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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ROBERT NOLTE and GENIENNE NOLTE, husband and wife, Plaintiffs, vs. ABBVIE INC. and ABBOTT LABORATORIES, INC., Defendants.	**MDL No. 2545** **COMPLAINT AND DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiffs, ROBERT NOLTE and GENIENNE NOLTE (hereinafter "Plaintiffs"), residing in Sierra Vista, Cochise County within the State of Arizona, by and through their undersigned counsel, hereby sue Defendants ABBVIE INC. and ABBOTT LABORATORIES, INC. ("Defendants") and allege as follows:

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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 was a safe and effective treatment for hypogonadism 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 a disease defendants created called "low T", which is Defendants' abbreviated phrase for "low testosterone."

4. According to the industry-leading "Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include "feeling "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, diagnoses of "Low T" have 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. Plaintiffs are citizens of Sierra Vista, Arizona.

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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, Abbot Laboratories, Inc. is a corporation organized and existing under the laws of the state of Illinois and maintains its principal place of business at 100 Abbot Park Road, Abbott Park, Illinois 60064.

10. 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. In 2013, Abbott Laboratories, Inc. created AbbVie, Inc. a company composed of Abbott's former proprietary pharmaceutical business, which included AndroGel.

JURISDICTION AND VENUE

11. The jurisdiction of this Court over the subject matter of this action is predicated on 28 U.S.C. Section §1332. The amount in controversy exceeds $75,000.00, exclusive of interest and costs.

12. Venue of this case is appropriate in the United States District Court for the Northern District of Illinois, pursuant to Judge Matthew F. Kennelly's Order, which permits directly filing into the United States District Court for the Northern District of Illinois, under Case MDL No. 2545, *In re: Testosterone Replacement Therapy Products Liability Litigation.* Plaintiff states that but for the Order permitting directly filing into the district of Illinois, Eastern Division, Plaintiff would have filed in the United States District Court, District of Arizona, Tucson Division. Therefore Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

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GENERAL ALLEGATIONS

13. This action is for damages brought on behalf of Plaintiff, Robert Nolte, who was prescribed and supplied with, received and who has taken and applied the prescription drug AndroGel, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable the Plaintiff, Robert Nolte, to treat and monitor the dangerous, severe, and life-threatening side effects caused by this drug.

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

15. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug AndroGel for the use and application by the consuming public.

16. At all times herein mentioned, Defendants were authorized to do business within Plaintiffs' state of residence.

17. 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 Robert Nolte herein.

18. Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by Plaintiff Robert Nolte.

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Plaintiffs could not, by the exercise of reasonable diligence, have discovered Plaintiff's injuries or losses at an earlier time because the injuries or losses were caused without perceptible trauma or harm, and when the Plaintiff's' injuries or losses were discovered their cause was unknown to Plaintiffs. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, that Plaintiff Robert Nolte 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. Additionally, Plaintiffs were prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug AndroGel is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiffs to discover a potential cause of action.

OVERVIEW

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

20. 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."

21. 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.

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22. Defendants coordinated a massive advertising campaign designed to convince men that they suffered from low testosterone. Defendants orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaign consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential AndroGel users, and online media including the unbranded website "IsItLowT.com."

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

24. 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?”

25. 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 up. Dr. Morely admits that he has “no trouble calling it a crappy questionnaire” and that it is “not ideal.” This is

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the "Low T Quiz" used on the "IsItLowT" website. Natasha Singer, *Selling that New-Man Feeling*, Nov. 23, 2013, N.Y. TIMES.

26. 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.

27. While running their disease awareness campaign, Defendants promoted their product AndroGel as an easy to use topical testosterone replacement therapy. Defendants contrast their product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

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

29. What consumers received, however, were not safe drugs, but a product which causes life-threatening problems, including strokes and heart attacks.

30. Defendants successfully created a robust and previously nonexistent market for their drug. Defendant Abbott Laboratories spent $80 million promoting AndroGel in 2012. The company also spent millions on its unbranded marketing including commercials and its websites, www.IsItLowT.com and www.DriveForFive.com, sites which recommend that men have regular checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

31. Defendants' advertising paid off in a return of $1.4 billion in sales during the past year, making AndroGel the biggest selling androgen drug in the United States. Sales of 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*

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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.

