UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Mary Alfimow, Individually and as the Representative of the Estate of Valerik E. Alfimow, Plaintiff, v. AbbVie Inc., and Abbott Laboratories, Inc., Defendants.	:	COMPLAINT AND DEMAND FOR JURY TRIAL Case No.

COMPLAINT

Plaintiff Mary Alfimow ("Plaintiff"), by and through the undersigned counsel, through her Complaint hereby alleges against AbbVie Inc. and Abbott Laboratories, Inc. the following:

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, thrombolytic events and death.

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 or grumpy", "experiencing deterioration in the ability to play sports" and "falling asleep after dinner." Available at: *http://www.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 aging process.

5. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, individuals diagnosed with Low T has increased exponentially. This has directly related to AndroGel's sales increasing to over $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, thrombolytic events and death.

PARTIES

7. Plaintiff Mary Alfimow and Decedent Valerik E. Alfimow ("Decedent"), at all times relevant, are and were residents of Shelbyville, Indiana.

8. 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.

9. Defendant Abbott 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 Abbott Park Road, Abbott Park, Illinois 60064.

10. Defendants AbbVie, Inc., and Abbott Laboratories, Inc. shall be referred to herein individually by name or jointly as "Defendants".

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

JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $150,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiff and Decedent at all times relevant are and were residents of

Indiana, which is different from the states where Defendants are incorporated and have their principal places of business.

13. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c) and because a substantial part of the events giving rise to Plaintiff's claims occurred in this jurisdiction.

GENERAL ALLEGATIONS

15. This action is for damages brought on behalf of Decedent who was prescribed and supplied with, received and who has used 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 relief to the Plaintiff for the untimely loss of Decedent, her husband, caused by this drug.

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

17. 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 Decedent.

18. At all times herein mentioned, Defendants were authorized to do business within the state of Indiana, where Decedent resided and Plaintiff resides.

19. At all times 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 tortious conduct which resulted in the injuries suffered by Plaintiff and Decedent.

20. Plaintiff files this lawsuit within the applicable limitations period of first suspecting Defendants' medication caused the appreciable harm sustained by Decedent. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Decedent's injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when Decedent's injuries were discovered, their cause was unknown to Plaintiff.

21. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants misrepresented and continue to misrepresent to the public, and the medical community, 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

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

23. 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."

24. 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, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

25. Defendants coordinated a massive advertising campaign designed to convince men that they suffer 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."

26. 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 these "symptoms." 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.

27. Defendants' 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?"

28. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this 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. Morely 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. Dr. Morely 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.

29. Since the FDA approved AndroGel, Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

30. While running its disease awareness campaign, Defendants promote 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.

31. 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 has been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

32. What consumers received, however, were not safe drugs, but a product which causes life-threatening problems, including strokes, heart attacks and the development of deep vein thrombosis, pulmonary embolism and death.

33. 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 performed, including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

34. Defendants' advertising resulted in $1.4 billion in sales during the past year, making AndroGel the biggest selling Androgen drug in the United States. Sales of 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.

35. In early 2013, Medical Marketing & Media named two 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/.

36. 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 statements to be false, and even though Defendants had no reasonable grounds to believe them to be true.

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

38. 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.

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

40. 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

41. The Food and Drug Administration approved AndroGel 1% on February 28, 2000 for the treatment of adult males who have low or no testosterone (AndroGel 1.62% was approved in April, 2011). After FDA approval, AndroGel was

widely advertised and marketed by Defendants as a safe and effective means of testosterone replacement therapy.

42. AndroGel is a hydroalcoholic gel containing testosterone in either 1% or 1.62%, is 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.

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

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

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

46. 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.

47. AndroGel may produce undesirable side effects to patients who use the drug, including but not limited to, myocardial infarction, stroke, deep vein thrombosis, pulmonary embolism and death.

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

49. 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 using AndroGel may experience enlarged prostates and increased serum prostate-specific antigen levels.

50. 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 damage in pregnant women who come into secondary contact with AndroGel.

51. Since 2000, Defendants' marketing strategy 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, would result from use of its products.

52. Defendants successfully marketed AndroGel by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent amount 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."

53. Defendants' advertising program sought to create the image and belief by consumers and their physicians 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. The Defendants had no reasonable grounds to believe them to be true.

54. 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.

55. Defendants concealed material relevant information from potential AndroGel users and minimized user and prescriber concern regarding the safety of AndroGel.

56. 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 Defendants adequately tested AndroGel for all likely side effects.

