

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO, EASTERN DIVISION**

Timothy Wilkes, Sr., and Pamela Wilkes)	COMPLAINT AND DEMAND
)	FOR JURY TRIAL
)	
Plaintiffs,)	
)	Case No. _____
-vs-)	
)	
AbbVie Inc., and Abbot Laboratories, Inc.)	
)	
)	
Defendants.)	
)	

COMPLAINT

Plaintiffs, Timothy Wilkes, Sr., and Pamela Wilkes by and through undersigned counsel, Scanlon & Elliott, by way of complaint against AbbVie Inc. and Abbott Laboratories, Inc. (hereinafter “Defendants”) allege as follows upon information and belief:

INTRODUCTION:

1. This case involves the prescription drug AndroGel, which is manufactured, sold, distributed and promoted by Defendants as a testosterone replacement therapy.
2. Defendants misrepresented that AndroGel is a safe and effective treatment for hypogonadism or “low testosterone,” when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thrombolytic events.
3. Defendants engaged in aggressive, award-winning direct-to-consumer and physician marketing and advertising campaigns for AndroGel. Further, Defendants engaged in an aggressive unbranded “disease awareness” campaign to alert men that they might be suffering from “low T.”

4. According to the industry-leading Androgen Deficiency in Adult Males (“ADAM”) or “Is it Low T?” quiz, the symptoms of “Low T” include being “sad and grumpy,” “experiencing deterioration in the ability to play sports,” and “falling asleep after dinner.” *Available at:* <http://isitlowt.com/do-you-have-low-t/low-t-quiz>. Most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural ageing process.
5. As a result of this “disease mongering,” as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of Low T have increased exponentially. This has directly related to AndroGel’s sales increasing to \$1.37 billion per year.
6. However, consumers of AndroGel were misled as to the drug’s safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thrombolytic events.

PARTIES

7. Plaintiff Timothy Wilkes, Sr. is a resident of Summit County, Ohio.
8. Plaintiff Pamela Wilkes is a resident of Summit County, Ohio.
9. Defendant AbbVie, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.
10. Defendant Abbot Laboratories, Inc. is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbot Park Road, Abbott Park, Illinois 60064.
11. By way of background, Unimed Pharmaceuticals, Inc. originally developed AndroGel and sought FDA approval in 1999. Before the drug was approved by the FDA in 2000, Solvay Pharmaceutical, Inc. acquired Unimed Pharmaceuticals, Inc. and subsequently brought

AndroGel to the market. In 2010, Defendant Abbott Laboratories, Inc. acquired Solvay's pharmaceutical division, which included Andorgel. Then, in 2013, Abbott created AbbVie, a company composed of Abbott's former proprietary pharmaceutical business, which included AndroGel.

JURISDICTION AND VENUE

12. The jurisdiction of this Court over the subject matter of this action is predicated on 28 U.S.C. Section § 1332. The amount in controversy exceeds \$75,000.00, exclusive of interest and costs.
13. Venue in this Court is proper pursuant to 28 U.S.C. Section § 1391 in that substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District, and Defendants are subject to personal jurisdiction in this District.

GENERAL ALLEGATIONS

14. This action is for damages brought on behalf of Plaintiff Timothy Wilkes, Sr., and his wife Pamela Wilkes. Plaintiff Timothy Wilkes, Sr. was prescribed and supplied with, received and who has taken and applied the prescription drug AndroGel, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Personal Injury Plaintiff to treat and monitor the dangerous, severe, and life-threatening side effects caused by this drug, as well as damages for loss of consortium.
15. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiffs' injuries and damages.

16. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug AndroGel for the use and application by the Personal Injury Plaintiff.
17. At all times herein mentioned, Defendants were authorized to do business within the state of residence of Plaintiffs.
18. At all times relevant herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortuous conduct which resulted in the injuries suffered by Plaintiffs herein.
19. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by Plaintiff. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when the Personal Injury Plaintiff's injuries were discovered their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortuous nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug AndroGel is safe and free from serious side effects, and Defendants have

fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

OVERVIEW

20. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone.
21. In 1999, when Unimed Pharmaceuticals, Inc., one of the Defendants' predecessor companies, asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men."
22. In 2000, when the FDA approved AndroGel, the company announced that the market was "four to five million American men." By 2003, the number increased to "up to 20 million men." However, a study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001-2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, one quarter of men did not even have their testosterone levels tested before the received the testosterone prescription.
23. Defendants coordinated a massive advertising campaign designed to convince men that they suffered from low testosterone. Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential AndroGel users, and online media including the unbranded website "IsItLowT.com."
24. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone

replacement therapy with their doctors if they experienced any of the “symptoms” of low testosterone. These “symptoms” include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

