Safety Monitoring Board (DSMB) overseeing the safety of the subjects enrolled in this study observed a significant number of adverse cardiovascular events in the testosterone-treated group.

162. The Basaria Paper concluded, among other things: "In this population of older men with limitations in mobility and a high prevalence of chronic disease, the application of a testosterone gel was associated with an increased risk of cardiovascular adverse events. The

[7]*See* FDA Drug Safety Communications (January 21, 2014). *FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products* at http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm384225.htm.
[8]*Id.*
[9]*N Engl J Med 363*(2):109-122 (July 8, 2010).

small size of the trial and the unique population prevent broader inferences from being made about the safety of testosterone therapy. (ClinicalTrials.gov number, NCT00240981.)."[10]

163. The FDA has noted:

> Testosterone is a hormone essential to the development of male growth and masculine characteristics. Testosterone products are FDA-approved only for use in men who lack or have low testosterone levels in conjunction with an associated medical condition.[11] Examples of these conditions include failure of the testicles to produce testosterone because of reasons such as genetic problems or chemotherapy. Other examples include problems with brain structures, called the hypothalamus and pituitary that control the production of testosterone by the testicles.
>
> None of the FDA-approved testosterone products are approved for use in men with low testosterone levels who lack an associated medical condition. FDA-approved testosterone formulations include the topical gel, transdermal patch, buccal system (applied to upper gum or inner cheek), and injection.[12]

164. The testosterone-containing product manufacturer herein advantaged the intentional ambiguity in the testosterone product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians. This ambiguity was additionally advantaged through the recruitment of "thought leaders," "key opinion leaders," and sponsored and funded researchers and research in testosterone replacement therapy, who promoted "off-label" testosterone product use and "label expansion" through the medical literature and presentations.

165. The testosterone-containing product herein is not indicated for the treatment of the *normal* age-related declines in testosterone levels and/or non-specific age-related symptoms.

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[10] *Id.*
[11] The medical conditions are specifically delineated in the product PPI.
[12] FDA Drug Safety Communications (January 21, 2014). *FDA evaluating risk of stroke, heart attack and death with FDA-approved testosterone products* at http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm384225.htm.

166. The testosterone-containing product manufacturer herein marketed and promoted these products for treatment of both the *normal* age-related declines in testosterone levels and/or non-specific age-related symptoms.

167. Constellations of age-related physiologic findings, including the *normal* age-related declines in testosterone levels and non-specific age-related symptoms, have been conscripted into a pharmaceutical industry created pseudo-medical condition known as "Low-T."

168. "Low T" is not a disease, and does not have an International Classification of Disease (ICD) code.

169. The testosterone-containing product manufacturer herein performed aggressive and highly effective marketing and promotional campaigns directed at both the consuming public and healthcare providers, and have driven a dramatic, unwarranted, and dangerous increase in testosterone product usage over the past decade. This has created a substantial public health problem in the United States and elsewhere.

170. A substantial number of prescription sales are for clinical uses of testosterone that are not approved by the FDA,[13] and are the result of aggressive and pervasive "off-label" promotion by testosterone-containing product manufacturers, including the manufacturer herein.

171. The scientifically established propensity of testosterone products to cause hypercoagulability and hyperviscosity syndromes was known prior to the launch of the testosterone-containing products described herein, and should have been warned about to physicians and the public *ab initio*.[14]

[13]Between 2001 and 2011, testosterone replacement therapy has increased three-fold. *See* Baillargeon, J., Urban, R.J., and Ottenbacher, K.J. (2013). Trends in Androgen Prescribing in the United States. *JAMA* 173(15):1465-1466.

[14]*See, e.g.,* Schrör K., Morinelli T.A.,Masuda A. (1994). Testosterone treatment enhances thromboxane A2 mimetic induced coronary artery vasoconstriction in guinea pigs. *European Journal of Clinical Investigation* 24 (Suppl. 1):50-52; *see also* Adesuyi A. L. Ajayi, A., Mathur, R. *et al.* (1999). Testosterone Increases Human Platelet Thromboxane A_2 Receptor Density and Aggregation Responses. *Circulation* 91**:** 2742-2747.

172. The scientifically established propensity of testosterone products to cause hypercoagulability and hyperviscosity syndromes was known prior to the launch of the testosterone-containing products described herein, and information concerning these propensities should have been provided in the safety information which the manufacturer herein undertook, as a duty, to provide to consumers and patients.

173. TRT Sponsors AbbVie, Auxilium Pharmaceuticals, Inc., Besins Healthcare, Clarus Therapeutics, Eli Lilly and Company, LillyEndo Pharmaceuticals, Lipocine, MonoSol Rx, TesoRx, Trimel Pharmaceuticals, Upsher Smith Laboratories, and Viramal have stated to the FDA in their *Advisory Committee Industry Briefing Document Testosterone Replacement Therapy* in advance of the September 17, 2014 Advisory Committee[15] hearing: "TRT Sponsors remain committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions."

174. At all times material hereto, despite being "committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions," these testosterone-containing product manufacturers, sellers, distributors, promoters, and marketers made no labelling changes concerning the risks associated with their testosterone containing product use, include the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

[15]Joint Meeting for Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSARM AC).

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

175. It is well-known that the *normal* aging process is accompanied by a physiologic decline in testosterone levels.

176. On July 8, 2010, Dr. W.J. Bremner published an editorial in the *New England Journal of Medicine* entitled "Testosterone Deficiency and Replacement in Older Men",[16] observing:

> The diagnosis of testosterone deficiency in older men is complicated by the fact that many older men (more than 20% in some studies) have testosterone levels that are lower than the normal range in younger men. In addition, the clinical presentation of male hypogonadism is nonspecific and overlaps with that of other illnesses and with the aging process itself. Therefore, it is frequently unclear in caring for individual older patients whether the diagnosis of hypogonadism is appropriate and whether testosterone administration might be helpful or might instead cause adverse effects.

177. Two observational studies have prompted the FDA to investigate the risk of adverse cardiovascular events associated with testosterone replacement therapy.

178. The Vigen Study identified a 30% increase in the risk of heart attack, stroke, or death in the study group prescribed testosterone therapy when compared to a group that did not receive testosterone replacement therapy.

179. The results of this study led Dr. Anne R. Cappola to observe:

> In light of the high volume of prescriptions and aggressive marketing by testosterone manufacturers, prescribers and patients should be wary. There is mounting evidence of a signal of cardiovascular risk, to which the study by Vigen et al. contributes. This signal warrants both cautious testosterone prescribing and additional investigation.[17]

[16] *N Engl J Med* 363(2):189-191.
[17] Cappola, A.R. (2013). Editorial: Testosterone Therapy and Risk of Cardiovascular Disease in Men. *JAMA* 310(17):1805-1806.

180. The Finkle Study reported a two-fold increase in the risk of heart attack in men 65 years of age and older in the first 90 days following their first testosterone prescription. In men less than 65 years of age who harbored a pre-existing history of heart disease, the Finkle Study reported a two- to three-fold increased risk of heart attack in the first 90 days following a first prescription.

181. Testosterone replacement therapy results in the potential increase in hematocrit[18] and serum estradiol level.[19]

182. Testosterone administration is associated with suppression of serum hepcidin.

183. Increases in hematocrit in older men during testosterone therapy are related to the greater effect of suppression of hepcidin. "Testosterone administration is associated with suppression of serum hepcidin. Greater increases in hematocrit in older men during testosterone therapy are related to greater suppression of hepcidin." [20]

184. Additionally, testosterone effects the expression of platelet thromboxane A2 receptors. The latter significantly increases platelet aggregation,[21] leading to a state of hypercoagulability.

185. Increases in hematocrit and estradiol are associated with hyperviscosity and hypercoagulability syndromes, and well-known risks of thrombosis leading to serious adverse cardiovascular and cerebrovascular ischemic events.[22]

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[18]Fernández-Balsells, M.M, Murad, M.H., Lane, M. *et al.* (2010). Adverse Effects of Testosterone Therapy in Adult Men: A Systematic Review and Meta-Analysis. *J Clin Endocrin Metab* 95(6):2560–2575; *see also* Bachman, E., Travison, T., Basaria, S. *et al.* (2013). Testosterone Induces Erythrocytosis via Increased Erythropoietin and Suppressed Hepcidin: Evidence for a New Erythropoietin/Hemoglobin Set Point. *J Gerontol A Biol Sci Med* at http://jmh.sagepub.com/content/early/2014/02/19/1557988314522642.full.pdf+html.

[19]Finkelstein, J.S., Lee, H., Burnett-Bowie, S.M. *et al.* (2013). Gonadal Steroids and Body Composition, Strength, and Sexual Function in Men, *N Eng J Med* 369:1011-22.

[20]Eric Bachman, E., Feng, R., Travison, T., *et al.* (2010). Testosterone Suppresses Hepcidin in Men: A Potential Mechanism for Testosterone-Induced Erythrocytosis. *J Clin Endocrinol Metab* 95: 4743–4747.

[21]Ajayi, A.A., Mathur, R., Halushka, P.V. (1995). Testosterone Increases Human Platelet Thromboxane A2 Receptor Density and Aggregation Responses. *Circulation* 91: 2742-2747.

186. In 1968, W. Fried and C.W. Gurney published an article in the *Annals of the New York Academy of Sciences* entitled "The Erythropoietic-Stimulating Effects of Androgens"[23] in which these authors described the capacity of androgenic steroids to induce erythrocytosis. "Drastic elevations of hematocrit may be detrimental to patients with underlying coronary, cerebral or peripheral vascular disease by possibly causing an increase in blood viscosity and increased risk of thrombosis."[24]

187. An elevated hematocrit is an independent risk factor for adverse cardiovascular events.[25]

188. The *Framingham Heart Study* demonstrated a strong, graded relationship between hematocrit level and the risk of developing congestive heart failure.[26] In 3,523 *Framingham Heart Study* participants aged 50 to 65 years who were free of a history of heart failure at baseline, and who were followed prospectively for up to 20 years, individuals with a hematocrit level greater than or equal to 50% had nearly double the risk of new-onset heart failure during follow-up.[27]

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[22]Wannamethee, G., Perry, I.J., Shaper, A.G. (1994). Haematocrit, hypertension and risk of stroke. *J Intern Med* 235(2):163-8; *see also* Coglianese, E., Qureshi, M.M., Vasan, R.S. *et al.* (2012). Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. *Am J Cardiol* 109(2): 241–245; Braekkan, S.K., Mathiesen, E.B., Njølstad, I. *et al.* (2010). Hematocrit and risk of venous thromboembolism in a general population. The Tromso study. *Haematologica* 95(2):270-5; Cinar,Y., Demir, G., Paç, M. *et al.* (1999). Effect of hematocrit on blood pressure via hyperviscosity. *Am J Hypertens* 12(7):739-43; Glueck, C.J., Friedman, J., Hafeez, A., *et al.* (2014). Testosterone, thrombophilia, thrombosis. *Blood Coagul Fibrinolysis* 25 (ePub ahead of print); Glueck, C.J., Richardson-Royer, C., Schultz, R. *et al.* (2014). Testosterone, thrombophilia, thrombosis. *Clin Appl Thromb Hemost* 20(1):22-30.

[23]*Ann NY Acad Sci* 149:356–365.

[24]Stergiopoulos, K., Brennan, J.J., Mathews *et al.* (2008). Anabolic Steroids, Acute Myocardial Infarction and Polycythemia: A Case Report and Review of the Literature. *Vascular Health and Risk Management* 4(6) 1475–1480.

[25]*See* Coglianese, E., Qureshi, M.M., Vasan, R.S. *et al.* (2012), *supra* at f.n.19; *see also* Kunnas, T., Solakivi,T., Huuskonen, K. *et al.* (2009). Hematocrit and the risk of coronary heart disease mortality in the TAMRISK study, a 28-year follow-up. *Prev Med* 49 (1):45–47 (In this study of 680 males conducted over 28 years in Finland, the data showed that men with a hematocrit level greater than or equal to 50% were 2.4 times more likely to die from coronary heart disease than men with hematocrit levels of less than 50%. Even after adjusting for established coronary risk factors, the increased risk remained 1.8-fold for the higher hematocrit cohort.).

[26]*Id.*

[27]*Id.*

189. An additional study using *Framingham Heart Study* data demonstrated that in lifetime nonsmokers, those in the highest hematocrit category (>45.0 for women, >49.0 for men) had greater than twice the risk for heart failure.[28]

190. The relationship between hematocrit level and cardiovascular risk is mediated by erythropoietin (EPO). Overexpression of the EPO gene in in-bred mice results in extremely high hematocrit levels and leads to increased cardiac weight, left ventricular dilation, and decreased survival compared to wild-type mice.[29]

191. An elevated hematocrit among users of exogenously administered testosterone results from an elevation in EPO levels. This effect is most pronounced at 1 and 3 months following initial treatment.[30]

192. EPO can also activate platelets, causing an enhanced risk of thrombosis as shown in patients receiving exogenous EPO who have underlying cardiovascular diseases.[31]

193. Elevated EPO and its effect on hematocrit has been positively correlated with an increased risk of developing heart failure, even after adjusting for conventional heart failure risk factors.[32]

194. Elevated estradiol levels are also an independent risk factor for adverse cardiovascular events.[33,34,35]

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[28] *Id.*
[29] Wagner, K.F., Katschinski, D.M., Hasegawa, J. *et al.* (2001). Chronic inborn erythrocytosis leads to cardiac dysfunction and premature death in mice overexpressing erythropoietin. *Blood* 97:536–542.
[30] *See* Bachman, E., Travison, T., Basaria, S. *et al.* (2013), *supra* at f.n. 16.
[31] Smith, K.J., Bleyer, A.J., Little, W.C. *et al.* (2003). The Cardiovascular Effects of Erythropoietin. *Cardiovasc Res* 59:538-548.
[32] Coglianese, E .E., Qureshi, M.M., Vasan, R.S. *et al.* (2012). Usefulness of the Blood Hematocrit Level to Predict Development of Heart Failure in a Community. *Am J Cardiol* 109(2): 241–245.
[33] Khader, Y.S., Rice, J., John, L. *et al.* (2003). Oral contraceptives use and the risk of myocardial infarction: a meta-analysis. *Contraception 68*(1):11-17; *see also* Baillargeon, J.P., McClish, D.K., Essah, P.A. *et al.* (2005). Association between the current use of low-dose oral contraceptives and cardiovascular arterial disease: a meta-analysis. *J Clin Endocrinol Metab* 90(7):3863-3870 .
[34] Mohamad, M.J., Mohammad, M.A., Karayyem, M. *et al.* (2007). Serum Levels of Sex Hormones in Men with Acute Myocardial Infarction. *Neuro Endocrinol Lett* 28(2):182-6.

195. Thromboxane A2 is a potent vasoconstrictor and platelet pro-aggregatory agent that has been implicated in the pathogenesis of cardiovascular disease.

