UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Donald Roberts, Plaintiff, v. AbbVie Inc., and Abbott Laboratories, Inc., Defendants.	:	COMPLAINT AND DEMAND FOR JURY TRIAL Case No.

COMPLAINT

Plaintiff Donald Roberts, by and through the undersigned counsel, through his 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, 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 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, and thrombolytic events.

PARTIES

7. Plaintiff Donald Roberts, ("Plaintiff") is a resident of Rochester, New York.

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 is a citizen of Rochester, New York, 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 Plaintiff 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 equitable relief in order to enable Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

16. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff'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 Plaintiff.

18. At all times herein mentioned, Defendants were authorized to do business within the state of New York, where 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.

20. Plaintiff files this lawsuit within the applicable limitations period of first suspecting Defendants' medication caused the appreciable harm sustained by Plaintiff. Plaintiff 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 Plaintiff's injuries were discovered, their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action.

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. 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. 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.

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 and pulmonary embolism.

33. Defendants successfully created a robust and previously nonexistent market for their drug. In 2012, Defendant Abbott Laboratories spent $80 million promoting AndroGel. 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. 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, 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 Plaintiff had known the risks and dangers associated

with AndroGel, Plaintiff would not have used AndroGel and consequently would not have been subject to its serious side effects.

SPECIFIC FACTUAL ALLEGATIONS

58. Plaintiff was approximately 45 years of age when he was prescribed and starting using AndroGel for symptoms he attributed to low testosterone.

59. In or about November 2009, Plaintiff saw his healthcare provider, Gina Fries, PA. On or about that date, Ms. Fries diagnosed Plaintiff with hypogonadism and she 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/or death to Ms. Fries, it was impossible for Ms. Fries to adequately discuss the true risks and benefits of AndroGel with Plaintiff. Consequently, it was impossible for Plaintiff to learn of the true risks associated with the use of AndroGel.

60. Plaintiff, after a consultation with Ms. Fries, began using AndroGel in or about November 2009. The AndroGel used by Plaintiff remained in substantially the same condition between when it left Defendants' control and when it was prescribed to Plaintiff. Ms. Fries would not have prescribed AndroGel to Plaintiff if Ms. Fries knew of the true risks associated with the use of AndroGel. In other words, Ms. Fries would not have prescribed AndroGel to Plaintiff if Ms. Fries knew the true risk of the development of a heart attack, stroke, pulmonary embolism, deep vein thrombosis and/or death.

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

62. Through no fault of his own, and no fault of his healthcare providers, in February 2010, Plaintiff suffered a deep vein thrombosis. The deep vein thrombosis caused pain and suffering, financial loss and caused permanent injury to Plaintiff.

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

64. Prior to using AndroGel, Plaintiff had not suffered a deep vein thrombosis.

CAUSES OF ACTION

COUNT I
MANUFACTURING DEFECT

65. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

66. AndroGel was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce by Defendants.

67. When it left the control of Defendants, AndroGel was expected to, and did reach Plaintiff without substantial change from the condition in which it left Defendants' control.

68. AndroGel was defective when it left Defendants' control and was placed in the stream of commerce, in that there were foreseeable risks that exceeded the benefits of the product and/or that it deviated from product specifications and/or applicable federal requirements, and posed a risk of serious injury and death.

69. Specifically, AndroGel was more likely to cause heart attack, stroke, pulmonary embolism, deep vein thrombosis and/or death than other similar medications.

70. Plaintiff used AndroGel in substantially the same condition as when it left control of Defendants and any changes or modifications were foreseeable by Defendants.

71. Plaintiff and his healthcare providers did not misuse or materially alter the AndroGel he used.

72. As a direct and proximate result of the Plaintiff's use of AndroGel, he suffered serious physical injury, harm, damages and economic loss, and will continue to suffer such harm, damages and economic loss in the future.

73. Defendants are strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling, and placing AndroGel into the stream of commerce, and for all damages caused to Plaintiff by his use of AndroGel because the product was defective.

74. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

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

COUNT II
DESIGN DEFECT

75. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

76. AndroGel was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiff.

77. Defendants placed AndroGel into the stream of commerce with wanton and reckless disregard for the public safety.

78. AndroGel was defective in design in that, when it left Defendants' control, the foreseeable risks of the product exceeded the benefits associated with its design, and it was more dangerous than an ordinary consumer or ordinary healthcare provider would expect.

79. The foreseeable risks associated with AndroGel's design include the fact that its design is more dangerous than a reasonably prudent consumer or

healthcare provider would expect when used in an intended or reasonably foreseeable manner.

80. AndroGel was in an unsafe, defective, and inherently dangerous condition, which was unreasonably dangerous to its users and in particular, Plaintiff.