57. 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 Decedent had known the risks and dangers associated with AndroGel, Decedent would not have used AndroGel and consequently would not have been subject to its serious side effects.

SPECIFIC FACTUAL ALLEGATIONS

58. Decedent was approximately 55 years of age when he was prescribed and starting using AndroGel for symptoms he attributed to low testosterone.

59. On or about August 19, 2010, Decedent saw his physician, Dr. Amir Habib. On or about that date, Dr. Habib diagnosed Decedent with hypogonadism and he prescribed AndroGel to treat this condition. Because Defendants did not disclose the true risks of the development of a heart attack, stroke, pulmonary embolism, deep vein thrombosis and death to Dr. Habib, it was impossible for Dr. Habib to adequately discuss the true risks and benefits of AndroGel with Decedent. Consequently, it was impossible for Decedent to learn of the true risks associated with the use of AndroGel.

60. Decedent, after a consultation with Dr. Habib, began using AndroGel on or about August 19, 2010. The AndroGel used by Decedent remained in substantially the same condition between when it left Defendants' control and when it was prescribed to Decedent. Dr. Habib would not have prescribed AndroGel to Decedent if Dr. Habib knew of the true risks associated with the use of AndroGel. In other words, Dr. Habib would not have prescribed AndroGel to Decedent if Dr. Habib knew the true risk of the development of a heart attack, stroke, pulmonary embolism , deep vein thrombosis and death.

61. Decedent would not have elected to use AndroGel if he knew of the true risks associated with the use of AndroGel. In other words, Decedent would not have used AndroGel if he knew the true risk of the development of a heart attack, stroke, pulmonary embolism, vein thrombosis and death.

62. Through no fault of his own, and no fault of his physician, on or about January 20, 2014, Decedent suffered cardiac arrest and died. The cardiac arrest and death of the Decedent caused pain and suffering, financial loss and caused permanent injury to both Decedent and Plaintiff.

63. The AndroGel Decedent used caused physical and emotional impairment, which affected his personal and professional life.

64. Prior to using AndroGel, Decedent had not suffered cardiac arrest.

CAUSES OF ACTION

COUNT I
IND. CODE ANN. § 34-20-1-1
PRODUCT DEFECTIVE DUE TO INADEQUATE WARNING OR INSTRUCTION

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

66. Defendants are manufacturers, as defined by Ann. Code § 34-6-2-77, who designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled and sold AndroGel to consumers.

67. Defendants placed their product, AndroGel, into the stream of commerce.

68. Defendants expected AndroGel to reach, and it did reach consumers, including Decedent, without substantial alteration in the condition in which it was sold.

69. Defendants marketed and promoted AndroGel to consumers, by using direct to consumer advertising, and doctors, by using trained pharmaceutical representatives. Decedent was prescribed AndroGel by his physicians and as such is a person that the Defendants could reasonably foresee as being harmed by AndroGel's defective condition.

70. The drug AndroGel used by Decedent was defective due to inadequate warnings or instructions at the time of marketing when it left Defendants' control, because the following applied:

a. At all times relevant to this action, Defendants knew or reasonably should have known that AndroGel was unreasonably dangerous and defective when used as directed. A reasonable, careful search and review of the scientific evidence and medical literature, and other information, should have indicated to Defendants that AndroGel use is causally related to the development of clotting events, stroke and/or cardiovascular related injuries.

b. At all relevant times to this action, Defendants knew or reasonably should have known that AndroGel was unreasonably dangerous and defective when used as directed.

c. Defendants failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning the risk of injury caused by the use of AndroGel, in light of the likelihood that AndroGel would cause harm claimed by Decedent, and in light of the likely seriousness of that harm.

71. The drug AndroGel used by Decedent was defective due to inadequate post-marketing warnings or instructions because, at all times relevant after AndroGel left control of its manufacturer, both of the following applied:

a. Defendants knew, or in the exercise of reasonable care, should have known that AndroGel, when used as directed, causes heart attacks, strokes, cardiovascular related injuries, and death.

b. Defendants failed to provide post-marketing warnings or instructions that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which Plaintiff seeks to recover damages, and in light of the likely seriousness of that harm.

72. AndroGel was defective due to inadequate warnings or instructions pursuant to when the drug left control of Defendants.