196. Thromboxane A2 is produced by activated platelets and has prothrombotic properties: It stimulates activation of new platelets as well as increases platelet aggregation.

197. A 1995 study demonstrated that testosterone treatment was associated with a significant increase in the maximum platelet aggregation response. This contributes to the thrombogenicity of androgenic steroids such as testosterone.[36]

198. Thromboxane A2 has been implicated in a range of cardiovascular diseases secondary to its acute and chronic effects on platelet aggregation, vasoconstriction, and vascular endothelial proliferation. In vitro, animal and human studies have established the central role of thromboxane A2 in cardiovascular disease.[37]

199. "Low-T" is a distinct and separate entity from the conditions for which testosterone replacement therapy has been FDA-approved; namely, for the conditions of primary hypogonadism and secondary hypogonadism.

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[35]Jankowska, E.A., Rozentryt, P., Ponikowska, B. *et al.* (2009). Circulating Estradiol and Mortality in Men with Systolic Chronic Heart Failure. *JAMA* 301(18):1892-1901.

[36]*See, e.g.,* Schrör, K., Morinelli, T.A., and Masuda, A. (1994). Testosterone treatment enhances thromboxane A2 mimetic induced coronary artery vasoconstriction in guinea pigs. *European Journal of Clinical Investigation* 24 (Suppl. 1):50-52; *see also* Adesuyi A. L. Ajayi, A., Mathur, R. *et al.* (1999). Testosterone Increases Human Platelet Thromboxane A_2 Receptor Density and Aggregation Responses. *Circulation* 91**:** 2742-2747.

[37]*See* Katugampola, S.D. and Davenport, A.P. (2001). Thromboxane receptor density is increased in human cardiovascular disease with evidence for inhibition at therapeutic concentrations by the AT1 receptor antagonist Losartan. *Br J Pharmacol* 134:1385–1392; *see also* Cheng, Y., Austin, S.C., Rocca, B. *et al.* (2002). Role of prostacyclin in the cardiovascular response to thromboxane A2. *Science* 296:539–541 (Demonstrating the reciprocal relationship between thromboxane and prostacyclin *in vivo*); Kobayashi, T., Tahara, Y., Matsumoto, M. *et al.* (2004). Roles of thromboxane A2 and prostacyclin in the development of atherosclerosis in ApoE-deficient mice. *J Clin Invest* 114:784–794; Xiao, C.Y., Hara, A., Yuhki, K., *et al.* (2001). Roles of prostaglandin I2 and thromboxane A2 in cardiac ischemia–reperfusion injury: a study using mice lacking their respective receptors. *Circulation* 104:2210–2215; Cayatte, A.J., Du, Y., Oliver-Krasinski, J. *et al.* (2000). The thromboxane receptor antagonist S18886 but not aspirin inhibits atherogenesis in ApoE-deficient mice: evidence that eicosanoids other than thromboxane contribute to atherosclerosis. *Arterioscler Thromb Vasc Biol* 20:1724–1728; Hirata, T., Kakizuka, A., Ushikubi, F. *et al.*, Arg60 to Leu mutation of the human thromboxane A2 receptor in a dominantly inherited bleeding disorder. *J Clin Invest* 94:1662–1667 (Reporting a naturally occurring TP mutation associated with a mild bleeding disorder).

200. "Hypogonadism in a male refers to a decrease in one or both of the two major functions of the testes: sperm production or testosterone production. These abnormalities can result from disease of the testes (primary hypogonadism) or disease of the pituitary or hypothalamus (secondary hypogonadism)."[38]

201. Outside the United States, foreign regulatory bodies are taking definitive action with respect to concerns related to the increased risk of adverse cardiovascular outcomes associated with testosterone replacement therapy.

202. On July 15, 2014, Health Canada initiated a safety review to evaluate the currently available information regarding the cardiovascular risks associated with the use of testosterone replacement products.[39] Following a detailed safety review, Health Canada made the following conclusion with respect to the association between adverse cardiovascular outcomes and the use of testosterone replacement therapy:

> The current available evidence suggests the possibility that cardiovascular problems, other than those already identified, may occur with the use of testosterone replacement products. The use of these products in Canada (and internationally) has been increasing and findings from a Canadian study raise additional concerns that these products may not always be used within the approved patient population.[40]

203. As a result of the above-identified conclusions, Health Canada implemented the following actions:

a. Health Canada is working with manufacturers to update the Canadian product label for testosterone replacement products regarding possible cardiovascular risks including heart attack, stroke, blood clots in the lungs or legs, and irregular heart rate;

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[38]Snyder, P.J. (2014). Clinical features and diagnosis of male hypogonadism. *Up-To-Date* at http://www.uptodate.com/contents/clinical-features-and-diagnosis-of-male-hypogonadism?source=search_result&search=hypogonadism&selectedTitle=1%7E150.
[39]*See* Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/review-examen/testosterone-eng.php.
[40]*Id.*

b. Health Canada has communicated to Canadians on the possible cardiovascular risk associated with testosterone replacement products; and

c. Health Canada is collaborating with foreign regulators including the U.S. Food and Drug Administration and the European Medicines Agency regarding this safety concern.[41]

204. The substantial "off-label" promotion and use of testosterone-containing products has been well-known to the product manufacturer herein.

205. As stated by the Committee on Assessing the Need for Clinical Trials of Testosterone Replacement Therapy in *Testosterone and Aging: Clinical Research Directions*, Institute of Medicine of the National Academies (2004):

> The benefits of testosterone therapy for markedly hypogonadal males have been well established. Hypogonadism is defined as "inadequate gonadal function, as manifested by deficiencies in gametogenesis and/or the secretion of gonadal hormones" (Stedman's Medical Dictionary, 2000). Male hypogonadism is categorized as primary or secondary (also termed central) based on the location of the disorder. In primary hypogonadism, the testes do not function properly for reasons including surgery, radiation, genetic and developmental disorders, infection, or liver and kidney disease. The most common genetic disorder resulting in primary hypogonadism in men is Klinefelter's syndrome, in which there is an extra sex chromosome, XXY. Primary hypogonadism is characterized by low levels of testosterone with elevated levels of the gonadotropins, FSH and LH.
>
> Secondary (or hypogonadotropic) hypogonadism is the result of disorders in the pituitary gland or hypothalamus. Causes of secondary hypogonadism include pituitary tumors, surgery, radiation, infections, inflammation, trauma, bleeding, genetic problems, nutritional deficiency, and iron excess (hemochromatosis) (Medline Plus, 2002). In secondary hypogonadism testosterone levels are low, while the levels of FSH and LH remain in the low to low-normal range.

[41] *Id.*

206. In 2004, The Institute of Medicine of the National Academies of Science Committee on Assessing the Need for Clinical Trials of Testosterone Replacement Therapy stated:

> The committee's task was to identify the research needed to determine if testosterone is an efficacious treatment option for older men. This approach does not directly address the research needed to determine whether current off-label use, particularly by middle-aged men, is either efficacious or safe. The committee has concerns about the growing use of testosterone by men who do not meet the clinical definition of hypogonadism in the absence of controlled trials needed to determine efficacy and safety.[42]

207. In 2006, Daniel A. Shames, M.D. from the FDA stated in the *New England Journal of Medicine*:

> More than 50 years ago, physicians began treating the "male climacteric" with testosterone. Since then, no standardized definition of this condition has been developed, no metric defining a therapeutic effect has been created, no randomized controlled studies have been conducted to support the widespread use of testosterone in men for this condition, and the adverse-event profile of the drug in this population has not been studied adequately. The Food and Drug Administration (FDA) has not approved testosterone for this condition.[43]

208. The Endocrine Society, which promulgates guidelines for the use of testosterone-containing medications, including AndroGel, among others, observed and stated in 2014 that "many patients in the U.S. are being prescribed testosterone for the treatment of age-related symptoms or age-related decline in testosterone levels, for which testosterone therapy has not been approved by the Food and Drug Administration."[44]

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[42]The Institute of Medicine of the National Academies of Science Committee on Assessing the Need for Clinical Trials of Testosterone Replacement Therapy (2004). *Testosterone and Aging Clinical Research Directions*. (Catharyn T. Liverman and Dan G. Blazer, eds.).

[43]*N Engl J Med* 350:2004-2006 (May 6, 2004).

[44]*The Risk of Cardiovascular Events in Men Receiving Testosterone Therapy: An Endocrine Society Statement* (February 7, 2014) at https://www.endocrine.org/~/media/endosociety/Files/Advocacy%20and%20Outreach/Position%20Statements/Other%20Statements/The%20Risk%20of%20Cardiovascular%20Events%20in%20Men%20Receiving%20Testosterone%20Therapy.pdf.

209. Dr. Peter J. Snyder from the University of Pennsylvania, who maintains a relationship with the pharmaceutical industry and testosterone replacement therapy market sector by way research sponsorship by Abbott, AbbVie, and or predecessors-in-interest, has stated:

> **Inappropriate use of testosterone in healthy middle-aged men** —There has been a dramatic increase in inappropriate use of testosterone therapy in healthy middle-aged and older men. This is likely due, at least in part, to direct-to-consumer advertising encouraging use of testosterone products for nonspecific symptoms, such as decreased energy and sexual interest.[45]

210. Increasing testosterone levels via the administration of exogenous testosterone in in men experiencing age-related declines in testosterone levels and age-related symptoms of "Low T" are not FDA-approved indications for the clinical use of current prescription testosterone-containing products, and represents "off-label" promotion for the clinical uses of the these pharmaceutical products.

211. Safer alternative formulations and strategies existed and continue to exist to treat these conditions.

212. Such uses of the testosterone-containing product described herein created, and continue to create, unreasonable and foreseeable health hazards, including the induction of hypercoagulable states, increased levels of estradiol generated by the metabolism of exogenously administered testosterone, a reduction in high-density lipoprotein ["HDL"], and an increase in low density lipoprotein ["LDL"], without any proven benefit from the use of "off-label" use of these products to treat "Low T".

213. These cardiovascular and cerebrovascular disease factors create a physiologic milieu in men which causes or increases the risk of:

a. heart attacks and consequent myocardial damage;

[45]Snyder, P.J. and Matsumoto, M.A. (updated May 16, 2014). Testosterone treatment of male hypogonadism. *Up-To-Date*.

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

214. Exposure of men to these health hazards and risks was and remains unwarranted and reflects and continues to reflect consumer exploitation via reckless, wanton, and fraudulent promotion and marketing of non-approved indications for the testosterone product described herein.

215. Induction of a hypercoagulable state, increased levels of estradiol, a reduction in HDL, and an increase in LDL are risk factors for serious adverse cardiovascular events and cerebrovascular accidents, and cause or increase the risk of harm of these events.

216. Longitudinal and cross-sectional studies of healthy men have demonstrated that a decrease in testosterone levels is a *normal* component of the aging process.[46]

217. This medical information was known in advance of and available at the time of the launch and/or during the product lifecycle of the testosterone-containing product herein.

218. Physiologic declines in testosterone levels are a component of the *normal* male aging process and affects approximately 20% or more of the United States male population over 50 years of age. Declines in *normal* testosterone levels continue thereafter with aging.

[46]Bagatell, C.J. and Bremner.W.J. (1998). II. Changes in Reproductive Hormones During the Aging Process. *JCE&M* 83(10):3436.

219. The standard treatment for age-related declines in testosterone levels and age-related symptoms in men is not testosterone therapy. These conditions are not subsumed under nor do they meet the definition of hypogonadism as set forth in the FDA-approved clinical indications for Androgel use.

220. Increasing testosterone levels via the administration of exogenous testosterone in men experiencing age-related declines in testosterone levels and age-related symptoms of "low energy levels, loss of sex drive, decreased muscle mass and mild depression" are not FDA-approved clinical indications for use of Androgel, and reflects and represents the "off-label" promotion and use of Androgel, and "label expansion" for Androgel use.

221. Such uses of the testosterone product herein create unreasonable and foreseeable health hazards, including the induction of hypercoagulable and hyperviscosity conditions and states, increased levels of estradiol generated by the metabolism of exogenously administered testosterone, a reduction in high-density lipoprotein, and an increase in low density lipoprotein, without any proven benefit from product use.

222. These factors create a physiologic milieu in men which causes or increases the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

223. Exposure of men to these health hazards and risks was unwarranted, and reflected consumer and patient exploitation through the reckless, wanton, deceptive, and fraudulent promotion and marketing of non-approved indications for testosterone-containing product prescription and use.

224. Induction of a hypercoagulable state, increased levels of estradiol, a reduction in HDL, and an increase in LDL are risk factors for serious adverse cardiovascular events and cerebrovascular accidents, and cause, or increase the risk of harm of these events, including the Plaintiff-husband's injuries and damages.

225. Longitudinal and cross-sectional studies of healthy men have demonstrated that a decrease in testosterone levels is a normal component of the aging process.[47]

226. The increased incidence of serious adverse life- and limb-threatening cardiovascular and cerebrovascular events was foreseeable to the testosterone-containing product manufacturers at or before the time of the product launch of the testosterone-containing products described herein.

227. The manufacturer of testosterone-containing product herein engaged a cadre of "thought leaders," "key opinion leaders," and speakers, including individuals with leadership positions in influential scientific organizations and societies (e.g., the Endocrine Society and the American Urological Association) to offer opinions which supported and advocated "off-label" clinical indications for testosterone therapy, including the products described herein.

[47]Bagatell, C.J. and Bremner, W.J. (1998). II. Changes in Reproductive Hormones During the Aging Process. *JCE&M* 83(10):3436.

228. In the 2010 *Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline*, the authoring Task Force from the Endocrine Society lists the following financial disclosures:

Financial Disclosure of Task Force

Shalender Bhasin, M.D. (Chair)—Consultation or Advisement: GlaxoSmithKline (GSK), Merck; Grant or Other Research Support: Abbott Laboratories, Ligand, Merck; Financial or Business/Organizational Interests: American Board of Internal Medicine. **Glenn R. Cunningham, M.D.**—Consultation or Advisement: Clarus, Columbia Lab, GSK, Endo Pharmaceuticals, Abbott Laboratories; Grant or Other Research Support: Abbott Laboratories; Columbia Lab, GSK; Speakers List: Columbia Lab, Endo Pharmaceuticals, Abbott Laboratories; Financial or Business/Organizational Interests: UpToDate; Significant Financial Interest or Leadership Position: none declared. **Frances J. Hayes, M.B., FRCPI**—Consultation or Advisement: Auxilium Pharmaceuticals, GSK, New England Research Institute; Speakers Bureau for Abbott Laboratories; Financial or Business/Organizational Interests: none declared; Significant Financial Interest or Leadership Position: none declared. **Alvin M. Matsumoto, M.D.**—Consultation or Advisement: Abbott Laboratories, Merck, Endo Pharmaceuticals, Tokai; Grant or Other Research Support: GSK, Abbott Laboratories; Financial or Business/Organizational Interests: UpToDate, U.S. Anti-Doping Agency/PCC; Significant Financial Interest or Leadership Position: none declared. **Peter J. Snyder, M.D.**—Consultation or Advisement: none declared; Grant or Other Research Support: Abbott Laboratories; Financial or Business/Organizational Interests: Abbott Laboratories, UpToDate; Significant Financial Interest or Leadership Position: UpToDate. **Ronald S. Swerdloff, M.D.**—Consultation or Advisement: Clarus, Abbott Laboratories, Endo Pharmaceuticals; Grant or Other Research Support: Actelion Pharma, ARYx Therapeutics, Inc., Auxilium, Bayer Corp., Besins/Ascend, Bristol-Myers Squibb, Clarus, Columbia, Corcept, GSK, Eli Lilly &Co., MacroChem Corp., Organon, Schering AG, Abbott Laboratories; Financial or Business/Organizational Interests: none declared; Significant Financial Interest or Leadership Position: none declared. ***Victor M. Montori, M.D.**—Financial or Business/Organizational Interests: none declared; Significant Financial Interest or Leadership Position: none declared.