25. Defendant’s national education campaign included the creation and continued operation of the website www.IsItLowT.com. The website asserts that millions of otherwise healthy men experience low testosterone and encourages male visitors to “Take the ‘Is it Low T’ Quiz.” The “Is it Low T” quiz asks men if they have experienced potential signs of low testosterone, including “Have you experienced a recent deterioration in your ability to play sports?”, “Are you falling asleep after dinner?”, “Are you sad and/or grumpy?”, and “Do you have a lack of energy?”
26. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed the quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a \$40,000 grant to his university. The pharmaceutical company instructed Dr. Morley, “Don’t make it too long and make it somewhat sexy.” Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morley admits that he has “no trouble calling it a crappy questionnaire” and that it is “not ideal.” This is the “Low T Quiz” used on the “IsItLowT” website. Natasha Singer, *Selling that New-Man Feeling*, Nov. 23, 2013, N.Y. Times.
27. Since the FDA approved AndroGel, Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that the conditions associated with normal aging could be caused by low testosterone levels.

28. While running its disease awareness campaign, Defendants promoted their product AndroGel as an easy to use topical testosterone replacement therapy. Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.
29. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.
30. What consumers received, however, were not safe drugs, but a product which causes life-threatening problems, including strokes, heart-attacks, pulmonary embolisms, chest pains, and various other ailments.
31. Defendants successfully created a robust and previously nonexistent market for their drug. Defendant Abbott Laboratories spent \$80 million promoting AndroGel in 2012. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men have regular checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.
32. Defendants' advertising paid off in a return of \$1.4 billion in sales during the past year, making AndroGel the biggest selling androgen drug in the United States. Sales of the replacement therapies have more than doubled since 2006, and are expected to triple to \$5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, *available at*: <http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra>.

33. In early 2013, Medical Marketing & Media named AbbVie executives as “the all-star large pharma marketing team of the year” for promotions of AndroGel and unbranded efforts to advance low T. *See Singer, Selling That New-Man Feeling*, supra; *See also*, Larry Dobrow, *All-star large pharma marketing team of the year: Androgel*. Jan 2, 2013, Medical Marketing & Media, *available at*: <http://www.mmm-online.com/all-star-large-pharma-marketing-team-of-the-year-androgel/article/273242/>.
34. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of AndroGel is safe for human use, even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.
35. There have been a number of studies suggesting that testosterone in men increases the risk of heart attacks and strokes.
36. In 2010, a New England Journal of Medicine Study entitled “Adverse Events Associated with Testosterone Administration” was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.
37. In November 2013, a JAMA study released entitled “Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels” which indicated that testosterone therapy raised the risk of death, heart attacks and strokes by about 30%.
38. On January 29, 2014, a study was released in PLOS ONE entitled “Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men” which indicated that testosterone use doubled the risk of heart attacks in men over sixty five years old and men younger than sixty five with a previous diagnosis of heart disease.

FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

39. The Food and Drug Administration approved AndroGel 1% on February 28, 2000 for treatment of adult males who have low or no testosterone (AndroGel 1.62% was approved in April, 2011).
40. AndroGel is a hydroalcoholic gel containing testosterone in either 1% or 1.62%, applied to the chest, arms or stomach and enters the body through transdermal absorption. The AndroGel 1.62% product also contains isopropyl myristate as an ointment and ethanol for absorption enhancement.
41. Testosterone is a primary androgenic hormone responsible for normal growth, development of male sex organs, and maintenance of secondary sex characteristics.
42. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.
43. In men, testosterone levels normally begin a gradual decline after the age of thirty.
44. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.
45. AndroGel may produce undesirable side effects to patients who use the drug, including but not limited to, myocardial infarction, stroke, and death.
46. In some patient populations, AndroGel use may increase the incidence of myocardial infarctions and death by over 500%.
47. In addition to the above, AndroGel has been linked to several severe and life changing medical disorders in both users and those who come into physical contact with users or the unwashed clothes of someone who applied AndroGel. Patients taking AndroGel may experience enlarged prostates and increased serum prostate-specific antigen levels.

48. Secondary exposure to AndroGel can cause side effects in others. In 2009, the FDA issued a black box warning for AndroGel prescriptions, advising patients of reported virilization in children who were secondarily exposed to the gel. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damages with pregnant women who come in secondary contact with AndroGel.
49. Defendants' marketing strategy beginning in 2000 has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.
50. Defendants successfully marketed AndroGel by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low-T."
51. AbbVie's advertising program, sought to create the image and belief by consumers and their physician that the use of AndroGel was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though Defendants had no reasonable grounds to believe them to be true.
52. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using AndroGel. Defendants deceived potential AndroGel users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

53. Defendants concealed material relevant information from potential AndroGel users and minimized users and prescriber concern regarding the safety of AndroGel.
54. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential cardiac or stroke side effects and falsely represents that AbbVie adequately tested AndroGel for all likely side effects.
55. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for AndroGel. If Plaintiff in this action had known the risks and dangers associated with AndroGel, the Personal Injury Plaintiff would not have taken AndroGel and consequently would not have been subject to its serious side effects.