73. The defects described above were the result of Defendants' failures including, but not limited to:

a. Their breach of duty of reasonable care, and failure to comply with existing standards of care, in that they negligently designed,

developed, researched, manufactured, monitored, tested, packaged, promoted, marketed, sold, and/or distributed AndroGel, which they introduced into the stream of commerce as an effective and safe product, which includes a duty to ensure that users would not suffer from unreasonable, dangerous, or untoward adverse side effects;

b. Failure to warn or instruct, and/or adequately warn users, including Decedent, of AndroGel's dangerous and defective characteristics;

c. Failure to adequately and properly design, develop, implement, administer, supervise, and/or monitor clinical trials for AndroGel;

d. Failure to perform appropriate pre-market testing of AndroGel;

e. Failure to perform appropriate post-market surveillance of AndroGel;

f. Failure to adequately and properly test AndroGel before and after placing it on the market;

g. Failure to conduct sufficient testing on AndroGel which, if properly performed, would have shown AndroGel's serious side effects;

h. Failure to adequately warn Decedent and his healthcare providers that the use of AndroGel carried a risk of clotting events, stroke, cardiovascular related injuries, and death;

i. Failure to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with AndroGel use;

j. Failure to adequately and timely inform Decedent and the healthcare industry of the risks of serious personal injury from AndroGel use as described herein; and

k. Failure to conform their representations that the drug was safe for its intended use by promoting AndroGel in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics, due to its propensity to cause clotting events, strokes, and/or cardiovascular related injuries.

74. Decedent relied on the skill and judgment and implied warranty of Defendants that AndroGel was of merchantable quality and safe and fit for the use for which it was intended.

75. Contrary to Defendants' implied warranty, AndroGel was not of merchantable quality and neither safe nor fit for the use for which it was intended in that it had serious risks of harm and dangerous propensities when used as intended, and would instead cause severe injuries to users of AndroGel, including Decedent.

76. The product defects alleged above were a foreseeable and substantial contributing cause of the injuries and damages suffered by Decedent, that would not have occurred but for the use of the product.

77. Decedent used Defendants' AndroGel in the manner for which it was intended and/or in a reasonably foreseeable manner.

78. Decedent was neither aware of, nor could he have reasonably discovered the dangerous side effects of AndroGel.

79. AndroGel was defectively manufactured, distributed, tested, sold, marketed, advertised and misrepresented by Defendants, and together with the defective warnings and labeling, was a foreseeable and substantial factor in bringing about the injuries to Decedent.

80. Had Defendants performed the tests and studies necessary to determine that AndroGel causes clotting events, strokes, cardiovascular related injuries and death, as they were required to do, before Decedent's physicians prescribed AndroGel to him, Decedent would not have suffered cardiac arrest and death and the injuries and damages described with particularity above.

81. Had Defendants properly disclosed the risks associated with AndroGel, Decedent would have avoided the risk of suffering cardiac arrest and death by not using AndroGel at all.

82. As a direct and proximate result of Defendants' failure to warn, Decedent suffered cardiac arrest and death and Plaintiff suffered and will continue to suffer emotional injuries. Plaintiff has endured and will continue to endure pain, suffering, and loss of enjoyment of life, and has suffered and will continue to suffer economic loss.

WHEREFORE, Plaintiff respectfully requests an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to

which she is entitled and such other relief as this Honorable Court deems appropriate.

COUNT II
FRAUD

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

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

85. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceived Decedent, Decedent'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 use, that using AndroGel is hazardous one's to health, and that AndroGel has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Decedent suffered.

86. Defendants concealed and suppressed the true facts concerning AndroGel with the intent to defraud Decedent, in that Defendants knew that Decedent's physicians would not prescribe AndroGel, and Decedent would not have used AndroGel, if they were aware of the true facts concerning its dangers.

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

WHEREFORE, Plaintiff respectfully requests an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled and such other relief as this Honorable Court deems appropriate.

COUNT III
VIOLATION OF INDIANA'S CONSUMER SALES ACT
IND. CODE ANN § 24-5-0.5-1, *ET SEQ.*

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

89. Defendants' sale, marketing, promotion and distribution of AndroGel under the guise that it was a safe and effective product were unfair and/or deceptive acts or practices.

90. Defendants represented that their product was of a particular standard and quality because of its safety and effectiveness. AndroGel is in fact not safe and/or effective making Defendants representations in violation of Ind. Code § 24-5-0.5-3(2).

91. Defendants knew, or should have known that AndroGel was not safe or effective and had side effects, which included the increased risk of heart attacks, strokes, cardiovascular related injuries, and death.

92. Consumers, including Decedent, purchased and used AndroGel based on representations made by Defendants that is was safe and effective.

93. By making false and misleading representations and omissions, Defendants intended that Decedent would rely on its false statements and material omissions and intended to induce Decedent to purchase and use AndroGel.