229. With respect to the 2010 *Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline*:

> Aside from medical societies' support of educational ventures and research, they advocate for their members and for patients, and provide guidance about professional behavior. Many, if not all of these activities, can be corrupted by financial conflicts. The existence of examples in which society/industry connections may have led to adverse consequences does not necessarily prove that the problems uncovered are widespread, but given the secrecy, it is simply not possible to know the extent of the problem. What follows are several specific examples that illustrate the various ways in which medical societies' activities can be compromised.
>
> The first example is a clinical recommendation. A practice guideline published by the Endocrine Society on androgen deficiency and its

> treatment in elderly men recommended that testosterone should be measured when hormone deficiency is suspected (they suggested all men over age 50), and that a course of testosterone treatment might be warranted even if testosterone levels were not low when a man's symptoms (lack of energy, for example) suggested hormone deficiency (Kassirer 2004).These recommendations were made not only despite the unreliability of tests for the diagnosis of testosterone deficiency, but in the face of the risk that testosterone treatment can accelerate the growth of prostate cancer, a condition that is common in the very age group proposed for treatment. Notably, a report on the same subject at nearly the same time from the National Institutes of Health (NIH) came to different conclusions (Thorner et al. 2001). It cited the difficulties in measuring testosterone and the lack of a well proven way to make the diagnosis, and urged great caution in treating men suspected of having the condition until more research was available. Why the discrepancy? In a 2002 issue of the New Yorker magazine, physician Jerome Groopman found a possible explanation. The experts at the NIH had no financial ties either with companies that offered testosterone testing or testosterone treatments. By contrast, many members of the Endocrine Society panel had financial ties with Solvay, the company that markets AndroGel, a widely used testosterone preparation. Solvay had also supported the panel's work financially and had nominated some Endocrine Society members who later joined the panel. The Endocrine Society's recommendations were tainted by the financial conflicts.[48]

230. As observed by Drs. L.M. Schwartz, and S. Woloshin in the article "Low T as a Template: How to Sell as Disease" in *JAMA* 173(15):1460-1462 (August 12/26, 2013) (emphasis added) concerning the "Low T" campaigns by the pharmaceutical industry:

> Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: ***a mass, uncontrolled experiment*** that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.
>
> We agree with Braun that there is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous. ***Before anyone makes millions of men aware of Low T, they should be required to do a large-scale randomized trial to demonstrate that testosterone therapy for healthy aging men does more good than harm***.

[48]Kassirer, J.P. (winter 2007). Professional Societies and Industry Support: what is the quid pro quo*?* *Perspectives in Biology and Medicine*. 50(1):7-17.

231. Performing "a mass, uncontrolled experiment" on patients by way of testosterone-containing product sales, distribution, "off-label" promotion, and marketing without the safeguards of informed consent, independent oversight of patient well-being, and Institutional Review Board approval is shocking, outrageous, reckless, wanton, and undertaken in reckless disregard to the safety and well-being of patients and the public-at-large.

232. The testosterone-containing product manufacturer herein engaged in false and deceptive screening of consumers and patients through the use of self-diagnostic questionnaires and "Low T" self-assessment quizzes.

233. Dr. John Morley ["Dr. Morley"], Director of Endocrinology and Geriatrics at the St. Louis University School of Medicine, developed the ADAM[49] Questionnaire at the request of the Dutch pharmaceutical company, Organon BioSciences ["Organon"], in exchange for a $40,000 grant to his university.

234. Organon instructed Dr. Morley: "Don't make it too long and make it somewhat sexy."

235. Thereafter, Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on pieces of toilet paper, and subsequently gave the questions to his secretary to type the next day.

236. Dr. Morley has stated that he has "no trouble calling it a crappy questionnaire," noting that it is "not ideal."[50]

237. At all times material hereto, both the Endocrine Society and the European Association of Urology had recommended against using "Low T"-type screening quizzes and

[49] "**A**ndrogen **D**eficiency in **A**dult **M**ales."
[50] Singer, N. (Nov. 13, 2013). Selling that New-Man Feeling, *NY Times*.

self-assessment questionnaires because these methods were known to be unreliable and unvalidated.

238. The ADAM Questionnaire was specifically designed to drive "off-label" prescription and use of testosterone-containing products, and to promote "label expansion."

239. The testosterone-containing product manufacturer herein knowingly misrepresented to consumers and patients that testosterone replacement therapy was approved by the FDA for the treatment of age-related declines in testosterone levels or age-related symptoms as "part of a broad effort to influence how doctors and the public think about what constitutes disease and when drugs are 'needed,'" and to "blur the line between public health or professional education and marketing."[51]

240. On June 19, 2014, the FDA mandated that a general warning be added to the testosterone-containing products concerning venous blood clots:[52]

FDA adding general warning to testosterone products about potential for venous blood clots

[06/19/2014] The U.S. Food and Drug Administration (FDA) is requiring manufacturers to include a general warning in the drug labeling of all approved testosterone products about the risk of blood clots in the veins. Blood clots in the veins, also known as venous thromboembolism (VTE), include deep vein thrombosis (DVT) and pulmonary embolism (PE). The risk of venous blood clots is already included in the labeling of testosterone products as a possible consequence of polycythemia, an abnormal increase in the number of red blood cells that sometimes occurs with testosterone treatment. Because there have been postmarket reports of venous blood clots unrelated to polycythemia, FDA is requiring a change to drug labeling of all testosterone products to provide a more general warning regarding venous blood clots and to ensure this risk is described consistently in the labeling of all approved testosterone products.

Because these clots occur in the veins, this new warning is not related to FDA's ongoing evaluation of the possible risk of stroke, heart attack, and death in patients taking testosterone products. We are currently evaluating the potential risk of these cardiovascular events, which are related to blood clots in the arteries and are described in the Drug Safety Communication posted on January 31, 2014.

Testosterone products are FDA-approved for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone for reasons such as genetic problems or chemotherapy.

[51] *"Low T": How to Sell Disease* (June 4, 2013) at http://tdi.dartmouth.edu/press/updates/low-t-how-to sell-disease.
[52] http://www.fda.gov/Drugs/DrugSafety/ucm401746.htm.

241. On October 5, 2014, the FDA Center for Drug Evaluation and Research published the approved Summary Minutes of the Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee held on September 17, 2014[53] [the October 5, 2014 minutes are referred to as "Summary Minutes of the Joint Meeting" and the two participating committees as the "Joint Committees"].

242. In the October 5, 2014 Summary Minutes of the Joint Meeting, the Joint Committees reported the following:

> The joint committees agreed that the use of testosterone replacement products in men with inherited or acquired loss of testosterone production in conjunction with a recognized disease condition ("classical hypogonadism") was supported by data. There was general consensus that the current paradigm for drug development is not capable of generating data in support of testosterone replacement therapy for "age-related hypogonadism". Committee members agreed that the current information supports an indication only for classical hypogonadism and not for age-related hypogonadism. There was consensus that the labeling for testosterone needs to be revised accordingly to reflect the appropriate indicated population. Some committee members expressed a concern that age-related hypogonadism had not yet been established as a disease condition. Two members opined that testosterone therapy may be justified in selected older men with significant hypogonadal signs/symptoms and documented 'very low' serum testosterone concentrations (e.g., less than 100 ng/dL). However, even these two committee members recognized the need for additional research to assess the effectiveness of testosterone therapy for this patient population. The joint committees agreed that the use of testosterone therapy for symptomatic men without documented low testosterone levels was not appropriate.

243. The Joint Committees further acknowledged in the Summary Minutes of the Joint Meeting that:

> [T]he available studies informing the cardiovascular safety signal with testosterone therapy are limited in scope, quality, design, and size. Nonetheless, there was agreement amongst committee members that a weak signal of cardiovascular risk had emerged from results of recent

[53]http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCom.

> large epidemiologic studies. Given this signal coupled with biologic plausibility for cardiovascular-related adverse events with testosterone use, committee members believed that the need for additional studies was critical and that some commented that clinical trials for safety would be necessary…Overall the committee agreed that the potential signal for cardiovascular risk should be added to the labeling. Most committee members recommended cautionary wording that would reflect the known information regarding potential risk, while a few others suggested a boxed warning.

244. The Summary Minutes of the Joint Meeting further reported that:

> There was virtual unanimous agreement that FDA should revise the current indication for the class of testosterone replacement therapy. Committee members stated that the indication should limit testosterone replacement therapy to men with classical hypogonadism. The committees commented that the label should include statements to address the potential cardiovascular risks of testosterone therapy, the importance of proper testing of serum testosterone concentrations to confirm the diagnosis, and that efficacy and safety in age-related hypogonadism have not been established.

245. The members of the Joint Committees "reiterated the need to revise the testosterone labeling to clarify that the efficacy and safety for testosterone therapy in age-related hypogonadism have not been established."

246. The labelling for the subject testosterone product was false, misleading, deceptive, and intentionally crafted and structured to render the false and misleading impression that "Low T" was a form of "classical hypogonadism."

247. "Low T" is not a form of "classical hypogonadism" as advertised, promoted, and marketed to consumers and patients, including the Plaintiff-husband.

248. "Low T" is not a form of "classical hypogonadism" as advertised, promoted, and marketed to physicians and other healthcare providers, including the Plaintiff-husband's prescribing physician.

249. The testosterone replacement product manufacturers, including the subject manufacturer set forth herein, utilized patients treated with testosterone-containing products for

the diagnosis of "Low T," including the Plaintiff-husband, as research subjects in "a mass, uncontrolled experiment." Such conduct is outrageous and shocks the conscience.

250. The testosterone replacement product manufacturers, including the subject manufacturer set forth herein, utilized patients, including the Plaintiff-husband, as research subjects in "a mass, uncontrolled experiment" by fraudulently characterizing "Low T" as a form of "classical hypogonadism" warranting testosterone-replacement therapy.

251. The testosterone replacement product manufacturers, including the subject manufacturer set forth herein, utilized patients, including the Plaintiff-husband, as research subjects in "a mass, uncontrolled experiment" by engaging in "label expansion" and "off-label" administration by representing to physicians, including the Plaintiff-husband's prescribing physician, that "Low T" or age-related decreases in testosterone levels and age related symptoms were a form of "classical hypogonadism" warranting testosterone-replacement therapy.

252. The testosterone replacement product manufacturers, including the subject manufacturer set forth herein, utilized the consuming public, including the Plaintiff-husband, as research subjects in "a mass, uncontrolled experiment" in "label expansion" and "off-label" testosterone product administration through false, misleading, and deceptive trade practices in which "Low T" was characterized as a form of "classical hypogonadism" warranting testosterone-replacement therapy.

ALLEGATIONS SPECIFIC TO THE PLAINTIFFS' INJURIES AND DAMAGES

253. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

254. Plaintiffs file this lawsuit within the applicable statute of limitations.

255. The Plaintiff-husband sought specific testing and treatment for "Low T" based upon the representations and medical information provided to him by direct-to-consumer educational and informational "Low T" awareness campaigns initiated and propagated by the aforementioned manufacturers of testosterone-containing product.

256. The Plaintiff-husband's prescribing physician would not have prescribed testosterone replacement therapy to his patient had he been advised of and warned of the dangers of cardiovascular events and cerebrovascular accident set forth herein caused by or increased with respect to the risk of harm by these testosterone-containing products.

257. The Plaintiff-husband would not have used the aforementioned testosterone-containing products had he been advised and warned of the of the dangers of serious adverse life- and limb-threatening cardiovascular and cerebrovascular injuries caused by or increased with respect to the risk of harm by these products.

258. The Plaintiff-husband justifiably relied upon the claims and representations of the aforementioned manufacturers that testosterone-replacement therapy of "Low T" had been clinically demonstrated to be safe and effective when used to raise testosterone levels for this clinical indication, and that these products were approved for use for that particular purpose.

259. Plaintiff-husband reasonably relied upon the implied and expressed claims and representations of the testosterone-containing manufacturers set forth herein that their products had been approved by the FDA for the treatment of "Low T," and were safe and effective.

260. Plaintiff-husband is 49 years old, and had a prior medical history of hyperlipidemia, sleep apnea, erectile dysfunction, and hypertension. Plaintiff-husband did not have classical hypogonadism and/or an approved clinical indication for testosterone replacement therapy.

261. Plaintiff-husband was treated with AndroGel when he was diagnosed with bilateral pulmonary emboli.

262. In or around February 2008, Plaintiff-husband sought medical care and treatment for progressive shortness of breath and exertional dyspnea.

263. Plaintiff-husband was diagnosed with bilateral pulmonary emboli on or about February 7, 2008.

264. Plaintiff-husband required inpatient hospitalization and anticoagulant therapy to treat his bilateral pulmonary emboli.

265. The Plaintiff-husband's pulmonary emboli were directly and proximately caused by, or had the risk of harm increased by the testosterone-containing topically applied medication AndroGel.

266. Because of his use of AndroGel, and the resultant pulmonary emboli caused, or increased in harm, by this products, the Plaintiff-husband has suffered, and continues to suffer:

a. pain and suffering

b. loss of life's pleasures

c. physical debility

d. mental anguish

e. fear and fright

f. embarrassment and humiliation

g. economic loss

h. requirement for medical monitoring

i. past, present, and future medical expenses

267. The Plaintiff-wife herein brings a derivative claim for the loss of marital consortium.

THEORIES OF LIABILITY AND DEMANDS FOR RELIEF

COUNT I-NEGLIGENCE

268. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

269. Abbott, AbbVie, and their predecessors-in-interest placed AndroGel into the stream of interstate commerce at the time of product launch in or about 2000.

270. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest had a duty to exercise reasonable and prudent care in AndroGel's design, promotion, advertising, marketing, labelling, warnings, instructions for use, post-marketing safety monitoring, surveillance and pharmacovigilance, and safety-signal detection.

271. The Plaintiff-husband's prescribing physician was within the market to which Abbott, AbbVie, and their predecessors-in-interest directed their product marketing, physician-detailing, advertising, and promotional strategies, initiatives, activities, and efforts, and accordingly was a reasonably foreseeable user.