81. AndroGel was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that AndroGel was defective and unsafe, even when used as instructed.

82. The nature and magnitude of the risk of harm associated with the design of AndroGel, including the risk of suffering a heart attack, stroke, pulmonary embolism, deep vein thrombosis and/or death, is high in light of the intended and reasonably foreseeable use of AndroGel.

83. The risks of harm associated with the design of AndroGel are higher than necessary.

84. It is highly unlikely that AndroGel users would be aware of the risks associated with AndroGel through either warnings, general knowledge or otherwise, and Plaintiff specifically was not aware of these risks.

85. The design did not conform to any applicable public or private product standard that was in effect when AndroGel left the Defendants' control.

86. AndroGel's design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable

manner as testosterone replacement therapy. It was more dangerous than Plaintiff expected.

87. The intended or actual utility of AndroGel is not of such benefit or to justify the risk of heart attack, stroke, pulmonary embolism, deep vein thrombosis and/or death.

88. At the time AndroGel left Defendants' control, it was both technically and economically feasible to have an alternative design that would not cause heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death or an alternative design that would have substantially reduced the risk of these injuries.

89. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

90. The unreasonably dangerous nature of AndroGel caused serious harm to Plaintiff.

91. As a direct and proximate result of the Plaintiff's use of the AndroGel, which was designed, manufactured, marketed, promoted, sold, and introduced into the stream of commerce by Defendants, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

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

COUNT III
FAILURE TO WARN

92. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

93. Defendants had a duty to warn Plaintiff and his healthcare providers of the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death associated with AndroGel.

94. Defendants knew, or in the exercise or reasonable care should have known, about the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

95. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death, in light of the likelihood that its product would cause these injuries.

96. Defendants failed to update warnings based on information received from product surveillance after AndroGel was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

97. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to men using AndroGel after FDA approval.

98. When it left Defendants' control, AndroGel was defective and unreasonably dangerous and Defendants to warn of the risk of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

99. Plaintiff used AndroGel for its approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

100. Plaintiff and Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived their danger because the risks were not open or obvious.

101. Defendants, as the manufacturers and distributors of AndroGel, are held to the level of knowledge of an expert in the field.

102. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

103. The warnings that were given by the Defendants failed to properly warn physicians of the risks associated with AndroGel, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and through his physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

104. Defendants had a continuing duty to warn Plaintiff and his physicians of the dangers associated with its product.

105. Had Plaintiff or his healthcare providers received adequate warnings regarding the risks associated with the use of the AndroGel, Plaintiff would not have used it.

106. As a direct and proximate result of the Plaintiff's use of AndroGel and Plaintiff's reliance on Defendants' representations regarding the character and quality of the product and Defendants' failure to comply with federal requirements,

Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

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

COUNT IV
NEGLIGENCE

107. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

108. Defendants had a duty to exercise reasonable and ordinary care in the design, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of AndroGel into the stream of commerce, including a duty to assure that its product did not pose an undue risk of bodily harm and adverse events, and to properly warn of all risks, and comply with federal requirements.

109. Defendants failed to exercise reasonable and ordinary care in the design, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of AndroGel into the stream of commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers. Specifically, Defendants failed to properly and thoroughly:

a. Test AndroGel before releasing it into the market;

b. Analyze the data resulting from the pre-marketing tests of AndroGel;

c. Conduct sufficient post-market testing and surveillance of AndroGel; and

d. Provide appropriate warnings for consumers and healthcare providers including disclosure of the known or potential risks or true or suspected rates of heart attack, stroke, deep vein thrombosis, pulmonary embolism and/or death.

110. Despite the fact that Defendants knew or should have known that their product posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market AndroGel for use by consumers and continued to fail to comply with federal requirements.

111. 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, including the failure to comply with federal requirements.

112. It was foreseeable that Defendants' product, as designed, would cause serious injury to consumers, including Plaintiff.

113. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

114. Defendants' conduct as described above, including but not limited to their failure to adequately design, test, and manufacture, as well as their continued marketing and distribution of AndroGel when they knew or should have known of the serious health risks it created and the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

115. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, and willful and wonton conduct, which warrants the imposition of punitive damages.

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

COUNT V
BREACH OF EXPRESS WARRANTY

116. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

117. Defendants expressly warranted that AndroGel was a safe and effective product for the treatment of low testosterone, and did not disclose the material risks that AndroGel could cause heart attacks, strokes, deep vein thrombosis, pulmonary embolism and/or death. The representations were not justified by the performance of AndroGel.

118. Members of the consuming public, including consumers such as Plaintiff, and his healthcare providers, were intended third party beneficiaries of the warranty.