94. Decedent was induced to purchase and use AndroGel by relying on the statements and representations made by Defendants that were false, misleading, and deceptive because AndroGel is not safe and effective to use.

95. The unfair, false, misleading and deceptive practices of Defendants caused Decedent to incur severe and permanent physical injuries, including but not limited to cardiac arrest and death. Decedent endured and Plaintiff will continue to endure pain, suffering, and loss of enjoyment of life, and has suffered and will continue to suffer economic loss.

96. Because Defendants intentionally, knowingly, and willfully, misrepresented that their product was of a particular standard and quality, Plaintiff is entitled to recover additional damages as provided by CODE ANN § 24-5-0.5-4(a).

97. If Plaintiff prevails in this action, she is entitled to attorneys' fees from Defendants as provided by CODE ANN § 24-5-0.5-4(a).

WHEREFORE, Plaintiff respectfully requests an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled and such other relief as this Honorable Court deems appropriate.

COUNT IV
WRONGFUL DEATH

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

99. As a result of Defendant's negligence, fraud and conduct in breach of the law of strict liability, as averred above, Plaintiff and Decedent have suffered pecuniary and non-pecuniary losses and are entitled to all damages recoverable under the applicable wrongful death statutes.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

PUNITIVE DAMAGES ALLEGATIONS

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

101. 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 Decedent 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 an example of Defendants.

102. Prior to the manufacturing, sale, and distribution of AndroGel, Defendants knew that AndroGel 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 Decedent and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using AndroGel.

103. Despite its knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in AndroGel and failed to warn the public, including Decedent, 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.

104. 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 Decedent, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests an award of punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

PRAYER FOR RELIEF

Plaintiff respectfully requests judgment against Defendants on each of the above counts as follows:

a. Compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries, healthcare costs, and funeral costs together with all interest and costs as provided by the law;

b. Exemplary damages for the wanton, willful, fraudulent, and reckless acts of Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff, in an amount sufficient to punish Defendants and deter future similar conduct;

c. Plaintiff's attorney's fees;

d. Plaintiff's costs of the proceedings; and

e. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

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

Dated: January 20, 2016

Respectfully Submitted,

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JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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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
Mary Alfimow, Individually and as the Representative of the Estate of Valerik E. Alfimow

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Dianne M. Nast, Daniel N. Gallucci, Joanne E. Matusko
NastLaw LLC
1101 Market Street, Suite 2801
Philadelphia, Pennsylvania 19107
Telephone: 215-923-9300

DEFENDANTS
AbbVie Inc., and Abbott Laboratories, Inc.

16 0238

County of Residence of First Listed Defendant Lake County, IL
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PRISONER PETITIONS

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

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

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

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

V. ORIGIN *(Place an "X" in One Box Only)*
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C.A. Section 1332
Brief description of cause:
Healthcare Personal Injury/Product Liability

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.
DEMAND $ more than 150,001
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:
JUDGE Transferred to Judge Matthew F. Kennelly DOCKET NUMBER MDL No. 2545

DATE 01/20/2016
SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

JAN 20 2016

JS

UNITED STATES DISTRICT COURT

16 0238

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 5622 Rambling Drive, Indianapolis, Indiana 46239

Address of Defendant: 1 North Waukegan Road, North Chicago, IL 60064

Place of Accident, Incident or Transaction: Shelbyville, Indiana

(*Use Reverse Side For Additional Space*)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☒

Does this case involve multidistrict litigation possibilities? Yes☒ No☐

RELATED CASE, IF ANY:

Case Number: MDL No. 2545 Judge Matthew F. Kennelly (ND of IL) Date Terminated: ----------

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?
   Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?
   Yes☐ No☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court?
   Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?
   Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases
    (Please specify) _____

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
   (Please specify) _____

ARBITRATION CERTIFICATION

(*Check Appropriate Category*)

I, Daniel N. Gallucci, counsel of record do hereby certify:

☐ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 01/20/2016 _____ Attorney-at-Law

81995 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

JAN 20 2016

DATE: _____ _____ Attorney-at-Law

_____ Attorney I.D.#

CIV. 609 (5/2012)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Mary Alfimow, Individually and as the Representative of the Estate of Valerik E. Alfimow
v.
AbbVie Inc., and Abbott Laboratories, Inc.

CIVIL ACTION
16 0238
NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

01/20/2016		Plaintiff
Date	**Attorney-at-law**	**Attorney for**
215-923-9300	215-923-9302	dgallucci@nastlaw.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

JAN 20 2016