32. 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/.

33. The marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of AndroGel is safe for human use, even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

34. There have been a number of studies indicating that testosterone in men increases the risk of heart attacks and strokes.

35. 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.

36. 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%.

37. 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.

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FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

38. The Food and Drug Administration approved AndroGel 1% on February 28, 2000 for the treatment of adult males who have low or no testosterone and AndroGel 1.62% was approved in April, 2011. After FDA approval, AndroGel was widely advertised and marketed by Defendant as a safe and effective testosterone replacement therapy.

39. AndroGel, is a hydroalcoholic gel containing testosterone in either 1% or 1.62%, applied to the chest, arms or stomach and enters the body through transdermal absorption. The AndroGel 1.62% product also contains isopropyl myristate as an ointment and ethanol for absorption enhancement.

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

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

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

43. 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.

44. AndroGel produces undesirable side effects to patients who use the drug, including but not limited to, myocardial infarction, stroke, and death.

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

46. 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

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the unwashed clothes of someone who applied AndroGel. Patients taking AndroGel may experience enlarged prostates and increased serum prostate-specific antigen levels.

47. 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 with pregnant women who come into secondary contact with AndroGel.

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

49. Defendants successfully marketed AndroGel by undertaking a "disease awareness" marketing campaign. This campaign sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low-T."

50. 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, and even though the Defendants had no reasonable grounds to believe them to be true.

51. 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.

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

53. 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 they adequately tested AndroGel for all likely side effects.

54. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for AndroGel. If Plaintiff in this action had known the risks and dangers associated with AndroGel, the he would not have taken AndroGel and consequently would not have been subject to its serious side effects.

SPECIFIC FACTUAL ALLEGATIONS

55. Plaintiff Robert Nolte was prescribed and used AndroGel from approximately June 2012 to November 2012.

56. Plaintiff viewed Defendants' advertising for AndroGel and decided to use the product after viewing those advertisements.

57. Plaintiff Robert Nolte's consumption of AndroGel caused physical and emotional impairment beginning in or about November 2012, which affected his personal and professional life.

58. As a result of his use of Androgel, Plaintiff Robert Nolte suffered physical and emotional injuries including, but not limited to, pulmonary embolism, which necessitated substantial treatment. As a result, he remained in the hospital for several days.

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

59. Plaintiffs incorporate by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

60. AndroGel was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff,

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(520) 620-3975

Robert Nolte, of the dangerous risks and reactions associated with the subject product, including, but not limited to, its propensity to cause permanent physical injuries including, but not limited to, developing cardiovascular disease, strokes, myocardial infarcts, and other serious injuries, side effects, and even death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for low testosterone. Thus, AndroGel was unreasonably dangerous because an adequate warning was not provided.

61. AndroGel was manufactured and supplied by Defendants and was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Androgel, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury and/or death.

62. Plaintiff Robert Nolte was prescribed and used AndroGel for its intended purpose.

63. Plaintiff Robert Nolte could not have discovered any defect in the subject product through the exercise of reasonable care.

64. Defendants, as manufacturers and/or distributors of the Androgel, are held to the level of knowledge of an expert in the field.

65. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

66. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, heart attack, stroke, thromboembolic events and death.

67. Plaintiff, Robert Nolte, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

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68. Defendants had a continuing duty to warn Plaintiff Robert Nolte of the dangers associated with AndroGel. Had Plaintiff Robert Nolte received adequate warnings regarding the risks of AndroGel, he would not have used it.

69. As a direct and proximate result of Plaintiff Robert Nolte's reasonably anticipated use of AndroGel as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

SECOND CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT

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

71. AndroGel is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or that the foreseeable risks exceed the benefits associated with its design and formulation.

72. At all times material to this action, AndroGel was expected to reach, and did reach, consumers in the State of Arizona and throughout the United States, including Plaintiff Robert Nolte, without substantial change in the condition in which it was sold.