272. The Plaintiff-husband was within the market to which Abbott, AbbVie, and their predecessors-in-interest directed their product marketing, physician-detailing, advertising, and promotional sales strategies, initiatives, activities, and efforts and accordingly was a reasonably foreseeable user.

273. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest had a duty to ensure that the AndroGel product did not cause end-users to suffer serious life- and limb-threatening cardiovascular and cerebrovascular injuries through the failure of Abbott,

AbbVie, and their predecessors-in-interest, and those promoting AndroGel on behalf of Abbott, AbbVie, and their predecessors-in-interest, to provide adequate warnings, information concerning the FDA-approved indications for use, and instructions for product use to prescribing physicians.

274. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest had a duty not to misbrand the AndroGel product, or to promote the product for "off-label" indications for use.

275. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest entered into a concerted drug detailing plan for the purpose of educating and raising the awareness of physicians about "Low T" and the clinical uses of AndroGel for the treatment of age-related declines in testosterone levels and age-related symptoms in order to inappropriately increase physician prescribing habits for the AndroGel product.

276. The goal of Abbott, AbbVie, and their predecessors-in-interest was to promote "off-label" prescribing and "label expansion" for the AndroGel product.

277. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest knew, or should have known, that the FDA-approved indications for use of the AndroGel product did not include "Low T" or age-related declines in testosterone levels or age-related symptoms men, and that detailing and promoting the product for these indications for use was inappropriate, unreasonably dangerous, and encouraged "off-label" prescribing and use.

278. Abbott, AbbVie, and their predecessors-in-interest had a duty to advise and warn physicians with respect to the FDA-approved uses for AndroGel, and to refrain from detailing and promoting the AndroGel product for "off-label" use.

279. The AndroGel product was imminently and unreasonably dangerous when used as intended for treating "Low T" or age-related declines in testosterone levels and age-related symptoms in men.

280. AndroGel was not reasonably fit, suitable or safe for the ordinary and foreseeable purpose for which it was sold by Abbott, AbbVie, and their predecessors-in-interest, which was the treatment of "Low T.

281. AndroGel was negligently designed for intended and promoted use of Abbott, AbbVie, and their predecessors-in-interest of treating "Low T" or age-related declines in testosterone levels and age-related symptoms in men.

282. Abbott, AbbVie, and their predecessors-in-interest knew, or should have known, that the AndroGel product was imminently and unreasonably dangerous when put to its detailed and promoted indications for use.

283. AndroGel was not FDA-approved to treat "Low T," and had no clinical profiles of either safety or effectiveness for this use or purpose.

284. Abbott, AbbVie, and their predecessors-in-interest failed to warn physicians of the lack of clinical safety and effectiveness profiles for the indications for which it was promoting the product for "off-label," non-FDA-approved indications for clinical use.

285. Abbott, AbbVie, and their predecessors-in-interest knew, or should have known, that the AndroGel product, which contained testosterone, would cause or increase the risk of harm of hypercoagulable and hyperviscosity states, increased estradiol levels via the known metabolic pathways for exogenously administered testosterone, decreased HDL, and increased LDL.

286. Abbott, AbbVie, and their predecessors-in-interest knew, or should have known, that AndroGel causes or increases the risk of harm of c serious life- and limb-threatening cardiovascular and cerebrovascular injuries and their consequences, including:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

287. This information and knowledge was available to and known by Abbott, AbbVie, and their predecessors-in-interest at the time of the AndroGel product launch in or about 2000, and should have been, but was not, disclosed to physicians by way of appropriate and adequate warnings.

288. Abbott, AbbVie, and their predecessors-in-interest knew, or should have known, during the period in which it was promoting the AndroGel product, that the AndroGel, as an exogenously administered testosterone-containing preparation, caused or increased the risk of harm of factors responsible for adverse c serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

289. This information and knowledge was available to and known by Abbott, AbbVie, and their predecessors-in-interest at the time of the AndroGel product launch in or about 2000, and throughout this product's lifecycle.

290. Abbott, AbbVie, and their predecessors-in-interest failed to warn physicians, including the Plaintiff-husband's prescribing physician, of the risk of serious adverse life- and limb-threatening cardiovascular and cerebrovascular injuries caused by or increased in the risk of harm by the use of AndroGel.

291. Abbott, AbbVie, and their predecessors-in-interest failed to warn physicians, including the Plaintiff-husband's prescribing physician, that the AndroGel product was not approved by the FDA for the treatment of age-related declines in testosterone levels or age-related symptoms in men, and that the drug was being detailed and promoted to physicians for extensive "off-label" prescribing and "label expansion."

292. Abbott, AbbVie, and their predecessors-in-interest failed to warn prescribing physicians, including the Plaintiff-husband's prescribing physician, by way of physician detailing, general marketing and promotion, labelling, the PPI, the Physician's Desk Reference, and Internet-based physician promotional campaigns, that AndroGel had no proven clinical profiles of safety or effectiveness when used to treat age-related decreases in testosterone levels and age-related symptoms in men.

293. The warnings to physicians provided by Abbott, AbbVie, and their predecessors-in-interest, including the Plaintiff-husband's prescribing physician, were inadequate, and caused or increased the risk of harm of the Plaintiff-husbands injuries and damages.

294. As designed, Abbott, AbbVie, and their predecessors-in-interest should not have placed AndroGel into the stream of interstate commerce for the treatment of age-related declines in testosterone levels or age-related symptoms in men.

295. Treatment of these conditions had approved and safer alternative treatment modalities, including medications for the treatment of erectile dysfunction, antidepressant

medications, weight loss medications, exercise programs, and counseling for depressive disorders.

296. The Plaintiff-husband's physician would not have prescribed testosterone therapy to his patient had he been adequately and appropriately warned about the accompanying risks of AndroGel administration, including serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

297. The Plaintiff-husband would have discussed the risks and benefits of AndroGel use with his physician had the Plaintiff-husband been advised and informed that AndroGel was being marketed and promoted for "off-label" indications for use, and of the foreseeable health hazards of serious life- and limb-threatening cardiovascular and cerebrovascular injuries caused or increased in the risk of harm by AndroGel.

298. The Plaintiff-husband would not have administered the AndroGel product had he been advised by his prescribing physician that "Low T" or age-related declines in testosterone levels and age-related symptoms were "off label" indications for product use which do not carry the approval of the FDA, and for which there was no demonstrated proof of benefit or safety.

299. The Plaintiff-husband's prescribing physician would have discussed the risks of serious life- and limb-threatening cardiovascular and cerebrovascular injuries with his patient, and would have informed his patient of those risks, if they had been made known to him, as they should have been, by Abbott, AbbVie, and their predecessors-in-interest.

300. Abbott, AbbVie, and their predecessors-in-interest failed to warn prescribing physicians in general, and the Plaintiff-husband's prescribing physician in particular, that Abbott, AbbVie, and their predecessors-in-interest was detailing and promoting AndroGel for "off-label"

use in a patient population where such treatment was inappropriate, unapproved, and with no proven benefit.

301. The breach of the duty to warn by Abbott, AbbVie, and their predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's grave injuries, and caused the loss of consortium experienced by the Plaintiff-wife.

302. The negligent design of the AndroGel product by Abbott, AbbVie, and their predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's grave injuries and damages, and caused the loss of consortium experienced by the Plaintiff-wife.

303. Accordingly, Abbott and AbbVie are liable for compensatory damages, as set forth in the *ad damnum* clause, to the Plaintiffs for their injuries, losses, and damages.

COUNT II—NEGLIGENCE

304. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

305. "One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of the other's person or things, is subject to liability to the other for physical harm resulting from his failure to exercise reasonable care to perform his undertaking, if (a) his failure to exercise such care increases the risk of such harm, or (b) the harm is suffered because of the other's reliance upon the undertaking."[54]

306. Abbott, AbbVie, and their predecessors-in-interest gratuitously undertook comprehensive patient awareness, educational, and interactive consumer and patient directed campaigns via:

[54] *Restatement (Second) of Torts § 323* (1965).

a. direct-to-consumer renditions of medical and diagnostic information; product testimonials and endorsements;

b. interactive questionnaires and quizzes;

c. proffered differential diagnoses for patient signs and symptoms;

d. comprehensive information concerning testosterone therapy and its clinical uses and safety;

e. solicitation of Protected Health Information (PHI);

f. providing various iterations, characterizations, and definitions of the pathologic "disease" which it denominated as "Low T;"

g. recommendations for laboratory testing;

h. assistance with medical insurance and third-party payer coverage for AndroGel therapy;

i. physician referrals;

j. prescription refill reminders; and

k. offers of ongoing contact regarding medical information and treatment plans.

307. Abbott, AbbVie, and their predecessors-in-interest set out to recast well-defined disease states and pathologic conditions of the testes and the hypothalamic-pituitary-gonadal axis, which comprise primary and secondary hypogonadism, to include the diagnosis of "Low T."

308. "Low T" is an age-related decrease in testosterone levels and age-related symptoms in men.

309. Abbott, AbbVie, and their predecessors-in-interest recast "Low T" as a form of hypogonadism to create a market niche for the "off-label" use of the AndroGel product.

310. Abbott, AbbVie, and their predecessors-in-interest knew, or should have known, that age-related declines in testosterone levels and age-related symptoms in men were not included in the FDA-approved spectrum of indications for use of AndroGel, and that the AndroGel product was being marketed and promoted for "off-label" use directly to consumers and patients, including to the Plaintiff-husband.

311. Abbott, AbbVie, and their predecessors-in-interest sought to misrepresent and conflate the age-related decline in testosterone levels and age-related symptoms in men with a true disease condition, hypogonadism, and should have known, that such a misrepresentation would drive men to seek medical diagnostic evaluation, testing, and treatment for "Low T."

312. Abbott, AbbVie, and their predecessors-in-interest assumed and undertook duties separate and apart from, but coterminous with, roles traditionally reserved for and undertaken by healthcare providers, including:

a. offering consumers and patients extensive medical information concerning a "disease," including signs, symptoms, etiology, and associated co-morbidities;

b. advising patients concerning the treatment and/or treatment options for that "disease;"

c. providing assistance in the diagnosis of the "disease" by taking a detailed history of patient signs and symptoms, and recommending or directing laboratory testing for the "disease;"

d. providing information about specific drug therapy for the "disease;"

e. providing patients with physician referrals for evaluation and treatment;

f. soliciting Protected Health Information (HPI) and data concerning the health status of patients, including prior or current signs and symptoms; and

g. maintaining an ongoing and relationship with the patient to provide further medical information.

313. Abbott, AbbVie, and their predecessors-in-interest owed a duty of care to the Plaintiff-husband to provide accurate, true, and correct information to avoid physical harm.

314. In fact, AbbVie, along with other testosterone replacement therapy ["TRT"] manufacturers,[55] has stated in the *Advisory Committee Industry Briefing Document Testosterone Replacement Therapy* submitted to the FDA in advance of the September 17, 2014 Advisory Committee[56] hearing: "TRT Sponsors remain committed to educating clinicians ***and patients*** on the benefits and risks of TRT, so that ***they*** can make informed treatment decisions."

315. Abbott, AbbVie, and their predecessors-in-interest knew, or should have known, that there were no long-term, placebo-controlled, double-blind, sufficiently powered, and independent clinical studies or trials which demonstrated any benefit to testosterone therapy for age-related declines in testosterone levels and age-related symptoms in men, and should have provided, but did not provide, such information in its promotions to consumers and patients.

316. Abbott, AbbVie, and their predecessors-in-interest undertook to educate and inform consumers and patients about the medical condition of "Low T" and its treatment, and owed a duty to inform consumers and patients, including the Plaintiff-husband, that testosterone

[55] The "TRT Sponsors" include AbbVie, Auxilium Pharmaceuticals, Inc., Besins Healthcare, Clarus Therapeutics, Eli Lilly and Company, LillyEndo Pharmaceuticals, Lipocine, MonoSol Rx, TesoRx, Trimel Pharmaceuticals, Upsher Smith Laboratories, and Viramal.

[56] Joint Meeting for Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSARM AC).

therapy for age-related declines in testosterone levels or age-related symptoms in men were not FDA-approved uses or clinical indications for product use.

317. Abbott, AbbVie, and their predecessors-in-interest knew that the FDA had not approved AndroGel for the treatment of "Low T," and that "Low T" was not a disease or a form of hypogonadism.

318. Abbott, AbbVie, and their predecessors-in-interest owed a duty to inform consumers and patients of the risks of serious life- and limb-threatening cardiovascular and cerebrovascular injuries caused or increased in the risk of harm by AndroGel.

319. The Risk Evaluation and Mitigation Strategy ["REMS"] of Abbott and AbbVie acknowledged and continues to acknowledge a duty owed directly to "inform patients about the serious risks associated with the use of AndroGel (testosterone gel) 1%:"

Initial REMS Approval: 09/2009

Most Recent Modification: 06/2014

NDA 21-015 ANDROGEL® (testosterone gel) 1% CIII

Drug Class and Formulation: Testosterone Drug Products

AbbVie Inc.
1 N. Waukegan Road
North Chicago, IL 60064
1-800-633-9110

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

To inform patients about the serious risks associated with the use of AndroGel (testosterone gel) 1%.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each AndroGel (testosterone gel) 1% prescription in accordance with 21 CFR 208.24.

320. The Risk Evaluation and Mitigation Strategy ["REMS"] of Abbott and AbbVie acknowledged and continues to acknowledge a duty owed directly to "inform patients about the serious risks associated with the use of AndroGel (testosterone gel) 1.62%:"

Initial REMS Approval: 04/2011

Most Recent Modification: 06/2014

NDA 22-309 AndroGel® (testosterone gel) 1.62% CIII

Drug Class and Formulation: Testosterone Drug Products

AbbVie Inc.
1 N. Waukegan Road
North Chicago, IL 60064
1-800-633-9110

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II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each AndroGel (testosterone gel) 1.62% prescription in accordance with 21 CFR 208.24.

321. Abbott, AbbVie, and their predecessors-in-interest acknowledged, and continue to acknowledge, a duty to inform and advise consumers of AndroGel risks by providing the following information by way of a "Medication Guide:"

Medication Guide

ANDROGEL® (AN DROW JEL) CIII

(testosterone gel) 1.62%

Read this Medication Guide before you start using ANDROGEL 1.62% and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about ANDROGEL 1.62%?

1. **Early signs and symptoms of puberty have happened in young children who were accidentally exposed to testosterone through contact with men using ANDROGEL 1.62%.**

Signs and symptoms of early puberty in a child may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

ANDROGEL 1.62% can transfer from your body to others.

2. **Women and children should avoid contact with the unwashed or unclothed area where ANDROGEL 1.62% has been applied to your skin.**

Stop using ANDROGEL 1.62% and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have occurred through accidental exposure to ANDROGEL 1.62%.