119. Plaintiff and his healthcare providers reasonably relied on these express representations.

120. The AndroGel manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to the Plaintiff when used as recommended and directed, and these risks were not disclosed to Plaintiff or his healthcare providers.

121. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

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

COUNT VI
BREACH OF IMPLIED WARRANTY

122. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

123. When Defendants designed, manufactured, marketed, sold, and distributed their AndroGel for use by the Plaintiff, Defendants knew of the use for which it was intended and impliedly warranted the product to be of merchantable

quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

124. Plaintiff and his physicians reasonably relied upon the Defendants' representations of the product's merchantable quality and that it was safe for its intended use, and upon Defendants' implied warranty, including that it was in compliance with all federal requirements.

125. Contrary to such implied warranty, AndroGel was not of merchantable quality or safe for its intended use, because the product was defective, as described herein, and it failed to comply with federal requirements.

126. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

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

COUNT VII
FRAUD

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

128. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed AndroGel, and up to the present, willfully deceived Plaintiff by concealing from him, his physicians and

the general public, the true facts concerning AndroGel, which the Defendants had a duty to disclose.

129. At all 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 a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

130. 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.

131. 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 he is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT VIII
NEGLIGENT MISREPRESENTATION

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

133. 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 the misrepresentation that AndroGel was safe, fit and effective for human use. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale of AndroGel and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of AndroGel.

134. 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, patients and the public, with the intention of inducing reliance and the prescription, purchase and use AndroGel.

135. 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 one's health, and AndroGel has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

136. 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.

137. 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.

138. As a result of the foregoing negligent misrepresentations by Defendants, 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 he is entitled under law and such other relief as this Honorable Court deems appropriate.

PUNITIVE DAMAGES ALLEGATIONS

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

140. 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 an example of Defendants.

141. 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 Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using AndroGel.

142. 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 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.

143. 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 respectfully requests an award of punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to

which he 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, medical monitoring 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 attorneys' fees;

d. Plaintiff's costs of the proceedings; and

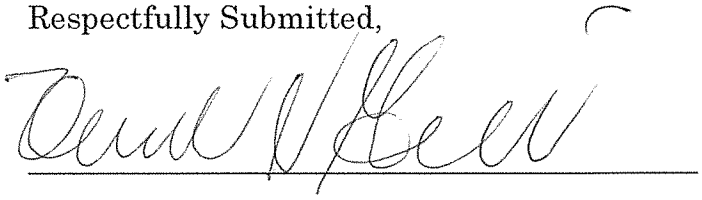
e. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

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

Dated: January 28, 2016

Respectfully Submitted,



Dianne M. Nast (PA Atty. ID No. 24424)
Daniel N. Gallucci (PA Atty. ID No. 81995)
Joanne E. Matusko (PA Atty. ID No. 91059)
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Attorneys for Plaintiff

JS 44 (Rev. 12/12) PBT 16.CV.466

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
Donald Roberts

DEFENDANTS
AbbVie Inc., and Abbott Laboratories, Inc.

16 0466

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

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.

(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

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	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 400 State Reapportionment
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 410 Antitrust
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 430 Banks and Banking
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 450 Commerce
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 840 Trademark	☐ 460 Deportation
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
☐ 196 Franchise				☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	☐ 462 Naturalization Application	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 895 Freedom of Information Act
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions	☐ 871 IRS—Third Party 26 USC 7609	☐ 896 Arbitration
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence			☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General			☐ 950 Constitutionality of State Statutes
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities Employment	☐ 535 Death Penalty			
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities Other	Other:			
	☐ 448 Education	☐ 540 Mandamus & Other			
		☐ 550 Civil Rights			
		☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

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

S.T.

DATE 01/28/2016

SIGNATURE OF ATTORNEY OF RECORD

JAN 28 2016

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

PBT

UNITED STATES DISTRICT COURT

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: 25 Salem Road, Rochester, New York 14622

Address of Defendant: 1 North Waukegan Road, North Chicago, IL 60064 16 0466

Place of Accident, Incident or Transaction: Monroe County, New York
(*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: 1/28/2016 Daniel N. Gallucci 81995
Attorney-at-Law 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.

DATE: _____ _____ JAN 28 2016
Attorney-at-Law Attorney I.D.#

CIV. 609 (5/2012)

PBT

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

CASE MANAGEMENT TRACK DESIGNATION FORM

Donald Roberts	:	CIVIL ACTION
v.	:	16 0466
AbbVie Inc., and Abbott Laboratories, Inc.	:	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. ( )

01/28/2016		Plaintiffs
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 28 2016