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

a. When placed in the stream of commerce, AndroGel contained unreasonably dangerous design defects and was not reasonably safe for its intended use, subjecting Robert Nolte to risks that exceeded the benefits of the subject product including, but not limited to, permanent personal injuries including, but

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not limited to, developing cardiovascular disease, strokes, myocardial infarctions, and other serious injuries and side effects;

b. When placed in the stream of commerce, AndroGel was defective in design and formulation, making the use of AndroGel more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat low testosterone;

c. The design defects found in AndroGel existed before it left the control of the Defendants;

d. AndroGel was insufficiently and inadequately tested;

e. AndroGel caused harmful side effects in Plaintiff Robert Nolte and the public as a whole that outweighed any potential utility; and

f. AndroGel was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff Robert Nolte, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiffs.

74. In addition, at the time AndroGel left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff Robert Nolte's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff Robert Nolte's injuries without substantially impairing the products' utility.

THIRD CAUSE OF ACTION
NEGLIGENCE

75. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though set forth herein.

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76. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of AndroGel.

77. At all times herein mentioned, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold AndroGel and failed to adequately test and warn of the risks and dangers of AndroGel.

78. Despite the fact that Defendants knew or should have known that AndroGel caused unreasonable, dangerous side effects, Defendants continued to market AndroGel to consumers including Plaintiff, Robert Nolte, when there were safer alternative methods of treating loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions AndroGel's advertising claims are caused by low testosterone.

79. Defendants knew or should have known that consumers such as Plaintiff Robert Nolte would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

80. Defendants' negligence was a proximate cause of Plaintiff Robert Nolte's injuries, harm and economic loss, which Plaintiffs suffered, and will continue to suffer, as described and prayed for herein.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

81. Plaintiffs incorporate by reference here each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

82. Prior to the time that the aforementioned product was used by Plaintiff, Robert Nolte, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that AndroGel was of merchantable quality and safe and fit for the use for which it was intended.

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Tucson, AZ 85705
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83. Plaintiffs were and are unskilled in the research, design and manufacture of the products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using AndroGel.

84. AndroGel was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that AndroGel has dangerous propensities when used as intended and will cause severe injuries to users.

85. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff Robert Nolte suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

86. Plaintiffs incorporate by reference here each of the allegations set forth in this Complaint as though fully set forth here.

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

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

89. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff Robert Nolte suffered injuries and damages as alleged herein.

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Tucson, AZ 85705
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SIXTH CAUSE OF ACTION
FRAUD

90. Plaintiffs incorporate by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

91. 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, Plaintiff's physicians and the general public, the true facts concerning AndroGel, which the Defendants had a duty to disclose.

92. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the 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 Robert Nolte suffered.

93. Defendants concealed and suppressed the true facts concerning AndroGel with the intent to defraud Plaintiffs, in that Defendants knew that Plaintiff Robert Nolte's physicians would not prescribe AndroGel, and Plaintiff Robert Nolte would not have used AndroGel, if they were aware of the true facts concerning its dangers and its lack of efficacy.

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

SEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

95. Plaintiffs incorporate by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

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Tucson, AZ 85705
(520) 620-3975

96. 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 Robert Nolte, his physicians and the general public, including, but not limited to, the misrepresentation that AndroGel was safe, fit and effective for human consumption. At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of AndroGel and willfully deceived Plaintiff Robert Nolte, his physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

97. The Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

98. The representations by the Defendants were in fact false, in that AndroGel is not safe, fit and effective for human consumption. Instead, using AndroGel is hazardous to health, and AndroGel has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff Robert Nolte.

99. 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.

100. In reliance on the misrepresentations made by the Defendants, and each of them, Plaintiff Robert Nolte was induced to purchase and use AndroGel. If Plaintiff Robert Nolte had known of the true facts and the facts concealed by the Defendants, he would not have used AndroGel. His reliance 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.

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Tucson, AZ 85705
(520) 620-3975

101. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff Robert Nolte suffered injuries and damages as alleged herein.