Signs and symptoms of exposure to ANDROGEL 1.62% in children may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

Signs and symptoms of exposure to ANDROGEL 1.62% in women may include:

- changes in body hair
- a large increase in acne

- **To lower the risk of transfer of ANDROGEL 1.62% from your body to others, you should follow these important instructions:**
  - Apply ANDROGEL 1.62% **only** to your shoulders and upper arms that will be covered by a short sleeve t-shirt.
  - Wash your hands **right away** with soap and water after applying ANDROGEL 1.62%.
  - After the gel has dried, **cover the application area with clothing**. Keep the area covered until you have washed the application area well or have showered.

- **If you expect to have skin-to-skin contact with another person, first wash the application area well with soap and water.**
- **If a woman or child makes contact with the ANDROGEL 1.62% application area, that area on the woman or child should be washed well with soap and water right away.**

What is ANDROGEL 1.62%?

ANDROGEL 1.62% is a prescription medicine that contains testosterone. ANDROGEL 1.62% is used to treat adult males who have low or no testosterone.

Your healthcare provider will test your blood before you start and while you are taking ANDROGEL 1.62%.

It is not known if ANDROGEL 1.62% is safe or effective in children younger than 18 years old. Improper use of ANDROGEL 1.62% may affect bone growth in children.

ANDROGEL 1.62% is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your ANDROGEL 1.62% in a safe place to protect it. Never give your ANDROGEL 1.62% to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and is against the law.

ANDROGEL 1.62% is not meant for use in women.

Who should not use ANDROGEL 1.62%?

Do not use ANDROGEL 1.62% if you:

- have breast cancer
- have or might have prostate cancer
- are pregnant or may become pregnant or are breast-feeding. ANDROGEL 1.62% may harm your unborn or breast-feeding baby.
  Women who are pregnant or who may become pregnant should avoid contact with the area of skin where ANDROGEL 1.62% has been applied.

Talk to your healthcare provider before taking this medicine if you have any of the above conditions.

What should I tell my healthcare provider before using ANDROGEL 1.62%?

Before you use ANDROGEL 1.62%, tell your healthcare provider if you:

- have breast cancer
- have or might have prostate cancer
- have urinary problems due to an enlarged prostate
- have heart problems
- have kidney or liver problems
- have problems breathing while you sleep (sleep apnea)
- have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using ANDROGEL 1.62% with certain other medicines can affect each other.

Especially, tell your healthcare provider if you take:

- insulin
- medicines that decrease blood clotting
- corticosteroids

Know the medicines you take. Ask your healthcare provider or pharmacist for a list of all of your medicines, if you are not sure. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

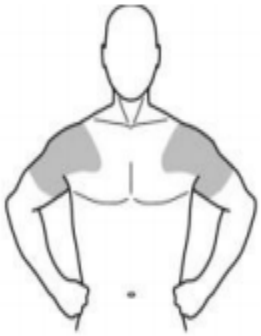
How should I use ANDROGEL 1.62%?

- It is important that you apply ANDROGEL 1.62% exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much ANDROGEL 1.62% to apply and when to apply it.
- Your healthcare provider may change your ANDROGEL 1.62% dose. **Do not** change your ANDROGEL 1.62% dose without talking to your healthcare provider.
- **ANDROGEL 1.62% is to be applied to the area of your shoulders and upper arms that will be covered by a short sleeve t-shirt. Do not** apply ANDROGEL 1.62% to any other parts of your body such as your stomach area (abdomen), penis, or scrotum.
- Apply ANDROGEL 1.62% at the same time each morning. ANDROGEL 1.62% should be applied after showering or bathing.
- **Wash your hands right away** with soap and water after applying ANDROGEL 1.62%.
- Avoid showering, swimming or bathing for at least 2 hours after you apply ANDROGEL 1.62%.
- ANDROGEL 1.62% is flammable until dry. Let ANDROGEL 1.62% dry before smoking or going near an open flame.
- Let the application site dry completely before putting on a t-shirt.

Applying ANDROGEL 1.62%:

ANDROGEL 1.62% comes in a pump or in packets.

- **Before applying ANDROGEL 1.62% make sure that your shoulders and upper arms are clean, dry, and that there is no broken skin.**
- The application sites for ANDROGEL 1.62% are the upper arms and shoulders that will be covered by a short sleeve t-shirt (See Figure A).



(Figure A)

If you are using ANDROGEL 1.62% pump:

- Before using a new bottle of ANDROGEL 1.62 % for the first time, you will need to prime the pump. To prime the ANDROGEL 1.62% pump, slowly push the pump all the way down 3 times. **Do not** use any ANDROGEL 1.62% that came out while priming. Wash it down the sink to avoid accidental exposure to others. Your ANDROGEL 1.62% pump is now ready to use.
- Remove the cap from the pump. Then, position the nozzle over the palm of your hand and slowly push the pump all the way down. Apply ANDROGEL 1.62% to the application site. You may also apply ANDROGEL 1.62% directly to the application site.
- **Wash your hands with soap and water right away.**

Find Your Dose as Prescribed by Your Healthcare Provider		Application Method
1 PUMP DEPRESSION	20.25 mg	Apply 1 pump depression of ANDROGEL 1.62% to 1 upper arm and shoulder.
2 PUMP DEPRESSIONS	40.5 mg	Apply 1 pump depression of ANDROGEL 1.62% to 1 upper arm and shoulder and then apply 1 pump depression of ANDROGEL 1.62% to the opposite upper arm and shoulder.
3 PUMP DEPRESSIONS	60.75 mg	Apply 2 pump depressions of ANDROGEL 1.62% to 1 upper arm and shoulder and then apply 1 pump depression of ANDROGEL 1.62% to the opposite upper arm and shoulder.
4 PUMP DEPRESSIONS	81 mg	Apply 2 pump depressions of ANDROGEL 1.62% to 1 upper arm and shoulder and then apply 2 pump depressions of ANDROGEL 1.62% to the opposite upper arm and shoulder.

If you are using ANDROGEL 1.62% packets:

- Tear open the packet completely at the dotted line. Squeeze from the bottom of the packet to the top.
- Squeeze all of the ANDROGEL 1.62% out of the packet into the palm of your hand. Apply ANDROGEL 1.62% to the application site. You may also apply ANDROGEL 1.62% directly to the application site.

- ANDROGEL 1.62% should be applied right away.
- **Wash your hands with soap and water right away.**

Find Your Dose as Prescribed by Your Healthcare Provider		Application Method
One 20.25 mg packet	20.25 mg	Apply 1 packet of ANDROGEL 1.62% to 1 upper arm and shoulder.
One 40.5 mg packet	40.5 mg	Apply half of the 40.5 mg packet of ANDROGEL 1.62% to 1 upper arm and shoulder and then apply the remaining packet contents to the opposite upper arm and shoulder.
One 40.5 mg packet and one 20.25 mg packet	60.75 mg	Apply one 40.5 mg packet of ANDROGEL 1.62% to 1 upper arm and shoulder and then apply one 20.25 mg packet of ANDROGEL 1.62% to the opposite upper arm and shoulder.
Two 40.5 mg packets	81 mg	Apply one 40.5 mg packet of ANDROGEL 1.62% to 1 upper arm and shoulder and then apply one 40.5 mg packet of ANDROGEL 1.62% to the opposite upper arm and shoulder.

What are the possible side effects of ANDROGEL 1.62%?

See "What is the most important information I should know about ANDROGEL 1.62%?"

ANDROGEL 1.62% can cause serious side effects including:

- **If you already have enlargement of your prostate gland your signs and symptoms can get worse while using ANDROGEL 1.62%.** This can include:
  - increased urination at night
  - trouble starting your urine stream
  - having to pass urine many times during the day
  - having an urge that you have to go to the bathroom right away
  - having a urine accident
  - being unable to pass urine or weak urine flow
- **Possible increased risk of prostate cancer.** Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you use ANDROGEL 1.62%.
- **In large doses ANDROGEL 1.62% may lower your sperm count.**
- **Swelling of your ankles, feet, or body, with or without heart failure.**
- **Enlarged or painful breasts.**
- **Have problems breathing while you sleep (sleep apnea).**
- **Blood clots in the legs or lungs.** Signs and symptoms of a blood clot in your leg can include leg pain, swelling, or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.

Call your healthcare provider right away if you have any of the serious side effects listed above.

The most common side effects of ANDROGEL 1.62% include:

- increased prostate specific antigen (a test used to screen for prostate cancer)
- mood swings
- hypertension
- increased red blood cell count
- skin irritation where ANDROGEL 1.62% is applied

Other side effects include more erections than are normal for you or erections that last a long time.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ANDROGEL 1.62%. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ANDROGEL 1.62%?

- Store ANDROGEL 1.62% at 59ºF to 86ºF (15ºC to 30ºC).
- When it is time to throw away the pump or packets, safely throw away used ANDROGEL 1.62% in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep ANDROGEL 1.62% away from fire.

Keep ANDROGEL 1.62% and all medicines out of the reach of children.

General information about the safe and effective use of ANDROGEL 1.62%

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ANDROGEL 1.62% for a condition for which it was not prescribed. Do not give ANDROGEL 1.62% to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about ANDROGEL 1.62%. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about ANDROGEL 1.62% that is written for health professionals.

For more information, go to www.androgel.com or call 1-800-633-9110.

What are the ingredients in ANDROGEL 1.62%?

Active ingredient: testosterone

Inactive ingredients: carbopol 980, ethyl alcohol, isopropyl myristate, purified water and sodium hydroxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

322. This "Medication Guide" offered by Abbott, AbbVie, and their predecessors-in-interest to consumers and patients for the safety and well-being of consumers patients, including the Plaintiff-husband, is inadequate, and fails to inform and advise consumers about the serious adverse life- and limb-threatening cardiovascular and cerebrovascular events which are caused or increased in the risk of harm by AndroGel.

323. Abbott, AbbVie, and their predecessors-in-interest failed to inform consumers, including the Plaintiff-husband, that the AndroGel product was not indicated for the treatment of "Low T" or the relief of symptoms claimed to be secondary to "Low T" on the AndroGel website.

324. Abbott, AbbVie, and their predecessors-in-interest breached their duty of care to provide true, accurate, and correct medical information to the Plaintiff-husband, which it gratuitously undertook to perform, and thereby caused or increased the risk of harm of injury and damages to the Plaintiff-husband.

325. The Plaintiff-husband would not have sought treatment for "Low T" or used AndroGel had he been appropriately and adequately informed by Abbott, AbbVie, and their predecessors-in-interest, through their comprehensive medical information and awareness campaigns with respect to the AndroGel product, of the true, correct, and accurate FDA-approved status of AndroGel, including the approved indications for clinical use of AndroGel.

326. The Plaintiff-husband would not have administered or continued to administer AndroGel to himself had he been informed by Abbott, AbbVie, and their predecessors-in-interest that the FDA-approved indications for use for AndroGel did not include the treatment of age-related declines in testosterone or age-related symptoms in men, and that he was being

prescribed a product that Abbott, AbbVie, and their predecessors-in-interest were promoting for "off-label" use to physicians.

327. The Plaintiff-husband would not have administered AndroGel had he been informed by Abbott, AbbVie, and their predecessors-in-interest that he was a participant in "a mass, uncontrolled experiment" through his use of the AndroGel product.

328. The Plaintiff-husband reasonably and justifiably relied upon the representations and medical information provided by Abbott, AbbVie, and their predecessors-in-interest concerning their AndroGel product to his detriment, and suffered bodily injury and damages caused by or increased in the risk of harm by his use of AndroGel.

329. The negligence of Abbott, AbbVie, and their predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's injuries and damages, and caused the loss of consortium experienced by the Plaintiff-wife.

330. Accordingly, Abbott and AbbVie are liable for compensatory damages, as set forth in the *ad damnum* clause, to the Plaintiffs for their injuries, losses, and damages.

COUNT III-RECKLESSNESS AND WANTONESS

331. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

332. The reckless and wanton conduct of Abbott, AbbVie, and their predecessors-in-interest, and their reckless disregard for the safety and well-being of the Plaintiff-husband, gives rise to a claim for punitive damages.

333. Abbott, AbbVie, and their predecessors-in-interest consciously, willfully, and deliberately engaged in conduct which was carried out with a reckless, wanton, and conscious disregard for the rights and safety of others, including the Plaintiffs and the public-at-large.

334. Abbott, AbbVie, and their predecessors-in-interest used the Plaintiff-husband as a participant in "a mass, uncontrolled experiment" through his use of the AndroGel product.

335. Human experimentation without appropriate safeguards and consent is outrageous, wanton, reckless, and shocks the conscience.

336. Abbott, AbbVie, and their predecessors-in-interest crafted a two-pronged promotional scheme which included willfully and wantonly providing consumers and patients with misinformation about the indications for use of the AndroGel product in order to drive consumer-originated demand for diagnostic evaluation of and treatment for "Low T;" coupled with an aggressive campaign of deceptive and misleading physician education, promotion, and detailing with misinformation about the approved clinical uses of AndroGel.

337. This two-pronged scheme was formulated and executed to encourage, promote, and increase "off-label" treatment of men with AndroGel, and to initiate "label expansion" of the AndroGel clinical indications for use.

338. Abbott, AbbVie, and their predecessors-in-interest was complicit with co-promoters of the AndroGel product in an insidious and well-crafted two-pronged promotional scheme, which included:

a. the willful and wanton promotion, co-promotion, and marketing strategy to consumers and patients which consisted of intentionally misinformation about the indications for clinical use of the AndroGel product in order to drive consumer-originated demand for diagnostic evaluation of and treatment for "Low T;"

b. coupled with an aggressive and deceptive campaign of physician education, promotion, and detailing with misinformation regarding the approved clinical uses, safety, and effectiveness of AndroGel.

339. Abbott, AbbVie, and their predecessors-in-interest intentionally and deliberately undertook these activities to encourage, promote, and increase "off-label" treatment of men with AndroGel.

340. This combined consumer marketing and physician detailing strategy and plan was undertaken with actual knowledge that AndroGel's label was being inappropriately expanded beyond the confines of its FDA-approved indications for clinical use, and in the absence of scientific and clinical evidence with respect to the safety and effectiveness profiles of AndroGel in the setting of expanded and "off-label" product use to treat "Low T."

341. Abbott, AbbVie, and their predecessors-in-interest willfully, and in reckless and wanton disregard for public safety, including the safety and well-being of the Plaintiff-husband, expanded the label of AndroGel therapy beyond primary and secondary hypogonadism, to include age-related declines in testosterone levels and age-related symptoms in men. This constituted "a mass, uncontrolled experiment" that was shocking and unconscionable.

342. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest knew that the FDA had not approved AndroGel for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

343. At all times material hereto, and since the time of that AndroGel was approved by the FDA, Abbott, AbbVie, and their predecessors-in-interest knew that the FDA had not approved AndroGel as therapy:

a. to improve mood;

b. to increase sexual interest;

c. to restore erectile function;

d. to increase muscle mass; or

e. to increase strength of bones.

344. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest knew and understood that the FDA was unaware of any data to support these indications for clinical use of AndroGel.

345. Abbott, AbbVie, and their predecessors-in-interest withheld and suppressed material information concerning the risks of serious life- and limb-threatening cardiovascular and cerebrovascular injuries causally associated with testosterone use.

346. Abbott, AbbVie, and their predecessors-in-interest willfully and wantonly set out to expose men to the AndroGel product, by way of "a mass, uncontrolled experiment," to treat conditions for which AndroGel was neither approved nor indicated for clinical use.

347. Abbott, AbbVie, and their predecessors-in-interest willfully and wantonly set out to expose men to the AndroGel product, by way of "a mass, uncontrolled experiment," to treat conditions for which AndroGel's clinical safety data and effectiveness profiles were lacking.

348. Abbott, AbbVie, and their predecessors-in-interest had actual knowledge of AndroGel's capacity to cause serious life- and limb-threatening cardiovascular and cerebrovascular injuries, including the Plaintiff-husband's injuries and damages, through biologic and physiologic mechanisms which were known at the time of the AndroGel product launch in or about 2000.

349. These mechanisms include the induction of hypercoagulable states, hyperviscosity and rheological abnormalities of blood flow, increases in estradiol levels generated by the metabolism of exogenously administered testosterone, a decrease in HDL, and an increase in LDL, all of which are well-known and well-established risk factors for serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

350. At all times material hereto, despite possessing actual knowledge of the grave risks of injuries and death to consumers and patients which result from predicate factors for serious life- and limb-threatening cardiovascular and cerebrovascular injuries, Abbott, AbbVie, and their predecessors-in-interest took no action to provide adequate or amended warnings to prescribing physicians or to consumers and patients.

351. Despite actual knowledge of known serious adverse potentially life- and limb-threatening risks associated with AndroGel therapy, Abbott, AbbVie, and their predecessors-in-interest failed to warn consumers, patients, and prescribing physicians.

352. At all times material hereto, despite actual knowledge of grave risks to consumers and patients of serious life- and limb-threatening cardiovascular and cerebrovascular injuries, and the presence of additional safety signals, Abbott, AbbVie, and their predecessors-in-interest took no action to provide accurate, true, and correct information to consumers concerning the use of the AndroGel product.

353. At all times material hereto, despite actual knowledge of grave risks to consumers and patients of serious adverse life- and limb-threatening cardiovascular and cerebrovascular events, and the presence of additional safety signals, Abbott, AbbVie, and their predecessors-in-interest took no action to provide accurate, true, and correct information to physicians concerning the prescription of the AndroGel product.

354. Abbott, AbbVie, and their predecessors-in-interest were reckless and wanton in their failure to provide prescribing physicians with appropriate warnings concerning the life- and limb-threatening cardiovascular and cerebrovascular events caused or increased in the risk of harm by the use of AndroGel, about which Abbott, AbbVie, and their predecessors-in-interest had actual knowledge.

355. Abbott, AbbVie, and their predecessors-in-interest were reckless and wanton in their failure to provide consumers and patients with warnings concerning the life- and limb-threatening cardiovascular and cerebrovascular events caused or increased in the risk of harm by the use of AndroGel, about which Abbott, AbbVie, and their predecessors-in-interest had actual knowledge.

356. Abbott, AbbVie, and their predecessors-in-interest knew, contemplated, and intended that consumers and patients would reasonably and justifiably rely on the comprehensive medical information provided to them by Abbott, AbbVie, and their predecessors-in-interest through patient awareness and educational campaigns, and this reliance was, in fact, a focal point in the scheme by Abbott, AbbVie, and their predecessors-in-interest to drive consumer demand for the AndroGel product.

357. Abbott, AbbVie, and their predecessors-in-interest knew, contemplated, and intended that consumers and patients would rely on the information provided to them by Abbott,

AbbVie, and their predecessors-in-interest concerning the AndroGel product through comprehensive awareness and educational campaigns, which were undertaken for the purpose of fostering the belief that the AndroGel product was approved for and was clinically indicated for the treatment of "Low T" or age-related declines in testosterone levels and age-related symptoms in men.

358. Abbott, AbbVie, and their predecessors-in-interest knew that the information they provided to consumers and patients promoted "off-label" product use and "label expansion," and that this information was false, deceptive, and misleading.

359. The willful, wanton, and reckless conduct of Abbott, AbbVie, and their predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's injuries and damages.

360. The Plaintiff-husband would not have sought treatment for "Low T" nor would have administered AndroGel had he been informed by Abbott, AbbVie, and their predecessors-in-interest, as he should have been, of the information concerning cardiovascular and cerebrovascular risks, which was known to Abbott, AbbVie, and their predecessors-in-interest at the time.

361. The Plaintiff-husband would not have sought treatment with AndroGel had he been informed by Abbott, AbbVie, and their predecessors-in-interest, as he should have been, that the clinical safety and efficacy profiles of this treatment were lacking, and that treatment of "Low T" with AndroGel was neither approved nor clinically indicated.

362. The Plaintiff-husband would not have sought treatment with AndroGel had he been informed by Abbott, AbbVie, and their predecessors-in-interest, as he should have been, that AndroGel was not approved for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

363. The Plaintiff-husband's prescribing physician would not have prescribed AndroGel to his patient had he been informed by Abbott, AbbVie, and their predecessors-in-interest that the FDA had not approved AndroGel for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido; (v) disorders of erectile function or erectile dysfunction;

e. loss of muscle mass; or

f. bone strength or density abnormalities.

364. The willful, wanton, and reckless conduct of Abbott, AbbVie, and their predecessors-in-interest caused or increased the risk of harm of the Plaintiff-husband's injuries and damages.

365. The willful, wanton, and reckless conduct of Abbott, AbbVie, and their predecessors-in-interest caused the Plaintiff-wife's loss of consortium.

366. Accordingly, Abbott and AbbVie are liable to the Plaintiffs for punitive and exemplary damages, as set forth in the *ad damnum* clause.

COUNT IV—BREACH OF EXPRESS WARRANTY

367. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

368. Abbott, AbbVie, and their predecessors-in-interest made statements, affirmations, and representations of fact concerning the AndroGel product through its comprehensive consumer awareness and educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients, and end-users of the AndroGel product that AndroGel was clinically indicated for the treatment of "Low T."

369. Abbott, AbbVie, and their predecessors-in-interest's statements, affirmations, and representations of fact concerning the AndroGel product and it clinical use in the treatment of "Low T" that were intended to and did reach the Plaintiff-husband, and which formed a "basis of the bargain" for his decision to seek treatment for "Low T" and accept AndroGel as an approved and clinically safe and effective treatment for "Low T."

370. Abbott, AbbVie, and their predecessors-in-interest expressly warranted that AndroGel was appropriate for the treatment of "Low T," including statements, affirmations, and representations on the AndroGel website, http://www.AndroGel.com and via branded television commercials and advertising.

371. The Plaintiff-husband knew about and was aware of these representations made by Abbott, AbbVie, and their predecessors-in-interest concerning AndroGel, and these

representations informed and guided his acceptance, use, and continued use of the AndroGel product.

372. Abbott, AbbVie, and their predecessors-in-interest expressly warranted that an appropriate indication for use of the AndroGel product was to restore testosterone levels in consumers with "Low T."

373. AndroGel did not conform to this express representation and warranty.

374. Specifically, AndroGel was not an approved treatment for:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

375. The Plaintiff-husband reasonably and justifiably relied upon the representations, statements, or affirmations of fact of Abbott, AbbVie, and their predecessors-in-interest in his choice to use and continue to use the AndroGel product.

376. The Plaintiff-husband was unskilled in the research, design and manufacture of medical drugs, including AndroGel, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of Abbott, AbbVie, and their predecessors-in-interest in his choice to use the AndroGel product.

377. Accordingly, AndroGel did not comply with or conform to the representations, statements, or affirmations of fact made by Abbott, AbbVie, and their predecessors-in-interest in terms of the express warranties made to consumers and patients, including the Plaintiff-husband.

378. The breach of the express warranty by Abbott, AbbVie, and their predecessors-in-interest caused injury and damages to the Plaintiff-husband; and gives rise to a loss of consortium claim on behalf of the Plaintiff-wife.

379. Accordingly, Abbott and AbbVie are liable to the Plaintiffs for their injuries, losses, and damages arising out of their breach of express warranty.

COUNT V—BREACH OF IMPLIED WARRANTY

380. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

381. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest knew or had reason to know of the particular purpose for which users of the AndroGel product were using AndroGel, and that the users of AndroGel were relying on the promotional and advertising materials of Abbott, AbbVie, and their predecessors-in-interest in their selection of the product for that particular use.

382. Abbott, AbbVie, and their predecessors-in-interest had reason to know that users of AndroGel were using the product to treat "Low T" or age-related declines in testosterone levels or age-related symptoms in men, and that consumers and patients were reasonably and justifiably relying on the representations of Abbott, AbbVie, and their predecessors-in-interest that AndroGel was a treatment for "Low T."

383. Through aggressive physician detailing and promotion, Abbott, AbbVie, and their predecessors-in-interest participated in the selection of AndroGel by both prescribers and consumers as a treatment for "Low T."

384. At all times material hereto, AndroGel did not have the requisite clinical safety or effectiveness profiles to be deemed fit for the particular purpose of treating "Low T."

385. At all times material hereto, the FDA had not approved the AndroGel product for this particular purpose of use of treating "Low T" or age-related symptoms and age-related declines in testosterone levels in men.

386. AndroGel did not conform to this implied warranty of fitness for the particular purpose of treating "Low T."

387. AndroGel was not suitable for or approved by the FDA for the treatment of "Low T;" was neither safe nor effective in its clinical profiles for this use; and was not approved or indicated for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

388. Prior to the time that AndroGel was used by the Plaintiff-husband, Abbott, AbbVie, and their predecessors-in-interest impliedly warranted to the Plaintiff-husband and his

prescribing physician that AndroGel was of merchantable quality and safe and fit for the use for which it was intended.

389. Specifically, Abbott, AbbVie, and their predecessors-in-interest warranted to the Plaintiff-husband that its product was intended to treat a condition called "Low T" and that it was safe and fit for that use.

390. Abbott, AbbVie, and their predecessors-in-interest failed to disclose that "Low T" is not a recognized medical condition and that AndroGel was not FDA approved to treat "Low T."

391. The Plaintiff-husband was unskilled in the research, design, and manufacture of medical drugs, including AndroGel, and reasonably and justifiably relied entirely on the skill, judgment and implied warranty of in using AndroGel.

392. As a result, the Plaintiff-husband used AndroGel as intended and warranted by Abbott, AbbVie, and their predecessors-in-interest.

393. AndroGel was neither safe for its intended use nor of merchantable quality, as warranted by Abbott, AbbVie, and their predecessors-in-interest, in that AndroGel had and continues to have dangerous propensities when used as intended, and will cause or increase the risk of harm of severe injuries to end-users.

394. The breach of the implied warranty of fitness for a particular purpose by Abbott, AbbVie, and their predecessors-in-interest caused personal injury and damages to the Plaintiff-husband; and gives rise to a loss of consortium claim on behalf of the Plaintiff-wife.

395. Accordingly, Abbott, AbbVie, and their predecessors-in-interest are liable to the Plaintiff-husband for their injuries, losses, and damages arising out of the breach of implied warranty for a particular purpose.

396. Abbott, AbbVie, and their predecessors-in-interest's breach of the implied warranty of merchantability caused personal injury to the Plaintiff-husband; and gives rise to a loss of consortium claim on behalf of the Plaintiff-wife.

397. Accordingly, Abbott and AbbVie are liable to the Plaintiffs for their injuries, losses, and damages arising out of the breach of implied warranty of merchantability.

COUNT VI–FRAUD

398. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

399. Plaintiff herein pleads the elements of fraud with particularity, to include:

a. the knowingly false statements and misrepresentations of material fact made by Abbott, Abbie, and their predecessors-in-interest concerning the FDA-approved indications for clinical use of AndroGel; the clinical safety and effectiveness profiles of AndroGel; the clinical entities of primary and secondary hypogonadism which AndroGel was FDA-approved to treat; and the definition of hypogonadism;

b. the knowledge on the part of Abbott, AbbVie, and their predecessors-in-interest that these statements concerning AndroGel and its clinical indications for use of the AndroGel product were untrue;

c. the intent on the part of Abbott, AbbVie, and their predecessors-in-interest to deceive consumers, including the Plaintiff-husband, concerning the AndroGel product for the purpose of financial and economic gain;

d. the reasonable and justifiable reliance of the Plaintiff-husband on the fraudulent statements of Abbott, AbbVie, and their predecessors-in-interest;

e. the resulting injuries and damages suffered by the Plaintiff-husband, and the derivative loss of consortium suffered by the Plaintiff-wife, caused by the Plaintiff-husband's reasonable and justifiable reliance on these fraudulent statements and the willful lack of disclosure and fact suppression by Abbott, AbbVie, and their predecessors-in-interest.

400. Abbott, AbbVie, and their predecessors-in-interest undertook and had a duty to disclose all material facts relating to the use of AndroGel to consumers and patients via its multi-platform comprehensive consumer awareness, educational, informational, and marketing formats and campaigns, including to the Plaintiff-husband.

401. Abbott, AbbVie, and their predecessors-in-interest knew, understood, and contemplated that consumer belief in the clinical safety and effectiveness profiles of the AndroGel product was pivotal to the sale, use, and demand for AndroGel.

402. Abbott, AbbVie, and their predecessors-in-interest additionally knew that consumers would otherwise believe that the promoted use of AndroGel to treat "Low T" was an approved and indicated clinical use absent truthful statements to the contrary.

403. Abbott, AbbVie, and their predecessors-in-interest had a duty to provide consumers with full, complete, accurate, and truthful information concerning the AndroGel product, its FDA-approved spectrum of indications for clinical use, and the appropriate and medically sound definitions of hypogonadism and "Low T."

404. Abbott, AbbVie, and their predecessors-in-interest knew that AndroGel was not approved by the FDA for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

405. At all times material hereto, the FDA was unaware of any data to support these indications for the use of AndroGel, and Abbott, AbbVie, and their predecessors-in-interest were aware of the both the FDA's state of knowledge and the FDA-approved clinical uses for the AndroGel product.

406. Nonetheless, Abbott, AbbVie, and their predecessors-in-interest encouraged consumers to self-screen for these signs and symptoms via self-assessment questionnaires and "Low T" quizzes and clinical questions which solicited signs and symptoms of "Low T" to foster the false belief among consumers that they harbored a "disease" requiring testosterone replacement therapy with the AndroGel product.

407. Abbott, AbbVie, and their predecessors-in-interest engaged in fraudulent representations of material fact to consumers and patients, and willfully failed to disclose material facts to consumers and patients, including to the Plaintiff-husband, concerning the approved clinical indications for AndroGel use; the clinical safety and effectiveness profiles of

AndroGel; the "off-label" use of AndroGel and the "label expansion" that was occurring with the AndroGel product; and the nature of "Low T" and the medical definition of hypogonadism.