SPECIFIC FACTUAL ALLEGATIONS

56. Plaintiff Timothy Wilkes, Sr. was 54 years old when he was prescribed and used AndroGel for symptoms he attributed to low testosterone after viewing Defendants' advertisements.
57. Plaintiff Timothy Wilkes, Sr. is a retiree living in the City of Tallmadge, the County of Summit, State of Ohio.
58. Plaintiff was prescribed and used AndroGel from a period of September 2011 through January 2013.
59. The AndroGel taken by Plaintiff caused physical and emotional impairment which affected his personal and professional life. The impairments include, but are not limited to multiple pulmonary emboli, severe chest pains and stomach pains, shortness of breath, and a variety of other impairments which continue to affect Plaintiff.
60. Prior to using AndroGel Plaintiff had no history of any respiratory or cardiac events.

FIRST CLAIM FOR RELIEF

FIRST CAUSE OF ACTION FOR STRICT LIABILITY – FAILURE TO WARN

61. Plaintiff incorporate by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.
62. The AndroGel manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks. The AndroGel manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of AndroGel, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.
63. As a direct and proximate result of Plaintiff's reasonably anticipated use of AndroGel as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages, and losses in the future.

SECOND CAUSE OF ACTION
FOR NEGLIGENCE

64. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.
65. At all relevant times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe and adequately warn of the risks and dangers of AndroGel.
66. At all relevant times herein mentioned, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected,

distributed, marketed, labeled, packaged, prepared for use and sold AndroGel and failed to adequately test and warn of the risks and dangers of AndroGel.

67. Despite the fact that Defendants knew or should have known that AndroGel caused unreasonable, dangerous side effects, Defendants continued to market AndroGel to consumers including Plaintiff, when there were safer alternative methods of treating loss of energy, libido, erectile dysfunction, depression, loss of muscle mass and other conditions AndroGel's advertising claims are caused by low testosterone.
68. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.
69. Defendants' negligence was a proximate cause of Personal Injury Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed herein.

THIRD CAUSE OF ACTION
FOR BREACH OF IMPLIED WARRANTY

70. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.
71. Prior to the time that the aforementioned products were used by the Personal Injury Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that AndroGel was of merchantable quality and safe and fit for the use for which it was intended.
72. Plaintiff was and is unskilled in the research, design and manufacture of the products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using AndroGel.
73. AndroGel was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that AndroGel has dangerous propensities when used as intended and will cause severe injuries to users.

74. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered as though fully set forth here.

FOURTH CAUSE OF ACTION
FOR BREACH OF EXPRESS WARRANTY

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

76. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients, and the general public, that AndroGel is safe, effective, fit and proper for its intended use. Plaintiff purchased AndroGel relying upon these warranties.

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

78. As a result of the aboveformentioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages alleged herein.

FIFTH CAUSE OF ACTION
FOR FRAUD

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

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

81. At all relevant times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using AndroGel. Defendants knew of the foregoing, that AndroGel is not safe, fit and effective for human consumption, that using AndroGel is hazardous to health, and that AndroGel has serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.
82. Defendants concealed and suppressed the true facts concerning AndroGel with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not prescribe AndroGel, and Plaintiff would not have used AndroGel, if they were aware of the true facts concerning its dangers.
83. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION
FOR NEGLIGENT MISREPRESENTATION

84. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.
85. From the time AndroGel was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to misrepresentations that AndroGel was safe, fit and effective for human consumption. At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

86. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.
87. The representations by the Defendants were in fact false, in that AndroGel is not safe, fit and effective for human consumption, using AndroGel is hazardous to health, and AndroGel has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.
88. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of AndroGel.
89. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use AndroGel. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used AndroGel. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.
90. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged.

PUNITIVE DAMAGES ALLEGATIONS

91. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.
92. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the

rights of Plaintiff and other AndroGel users and for the primary purpose of increasing Defendants' profits from the sale and distribution of AndroGel. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make examples of Defendants.

93. Prior to the manufacturing, sale, and distribution of AndroGel, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using AndroGel.