EIGHTH CAUSE OF ACTION
NEGLIGENCE PER SE—VIOLATION OF 21 U.S.C. §§ 331(a) & 352

102. As part of their duty to exercise reasonable care, Defendants were obligated to follow public laws and regulations enacted to protect the safety of persons such as Plaintiff, Robert Nolte, including 21 U.S.C. § 331(a), § 352, and other statutes and regulations, which make it unlawful to sell misbranded prescription drug products.

103. The labeling for AndroGel failed to conform to the requirements of 21 U.S.C. § 352, including subsections (a), (c), and (j), and the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), which prohibits the sale of misbranded drugs.

104. The label and package insert for AndroGel is misbranded within the meaning of 21 U.S.C. § 352(a) and (f) because it was false and misleading and failed to give adequate warnings and directions for use by physicians who prescribe AndroGel.

105. AndroGel is misbranded pursuant to 21 U.S.C. § 352 because:

(a) Words, statements, or other information required under that section are not prominently placed with such conspicuousness and in such ways as to render it likely to be read and understood by the ordinary individual or prescriber under customary conditions of purchase and use.

(b) The labeling does not bear adequate directions for use, and the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage, methods, or application in such manner and form as are necessary for the protection of patients.

(c) It is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

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106. Because Defendants had a statutory duty under 21 U.S.C. § 352 (a) and (f) not to misbrand AndroGel, and because they violated this duty, they are guilty of negligence per se.

107. AndroGel is misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

108. Defendants violated 21 C.F.R. § 201.57 because:

(a) As shown, the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug (i.e., heart attacks, strokes, and other blood clotting injuries).

(b) They failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug AndroGel. The safety considerations regarding AndroGel are such that the drug should be reserved for certain situations, and the Defendants failed to state such information.

(d) The labeling fails to describe serious adverse reactions and potential safety hazards, and steps that should be taken if they occur.

(e) The labeling does not state an upper limit dosing beyond which safety and effectiveness have not been established.

109. AndroGel violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

110. AndroGel violates 21 C.F.R. § 310.303 in that it is not safe and effective for its intended use.

111. Defendants violated 21 C.F.R. § 310.305 and § 314.80 by:

(a) Failing to report adverse events associated with AndroGel as soon as possible or at least within 15 days of the initial receipt by Defendants of the adverse drug experience.

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(b) Failing to conduct an investigation of each adverse event associated with AndroGel, evaluate the cause of the adverse event, submit follow-up reports within the prescribed 15 calendar days of receipt of new information or was requested by the FDA, and keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

(c) Failing to provide periodic reports to the FDA containing (1) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (2) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, (3) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated) and/or (4) a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

112. Defendants violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of AndroGel or otherwise received by Defendants from any sources, including information from any clinical or epidemiological studies, animal studies, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities.

113. Defendants failed to meet the standard of care set out in these statutes and regulations, which were intended for the benefit of individual consumers such as Plaintiff, Robert Nolte, making Defendants liable to Plaintiff. Because each of them violated the duties imposed by these statutes and regulations, they are guilty of negligence per se.

114. As a direct and proximate result of the actions and inactions of Defendants, Plaintiffs suffered damages, including personal injuries, economic damages, and non-economic

damages. Defendants' conduct was further wanton, egregious, and reckless so as to warrant the award of punitive damages.

NINTH CAUSE OF ACTION
LOSS OF CONSORTIUM

115. Plaintiffs incorporate by reference here each of the allegations set forth in this Complaint as though fully set forth herein.

116. Plaintiff, Genienne Nolte, at all times relevant was the lawful wife of Robert Nolte.

117. As a direct, legal, and proximate result of the culpability and fault of Defendants, be such fault through strict liability, negligence or otherwise, Plaintiff Genienne Nolte suffered the loss of support, services, love, companionship, affection, society, intimate relations, and other elements of consortium, all to her general damage in an amount in excess of the jurisdictional minimum of this court.