408. Abbott, AbbVie, and their predecessors-in-interest knew and understood that AndroGel was being marketed and promoted to consumers, patients, and physicians, including the Plaintiff-husband and his prescribing physician, to treat age-related symptoms, including:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; and

g. bone strength or density abnormalities.

409. Abbott, AbbVie, and their predecessors-in-interest knew and understood that it was necessary to generate and reinforce a belief amongst consumers and patients, including the Plaintiff-husband, which was knowingly false, deceptive, and misleading, that AndroGel was an appropriate and FDA-approved treatment for "Low T" or age-related declines in testosterone levels and age-related symptoms in men.

410. Abbott, AbbVie, and their predecessors-in-interest specifically targeted male consumers over 50 years of age, knowing that at least 20% of this population manifested an age-relate decline in testosterone levels, and that many in this population would additionally and coincidently experience age-related symptoms as part of the *normal* aging process.

411. Abbott, AbbVie, and their predecessors-in-interest advantaged the normal age-related decline in testosterone levels in the aging male population to create the illusion of an epidemic of hypogonadism, claiming that 20 million men suffered from a disease known as "Low T." This was false and misleading.

412. Abbott, AbbVie, and their predecessors-in-interest advantaged the intentional ambiguity in the AndroGel product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians. This ambiguity was additionally advantaged through the recruitment of "thought leaders," "key opinion leaders," and sponsored and funded researchers and research in testosterone replacement therapy, who promoted "off-label" AndroGel use and "label expansion" through the medical literature and presentations.

413. This knowledge formed a basis for AndroGel branding and marketing teams to design and execute various "Low T" consumer awareness and education campaigns, and to organize a concerted nationwide effort to encourage mass self-screening by consumers through the use of questionnaires and quizzes and an encouraged demand for clinical laboratory testosterone testing crafted to lead consumers to a diagnosis of "Low T" and AndroGel treatment.

414. Abbott, AbbVie, and their predecessors-in-interest coupled this consumer self-screening campaign to an aggressive and pervasive physician detailing, promotional, and educational campaigns of misinformation, designed to achieve a confluence of consumer-driven demand for AndroGel and increased "off-label" physician prescribing of the AndroGel product.

415. Abbott, AbbVie, and their predecessors-in-interest knew and understood that consumer attitudes and demand for the AndroGel treatment were a key driver for AndroGel's

revenue stream, earnings, and market share, and that it was necessary, in order to drive product sales, to convince men that AndroGel was an appropriate treatment modality for:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

416. The AndroGel website was not constructed for the treatment of primary or secondary hypogonadism; rather, it specifically discussed "Low T" as the central and only diagnosis driving AndroGel treatment by consumers and patients.

417. Abbott, AbbVie, and their predecessors-in-interest knowingly, intentionally, and with fraudulent intent made false, misleading, and inaccurate representations of fact, and suppressed and failed to disclose material facts, concerning the following:

a. "Low T" was not and never has been an approved clinical indication for treatment with AndroGel;

b. "Low T" is not a disease;

c. the definition of hypogonadism does not include the diagnosis of "Low T" or age-related decline in testosterone levels or age-related symptoms in men;

d. the diagnostic and clinically relevant criteria for the use of AndroGel as a testosterone replacement therapy modality are specifically primary and secondary hypogonadism, and not "Low T," and the conditions of primary and secondary hypogonadism refer to specific pathologic conditions;

e. clinical safety and effectiveness profiles of AndroGel as a treatment modality for "Low T" or age-related decline in testosterone levels or age-related symptoms in men are lacking;

f. clinical safety and effectiveness profiles for the use of AndroGel in the treatment of conditions which do not fall under the rubric of hypogonadism are lacking;

g. the FDA-approved appropriate indications for the clinical use of AndroGel do not include "Low T;"

h. the attendant serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks causally associated with the use testosterone, which occur through a spectrum of mechanisms known and described prior to the product launch of AndroGel; and

i. the "mass, uncontrolled experiment" that Abbott, AbbVie, and their predecessors-in-interest were performing on men being treated with AndroGel for age-related declines in testosterone levels and age-related symptoms.

418. Abbott, AbbVie, and their predecessors-in-interest had actual knowledge of the falsity of statements made to consumers and prescribers concerning AndroGel, and willfully and knowingly failed to disclose, or to accurately, fully and truthfully state, that:

a. primary and secondary hypogonadism, and not "Low T" or age-related declines in testosterone levels or age-related symptoms in men, were the FDA-approved indications for the clinical use of AndroGel;

b. the definition of hypogonadism is not synonymous with "Low T" or age-related declines in testosterone levels or age-related symptoms in men, and that primary and secondary hypogonadism are caused by specific testicular or hypothalamic-pituitary-gonadal axis diseases and pathologic conditions;

c. "Low T" is not a diagnosis or condition warranting AndroGel therapy, and in fact, "Low T" is an "off-label" clinical use for the AndroGel product which was not approved by the FDA;

d. the diagnostic, clinically relevant, and medically appropriate criteria for the use of AndroGel are not simply a low testosterone level and non-specific, age-related symptoms in men;

e. clinical safety and effectiveness profiles of AndroGel for the treatment of "Low T," and the long-term use of testosterone replacement therapy to treat age-related declines in testosterone levels or age-related symptoms in men are lacking;

f. clinical safety and effectiveness profiles for the use of AndroGel in the treatment of "Low T" are unsupported by any long-term, appropriately blinded, placebo-controlled, adequately powered, independent clinical study;

g. the attendant serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks causally associated with the use of AndroGel.

419. Abbott, AbbVie, and their predecessors-in-interest knew that:

a. the consumer awareness and consumer-directed multi-platform comprehensive educational, informational, and "Low T" screening questionnaires and interactive campaigns; and the drive to provoke, stimulate, and increase a consumer driven demand for "off-label" use of AndroGel to include the treatment of "Low T" or age-related declines in testosterone levels and age-related symptoms in men; and

b. the purported diagnostic criteria offered to consumers via questionnaires and other quizzes and non-specific diagnostic criteria crafted to lead men to self-diagnose potential "Low T" and to thereafter seek further evaluation and eventual treatment with AndroGel; and

c. the informational campaigns touting AndroGel as an accepted and approved treatment for "Low T;"

Would thereby create a belief among consumers and prescribers, which Abbott, AbbVie, and their predecessors-in-interest knew to be false, inaccurate, and misleading, that:

a. AndroGel was an FDA-approved, appropriate, and accepted treatment modality for "Low T" or age-related declines in testosterone levels and age-related symptoms in men; and

b. "Low T" was a variant of hypogonadism, and was therefore an indication for AndroGel therapy; and

c. AndroGel had known and favorable profiles of clinical safety and effectiveness for the treatment of "Low T" or age-related declines in testosterone or age-related symptoms; and

d. AndroGel carried no known risk of serious adverse life- or limb-threatening cardiovascular or cerebrovascular events.

420. Abbott, AbbVie, and their predecessors-in-interest intended that the aforementioned material falsehoods, fraudulent and deceptive representations, and willful failures to disclose be relied and acted upon by consumers, patients, and prescribers in order to increase AndroGel product demand, corporate revenues and profits, and the market share of AndroGel in the testosterone replacement therapy space.

421. Abbott, AbbVie, and their predecessors-in-interest further knew, understood, and intended, that consumer and prescriber reliance on these fraudulent representations and lack of disclosures would cause or increase the risk of harm of serious adverse life- and limb-threatening injury among AndroGel product users, including the risk of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens*, *phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

422. Abbott, AbbVie, and their predecessors-in-interest knew and understood that it was exposing, and attempting to further expose, millions of men (20% of the male population over 50 years of age) to the risks for AndroGel treatment for "Low T" for which there was no demonstrable profile of clinical safety or effectiveness, and more fundamentally, no approved indication for use. This was "a mass, uncontrolled experiment" conducted by Abbott, AbbVie, and their predecessors-in-interest.

423. The Plaintiff-husband reasonably and justifiably relied to his detriment upon these fraudulent and materially false, deceptive, and misleading representations, and would not have otherwise sought treatment for "Low T" or administered AndroGel had the fraudulent representations not been made to him or if he had not been induced to select treatment for "Low T" based upon these fraudulent statements and intentional failures to disclose by Abbott, AbbVie, and their predecessors-in-interest.

424. Abbott, AbbVie, and their predecessors-in-interest intentionally and willfully disseminated materially false and fraudulent statements to consumers and patients, including the Plaintiff-husband, and placed a product within the stream of interstate commerce substantially for "off-label" use and "label expansion," as a commercial enterprise for financial and economic benefit at the expense of public health and public safety, including the safety and well-being of the Plaintiff-husband.

425. Abbott, AbbVie, and their predecessors-in-interest knew that testosterone replacement preparations, including AndroGel:

a. were dangerous in their effects on blood coagulation and viscosity, estradiol levels, and the effects upon HDL and LDL levels;

b. lacked long-term clinical safety and effectiveness profiles;

c. were not approved by the FDA for the treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms in men;

d. were being aggressively detailed to physicians for "off-label" usage and "label expansion" without appropriate warnings or information to prescribing physicians concerning the FDA-approved indications for clinical use;

e. were being marketed and promoted to consumers and patients via comprehensive awareness and educational campaigns and mass-screening questionnaires and interactive websites soliciting Personal Health Information (PHI); and

f. did not inform consumers, patients, or physicians concerning the full spectrum and severity of serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks attendant with testosterone therapy.

426. Abbott, AbbVie, and their predecessors-in-interest fraudulently concealed or misrepresented these material facts.

427. Abbott, AbbVie, and their predecessors-in-interest knew and understood, throughout AndroGel product lifecycle including at the time of product launch in or about 2000, that declines in testosterone levels is a normal component of the male aging process, and that returning testosterone levels "physiologic" levels to treat the diagnosis of "Low T" in aging men would foreseeably and predictably cause or increase the risk of harm of serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

428. Abbott, AbbVie, and their predecessors-in-interest knew and understood that a decline in testosterone levels is a component of the male aging process, and that through

aggressive direct-to-consumer comprehensive awareness and promotional campaigns, including branded and unbranded consumer education, advertising, and medical information campaigns, all of which portrayed "Low T" as treatable "disease," that there would be an increasing demand for the treatment of "Low T" by middle-aged and elderly men with the AndroGel product.

429. Abbott, AbbVie, and their predecessors-in-interest knew and understood that AndroGel's revenue stream and bottom-line earnings would be favorably affected by the interface of increased consumer and patient product demand, driven and stimulated by the role of Abbott, AbbVie, and their predecessors-in-interest in creating and/or offering:

a. false and misleading direct-to-consumer renditions of comprehensive medical and diagnostic information concerning "Low T" and hypogonadism and the indications for clinical use of AndroGel;

b. false and misleading AndroGel product testimonials and endorsements;

c. interactive questionnaires and quizzes designed to elicit signs and symptoms purportedly diagnostic of a "disease," "Low T," treatable with AndroGel;

d. proffered differential diagnoses for signs and symptom complexes for which AndroGel is not an approved treatment option;

e. false and misleading information concerning testosterone therapy, its clinical usefulness to treat age-related declines in testosterone levels and age-related symptoms in men, and its clinical safety and effectiveness profiles;

f. the solicitation of Protected Health Information (PHI) to further drive consumer demand via direct-to-patient communication and "Low T"

treatment encouragement from and by Abbott, AbbVie, and their predecessors-in-interest;

g. recommendations for testosterone laboratory testing;

h. assistance with medical insurance and third-party payer coverage for AndroGel prescriptions;

i. referrals by Abbott, AbbVie, and their predecessors-in-interest to physicians known to be high-prescribers of the AndroGel product, as well as to physicians who are sponsored speakers, "thought-leaders," "key opinion leaders," and consultants paid or supported by Abbott, AbbVie, and their predecessors-in-interest; and

j. prescription refill reminders.

430. The aggressive promotional and detailing drives by Abbott, AbbVie, and their predecessors-in-interest were designed and executed to increase "off-label" prescription writing habits and "label expansion" by physicians.

431. Abbott, AbbVie, and their predecessors-in-interest knowingly sought to invent and reinforce a "disease" known as "Low T," and thereafter targeted the 20 million men middle-aged men whom Abbott, AbbVie, and their predecessors-in-interest knew would experience declines in testosterone levels and non-specific signs and symptoms of the aging process, to fraudulently induce them to become AndroGel users.

432. The fraudulent conduct of Abbott, AbbVie, and their predecessors-in-interest caused or increased the risk of harm of the injuries and damages suffered by the Plaintiff-husband, and the derivative loss of consortium damages of the Plaintiff-wife.

433. Accordingly, Plaintiffs are entitled to punitive and exemplary damages against Abbott and AbbVie, as set forth in the *ad damnum* clause, arising out of the fraudulent conduct of Abbott, AbbVie, and their predecessors-in-interest, as stated with particularity herein.

COUNT VII—NEGLIGENT MISPREPRESENTATION

434. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

435. Plaintiff herein pleads the elements of negligent misrepresentation, to include:

a. The statements and representations of Abbott, AbbVie, and their predecessors-in-interest of material fact to consumers and patients concerning the FDA-approved indications for clinical use of AndroGel; and the clinical safety and effectiveness profiles of AndroGel; and the signs and symptoms which AndroGel was FDA-approved to treat, which Abbott, AbbVie, and their predecessors-in-interest should have known were false;

b. The misrepresentation to consumers and patients by Abbott, AbbVie, and their predecessors-in-interest of the definition of hypogonadism and the distinction between "Low T" and hypogonadism, which Abbott, AbbVie, and their predecessors-in-interest should have known were false and misleading;

c. the failure by Abbott, AbbVie, and their predecessors-in-interest to know that the aforementioned statements of material fact concerning its AndroGel product were false and misleading;

d. the justifiable and reasonable reliance of the Plaintiff-husband on the negligent misrepresentations of Abbott, AbbVie, and their predecessors-in-interest;

e. the resulting injuries and damages suffered by the Plaintiff-husband, and the derivative loss of consortium suffered by the Plaintiff-wife, caused by the Plaintiff-husband's reasonable and justifiable reliance on these negligent misrepresentations, to his detriment, through his use of the AndroGel product.

436. Abbott, AbbVie, and their predecessors-in-interest had a duty to disclose all material facts relating to the use of AndroGel to consumers and patients via its multi-platform comprehensive consumer awareness, educational, informational, and marketing formats and campaigns, including to the Plaintiff-husband.

437. Abbott, AbbVie, and their predecessors-in-interest should have known and understood that consumer acceptance of and belief in the clinical safety and effectiveness profiles of the AndroGel product were central to the sale, use, demand for, and physician prescribing habits for AndroGel.