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

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

WHEREFORE, Plaintiff prays for judgment against the Defendants as follows, as appropriate to each claim for relief alleged and as appropriate to the particular standing of Plaintiff:

- A. General damages in the amount that will conform to proof at the time of trial;
- B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;
- C. Loss of earnings and impaired earning capacity according to the proof at the time of trial;
- D. Medical expenses, past and future, according to proof at the time of trial;
- E. For past and future mental and emotional distress, according to proof;
- F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;
- G. For punitive and exemplary damages according to proof at the time of trial;
- H. Restitution, disgorgement of profits, and other equitable relief;
- I. Injunctive relief;
- J. Attorney's fees;
- K. For costs of suit incurred herein;
- L. For pre-judgment interest as provided by law; and
- M. For such other and further relief as the Court may deem just and proper.

SECOND CLAIM FOR RELIEF
FOR LOSS OF CONSORTIUM

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

97. Plaintiff Pamela Wilkes is the wife of Plaintiff Timothy Wilkes, and by reason of his injuries and losses complained in the foregoing, and as a direct and proximate result of the aforementioned acts and omissions of Defendants, she has been deprived of the aid, comfort, and support of her husband for an indefinite period of time.

98. As a direct and proximate result of these reprehensible activities, Plaintiffs have suffered considerable injuries and damages aforementioned and are entitled to relief.

WHEREFORE, Plaintiff prays for judgment against the Defendants as follows, as follows:

- A. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;
- B. For punitive and exemplary damages according to proof;
- C. Attorney's fees;
- D. For costs of suit incurred herein;
- E. For pre-judgment interest as provided by law; and
- F. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Defendant hereby demands a trial by jury as to all issues in this action.

Respectfully submitted,

SCANLON & ELLIOTT

/s/Lawrence J. Scanlon

Lawrence J. Scanlon (0016763)

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Attorney for Plaintiff

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

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

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

DEFENDANTS

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

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

Attorneys (If Known)

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

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 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)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Contains various legal categories and checkboxes.

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, 6 Multidistrict Litigation

VI. CAUSE OF ACTION

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

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO**

I. Civil Categories: (Please check one category only).

1. General Civil
2. Administrative Review/Social Security
3. Habeas Corpus Death Penalty

*If under Title 28, §2255, name the SENTENCING JUDGE:

CASE NUMBER:

II. **RELATED OR REFILED CASES.** See LR 3.1 which provides in pertinent part: "If an action is filed or removed to this Court and assigned to a District Judge after which it is discontinued, dismissed or remanded to a State court, and subsequently refiled, it shall be assigned to the same Judge who received the initial case assignment without regard for the place of holding court in which the case was refiled. Counsel or a party without counsel shall be responsible for bringing such cases to the attention of the Court by responding to the questions included on the Civil Cover Sheet."

This action is **RELATED** to another **PENDING** civil case. This action is **REFILED** pursuant to **LR 3.1**.

If applicable, please indicate on page 1 in section VIII, the name of the Judge and case number.

III. In accordance with Local Civil Rule **3.8**, actions involving counties in the Eastern Division shall be filed at any of the divisional offices therein. Actions involving counties in the Western Division shall be filed at the Toledo office. For the purpose of determining the proper division, and for statistical reasons, the following information is requested.

ANSWER ONE PARAGRAPH ONLY. ANSWER PARAGRAPHS 1 THRU 3 IN ORDER. UPON FINDING WHICH PARAGRAPH APPLIES TO YOUR CASE, ANSWER IT AND STOP.

(1) **Resident defendant.** If the defendant resides in a county within this district, please set forth the name of such county

COUNTY:

Corporation For the purpose of answering the above, a corporation is deemed to be a resident of that county in which it has its principal place of business in that district.

(2) **Non-Resident defendant.** If no defendant is a resident of a county in this district, please set forth the county wherein the cause of action arose or the event complained of occurred.

COUNTY:

(3) **Other Cases.** If no defendant is a resident of this district, or if the defendant is a corporation not having a principle place of business within the district, and the cause of action arose or the event complained of occurred outside this district, please set forth the county of the plaintiff's residence.

COUNTY:

IV. The Counties in the Northern District of Ohio are divided into divisions as shown below. After the county is determined in Section III, please check the appropriate division.

EASTERN DIVISION

AKRON	(Counties: Carroll, Holmes, Portage, Stark, Summit, Tuscarawas and Wayne)
CLEVELAND	(Counties: Ashland, Ashtabula, Crawford, Cuyahoga, Geauga, Lake, Lorain, Medina and Richland)
YOUNGSTOWN	(Counties: Columbiana, Mahoning and Trumbull)

WESTERN DIVISION

TOLEDO	(Counties: Allen, Auglaize, Defiance, Erie, Fulton, Hancock, Hardin, Henry, Huron, Lucas, Marion, Mercer, Ottawa, Paulding, Putnam, Sandusky, Seneca VanWert, Williams, Wood and Wyandot)
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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin.** Place an "X" in one of the six boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.
- Date and Attorney Signature.** Date and sign the civil cover sheet.