118. Plaintiffs demand judgment against Defendants for compensatory and punitive damages such as a jury may award, and such other relief as the Court deems just and proper in order to remedy Plaintiff Genienne Nolte's loss of consortium.

TENTH CAUSE OF ACTION
PUNITIVE DAMAGES ALLEGATIONS

119. Plaintiffs incorporate by reference here each of the allegations set forth in this Complaint as though fully set forth herein.

120. 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 Robert Nolte 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

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punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

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

122. Despite its knowledge, Defendants, acting through its 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 Plaintiffs, 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.

123. 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, Robert Nolte, entitling Plaintiff to exemplary damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiffs:

A. General damages in an amount that will conform to proof at time of trial;

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B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;

C. Medical expenses, past and future, according to proof at the time of trial;

D. For past and future mental and emotional distress, according to proof;

E. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

F. For punitive or exemplary damages according to proof on the First, Second, Third, Sixth, Seventh, and Eighth causes of action;

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

H. Injunctive relief;

I. Attorney's fees;

J. For costs of suit incurred herein;

K. For pre-judgment interest as provided by law;

L. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

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

Respectfully submitted this 17th day of September, 2014.

GOLDBERG & OSBORNE

/s/ David J. Diamond
David J. Diamond
D. Greg Sakall
Attorneys for Plaintiffs

I hereby certify that on the 17th day of Ocotber, 2014, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing.

/s/ Kathy Hampton

JS 44 (Rev. 3/13)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Robert Nolte and Genienne Nolte

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

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

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Tucson, AZ 85701
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DEFENDANTS

Abbvie, Inc. and Abbott Laboratories, Inc.

County of Residence of First Listed Defendant Out of District
(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	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 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
					☐ 893 Environmental Matters
					☐ 895 Freedom of Information Act
					☐ 896 Arbitration
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	☐ 510 Motions to Vacate Sentence	☐ 462 Naturalization Application	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 950 Constitutionality of State Statutes
☐ 220 Foreclosure	☐ 441 Voting	**Habeas Corpus:**	☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)	☐ 871 IRS—Third Party 26 USC 7609	
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 530 General	☐ 465 Other Immigration Actions		
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 535 Death Penalty			
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities Employment	☐ 540 Mandamus & Other			
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities Other	☐ 550 Civil Rights			
	☐ 448 Education	☐ 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

(Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

28 U.S.C. § 1332 pip (28 USC 1332 diversity, personal injury, product liability)

VII. Previous Bankruptcy Matters

(For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.

VIII. REQUESTED IN COMPLAINT:

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

DEMAND $ $75,000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☑ Yes ☐ No

IX. RELATED CASE(S) IF ANY

(See instructions): JUDGE Matthew Kennelly DOCKET NUMBER 14 CV 1748

X. This case (check one box) ☑ **Is not a refiling of a previously dismissed action** ☐ is a refiling of case number _____ previously dismissed by Judge _____

DATE 10/17/14

SIGNATURE OF ATTORNEY OF RECORD /s/ David J. Diamond

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity cases.)

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

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

V. Origin. Place an "X" in one of the six boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

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

VII. Previous Bankruptcy Matters For nature of suit 422 and 423 enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this court. Use a separate attachment if necessary.

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

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

X. Refiling Information. Place an "X" in one of the two boxes indicating if the case is or is not a refilling of a previously dismissed action. If it is a refiling of a previously dismissed action, insert the case number and judge.

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

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D. Greg Sakall, Esq.
gsakall@goldbergandosborne.com
Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ROBERT NOLTE and GENIENNE NOLTE, husband and wife, Plaintiffs, vs. ABBVIE INC. and ABBOTT LABORATORIES, INC., Defendants.	**MDL No. 2545** **DEMAND FOR JURY TRIAL**

Pursuant to Rule 38(b), Fed. R. Civ. P., Plaintiffs hereby demand a jury trial on all claims.

Respectfully submitted this 17th day of September, 2014.

GOLDBERG & OSBORNE

/s/ David J. Diamond
David J. Diamond
D. Greg Sakall
Attorneys for Plaintiffs

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