438. Abbott, AbbVie, and their predecessors-in-interest had a duty to provide consumers and patients with full, complete, accurate, and truthful information concerning the AndroGel product, including the product's FDA-approved spectrum of indications for clinical use; and appropriate and medically sound and accurate definitions of hypogonadism and "Low T;" and the clinical safety and effectiveness profiles of AndroGel.

439. Abbott, AbbVie, and their predecessors-in-interest should have known that AndroGel was not approved by the FDA for the treatment of:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

440. At all times material hereto, Abbott, AbbVie, and their predecessors-in-interest knew, or should have known, that the FDA was unaware of any data to support these indications for the clinical use of AndroGel.

441. At all times material hereto, and since the time of FDA approval of the AndroGel product, Abbott, AbbVie, and their predecessors-in-interest knew or should have known that the FDA had not approved AndroGel as therapy:

a. to improve mood;

b. to increase sexual interest;

c. to restore erectile function;

d. to increase muscle mass; or

e. to increase strength of bones.

442. Nonetheless, Abbott, AbbVie, and their predecessors-in-interest encouraged consumers to self-screen for these signs and symptoms via questionnaires and selected and interactive quizzes and clinical questions, in order to foster the false belief among consumers that they harbored a "disease" requiring testosterone replacement therapy with AndroGel.

443. Abbott, AbbVie, and their predecessors-in-interest should have, but failed, to disclose material facts to consumers, including the Plaintiff-husband, concerning the approved indications for clinical use of AndroGel; the lack of clinical safety and effectiveness profiles of the AndroGel product; the "off-label" use of AndroGel and the "label expansion" that was occurring with the AndroGel product; the true nature of the condition known as "Low T;" and the correct medical definition of hypogonadism.

444. Abbott, AbbVie, and their predecessors-in-interest should have known that AndroGel was being marketed and promoted to consumers and patients, including the Plaintiff-husband, to treat age-related symptoms, including:

a. age-related declines in testosterone levels in men;

b. age-related symptoms;

c. mood disorders, including depression or "grumpiness" or inability to concentrate;

d. lack of sexual interest or decreased libido;

e. disorders of erectile function or erectile dysfunction;

f. loss of muscle mass; or

g. bone strength or density abnormalities.

445. Abbott, AbbVie, and their predecessors-in-interest should have known that:

a. "Low T" is not an approved indication for clinical treatment with AndroGel;

b. "Low T" or age-related declines in testosterone levels and age-related symptoms in men is not the same medical entity as primary or secondary

hypogonadism, which were the FDA-approved indications for AndroGel use;

c. the diagnostic and clinically relevant criteria for the use of AndroGel as a testosterone replacement treatment modality do not include age-related declines in testosterone levels and age-related symptoms;

d. clinical safety and effectiveness profiles of AndroGel as a treatment of "Low T" or age-related declines in testosterone levels and age-related symptoms were lacking;

e. clinical safety and effectiveness profiles for the use of AndroGel in the treatment of conditions which do not fall under the rubric of hypogonadism were untested and lacking, and that they were conducting "a mass, uncontrolled experiment" through its marketing and promotion of AndroGel to treat "Low T;"

f. the FDA-approved indications for the clinical use of AndroGel did not include "Low T;" and

g. there were and are attendant serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks causally associated with the use of testosterone-containing products, including AndroGel, which occur through a spectrum of metabolic mechanisms which should have been known to Abbott, AbbVie, and their predecessors-in-interest prior to the product launch of AndroGel in or about 2000.

446. Abbott, AbbVie, and their predecessors-in-interest should have known that:

a. primary and secondary hypogonadism, and not "Low T" or age-related declines in testosterone levels or age-related symptoms in men, are the appropriate FDA-approved indications for the clinical use for AndroGel;

b. the definition of hypogonadism is not synonymous with "Low T" or age-related declines in testosterone levels or age-related symptoms, and that primary and secondary hypogonadism are caused by specific testicular or hypothalamic-pituitary-gonadal axis diseases or conditions;

c. "Low T" is not a diagnosis or condition warranting AndroGel therapy, and in fact, "Low T" is an "off-label" indication for use or "label expansion" for the AndroGel product;

d. "Low T" is not a disease;

e. the diagnostic, clinically relevant, and medically appropriate criteria for the use of AndroGel are not simply a low testosterone level and non-specific, age-related symptoms in men;

f. clinical safety and effectiveness profiles of AndroGel for the treatment of "Low T" and the long-term use of testosterone replacement therapy to treat age-related declines in testosterone or age-related symptoms in men are lacking;

g. clinical safety and effectiveness profiles for the use of AndroGel in the treatment of "Low T" were unsupported by any long-term, appropriately blinded, placebo-controlled, sufficiently powered, and independent clinical studies; and

h. there are attendant serious life- and limb-threatening cardiovascular and cerebrovascular injuries and risks causally associated with the use of AndroGel.

447. Abbott, AbbVie, and their predecessors-in-interest should have known that:

a. the comprehensive consumer awareness and consumer-directed multi-platform educational, informational, and "Low T" screening questionnaires and interactive campaigns; and

b. the concerted drive to provoke, stimulate, and increase a consumer driven demand for "off-label" clinical use of the AndroGel product to include the treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms in men; and

c. the purported diagnostic criteria for "Low T" offered to consumers via the questionnaires and other quizzes and the encouragement to seek testosterone level testing which were crafted to lead men to self-diagnose "Low T" and to seek medical diagnosis and treatment with AndroGel; and

d. the informational campaigns touting AndroGel as an accepted and approved treatment for "Low T;"

Would thereby create a belief among consumers, which Abbott, AbbVie, and their predecessors-in-interest should have known to be false and inaccurate that:

a. AndroGel was an FDA-approved, appropriate, and accepted treatment modality for "Low T" or age-related declines in testosterone levels or age-related symptoms in men; and

b. "Low T" was a variant of hypogonadism and was therefore an indication for AndroGel therapy; and

c. AndroGel had a known and favorable profiles of clinical safety and effectiveness for the treatment of "Low T" or age-related declines in testosterone and age-related symptoms in men; and

d. AndroGel carried no known risk of serious adverse life- and limb-threatening cardiovascular or cerebrovascular events.

448. Abbott, AbbVie, and their predecessors-in-interest should have known that the aforementioned misrepresentations were material to consumer's and patient's use of the AndroGel product, and would be reasonably and justifiably relied and acted upon by consumers and patients who would thereby demand treatment for "Low T" with the AndroGel product.

449. Abbott, AbbVie, and their predecessors-in-interest should have known that discount and rebate coupons would drive consumer demand for treatment with AndroGel, and that the "off-label" promotion and detailing to physicians would increase unwarranted and unjustified AndroGel consumer and patient use.

450. Abbott, AbbVie, and their predecessors-in-interest should have known that consumer reliance on these negligent misrepresentations and failures to disclosure would cause or increase the risk of harm of serious adverse life-and limb-threatening cardiovascular and cerebrovascular events among AndroGel users, including the risks of:

a. heart attacks and consequent myocardial damage;

b. strokes and consequent neurologic injuries and impairment;

c. deep vein thrombosis and its potential sequelae of *phlegmasia cerulea dolens, phlegmasia alba dolens*, post-phlebitic leg syndrome, requirement for anticoagulation, and pulmonary embolism;

d. sudden cardiac death; and

e. other acute visceral and central venous and arterial thrombotic phenomena.

451. Abbott, AbbVie, and their predecessors-in-interest should have known that they were exposing, and attempting to further expose, millions of men to the unreasonable risks of AndroGel treatment for "Low T," because AndroGel had no demonstrable profile of clinical safety or effectiveness in the treatment of "Low T," and more fundamentally, because "Low T" or age-related declines in testosterone level and age-related symptoms were not FDA-approved indications for AndroGel use. Abbott, AbbVie, and their predecessors-in-interest should have known that they were conducting "a mass, uncontrolled experiment" with the AndroGel product, and thereby misrepresented the nature of AndroGel therapy for "Low T."

452. The Plaintiff-husband reasonably and justifiably relied to his detriment upon these negligent misrepresentations and failures to disclose material facts, and would not have otherwise sought treatment for "Low T" or administered or continued to administer AndroGel to himself had these misrepresentations and failures of disclosure not been made to him.

453. Abbott, AbbVie, and their predecessors-in-interest negligently disseminated materially false statements to consumers and patients, and negligently placed a product within the stream of interstate commerce substantially for "off-label" use and "label expansion," as a commercial enterprise for the contemplated financial and economic benefit to Abbott, AbbVie,

and their predecessors-in-interest at the expense of public health and public safety, including the safety and well-being of the Plaintiff-husband.

454. Abbott, AbbVie, and their predecessors-in-interest should have known that testosterone preparations, including AndroGel:

a. were dangerous in their effects on blood coagulation and viscosity, estradiol levels, and effects upon HDL and LDL levels;

b. lacked long-term clinical safety and effectiveness profiles;

c. were not approved by the FDA for the treatment of "Low T" or age-related declines in testosterone levels or age-related symptoms in men;

d. were being aggressively detailed to physicians for "off-label" usage and "label expansion" without appropriate warnings and without appropriate information to prescribing physicians concerning the FDA-approved indications for clinical use;

e. were being marketed and promoted to consumers via comprehensive awareness and educational campaigns and mass-screening questionnaires and interactive websites with inadequate and false information included; and

f. did not carry information for consumers or patients concerning the full spectrum of serious adverse life- and limb-threatening cardiovascular and cerebrovascular risks attendant with testosterone therapy.

455. Abbott, AbbVie, and their predecessors-in-interest should have known throughout AndroGel's product lifecycle, including at the time of product launch in or about 2000, that declines in testosterone levels is a component of the *normal* male aging process, and that

returning testosterone levels to "physiologic" levels to treat the diagnosis of "Low T" in aging men would foreseeably and predictably cause or increase the risk of harm of adverse serious life- and limb-threatening cardiovascular and cerebrovascular injuries.

456. Abbott, AbbVie, and their predecessors-in-interest should have known that a decline in testosterone levels is component of the *normal* male aging process, and that through aggressive direct-to-consumer advertising, including branded and unbranded consumer education and medical information campaigns and self-diagnosis questionnaires, all of and portrayed "Low T" as treatable "disease," there would be an increasing demand for treatment of "Low T" by middle-aged and elderly men with the AndroGel product.

457. Abbott, AbbVie, and their predecessors-in-interest negligently invented, reinforced, and represented to consumers and the public concerning a "disease" known as "Low T," and targeted the 20 million men middle-aged men whom Abbott, AbbVie, and their predecessors-in-interest knew would experience *normal* declines in testosterone levels and symptoms of the aging process to induce them through this presentation to seek treatment with AndroGel.

458. The negligent misrepresentations and failures to disclose on the part of Abbott, AbbVie, and their predecessors-in-interest caused or increased the risk of harm of the injuries suffered by the Plaintiff-husband, and the derivative loss of consortium of the Plaintiff-wife.

459. Accordingly, Abbott and AbbVie are liable for compensatory damages, as set forth in the *ad damnum* clause, to the Plaintiffs for their injuries, losses, and damages.

COUNT VIII—DECEPTIVE TRADE PRACTICES

460. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

461. Abbott, AbbVie, and their predecessors-in-interest represented to the Plaintiff-husband, through multi-platform marketing and promotions that AndroGel had sponsorship, approval, characteristics, uses, and benefits that the product, in fact, did not have.

462. Abbott, AbbVie, and their predecessors-in-interest represented through word and deed that AndroGel was approved by the FDA to treat "Low T." This was false, misleading, and deceptive.

463. Abbott, AbbVie, and their predecessors-in-interest represented through word and deed that AndroGel was clinically indicated for use to treat "Low T." This was false, misleading, and deceptive.

464. Abbott, AbbVie, and their predecessors-in-interest represented through word and deed that AndroGel was of proven clinical benefit in the treatment of "Low T." This was false, misleading, and deceptive.

465. Plaintiff-husband reasonably and justifiably relied to his detriment upon these materially false, deceptive, and misleading representations, and would not have otherwise sought treatment for "Low T" or administered AndroGel had these representations not been made to him.

466. Accordingly, Abbott, AbbVie, and their predecessors-in-interest is liable to the Plaintiff husband for their unfair trade practices, which caused the Plaintiff-husband to use the AndroGel product and which increased the risk of harm of his injury.

467. Plaintiffs claim all elements of damages recoverable against Abbott and AbbVie for their deceptive trade practices.

COUNT IX—LOSS OF CONSORTIUM
Plaintiff-Wife v. Abbott and AbbVie

468. Plaintiffs incorporate by reference the preceding paragraphs of this Civil Action Complaint as though fully set forth herein.

469. Plaintiff-wife herein brings this derivative loss of consortium claim arising out of the injuries caused by Abbott, AbbVie, and their predecessors-in-interest to her husband and claims entitlement to damages in her own right.

470. Because of the injuries suffered by her husband, Plaintiff-wife has experienced the loss of the company, society, cooperation, guidance, and companionship of her husband.

471. Accordingly, Abbott and AbbVie are liable for compensatory damages, as set forth in the *ad damnum* clause, to the Plaintiff-wife, in her own right, for the derivative injuries, losses, and damages she has suffered due to her husband's injuries and damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment against Defendants as follows:

a. General damages in a sum in excess of the jurisdictional minimum of this Court;

b. Medical, incidental, and hospital expenses according to proof;

c. Pre-judgment and post-judgment interest as provided by law;

d. Full refund of all purchase costs Plaintiff paid for testosterone;

e. Compensatory damages in excess of the jurisdictional minimum of this Court;

f. Consequential damages in excess of the jurisdictional minimum of this Court, including loss of consortium damages on behalf of the Plaintiff-wife;

g. Punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

h. Attorneys' fees, expenses, and costs of this action; and,

i. 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.

Respectfully submitted,

/s/*Mark A. Hoffman*

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JS 44 (Rev. 3/13)

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

Arthur Myers and Heather Myers, h/w
8601 East Hopi Drive
Prescott Valley Arizona 86314

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

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

Mark A. Hoffman, Esquire
Natalie E. Doria, Esquire
Ross Feller Casey LLP
1650 Market Street, Suite 3450, Philadelphia PA 19103
215 574 2000

DEFENDANTS

AbbVie, Inc., 1 North Waukegan Road, North Chicago IL 60064 and Abbott Laboratories, Inc. 100 Abbott Park Road, Abbott Park IL 60064

County of Residence of First Listed Defendant Lake County
(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 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
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 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
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 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 (Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

Pharmaceutical Product Liability

VII. Previous Bankruptcy Matters (For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.

VIII. REQUESTED IN COMPLAINT:

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

DEMAND $ 10,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

IX. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE Hon. Matthew F. Kennelly DOCKET NUMBER 14-cv-1748 (MDL 2545)

X. This case (check one box) ☑ Is not a refiling of a previously dismissed action ☐ is a refiling of case number _____ previously dismissed by Judge _____

DATE 2/3/15

SIGNATURE OF ATTORNEY OF RECORD /s/ Mark A. Hoffman, Esquire