

Carmen S. Scott  
Motley Rice, LLC  
28 Bridgeside Blvd.  
Mt. Pleasant, SC 29464  
(843) 216-9160 telephone  
(843) 216-9430 facsimile

*Attorneys for Plaintiff*

**THE UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**DOROTHY H. BOZUE AND JOHN J.  
BOZUE, SR.,**

Plaintiffs,

v.

**MERCK, SHARP & DOHME, CORP.,  
and WARNER CHILCOTT (US), INC.,**

Defendants.

MDL Docket No. 2243

CHIEF JUDGE JOEL A. PISANO

Civil Action No. \_\_\_\_\_

COMPLAINT WITH JURY DEMAND

**COMPLAINT**

COMES NOW Plaintiffs, DOROTHY H. BOZUE and JOHN J. BOZUE, SR., and for causes of action against MERCK SHARP & DOHME, CORP., f/k/a Merck & Co., Inc. ("MERCK"), and WARNER CHILCOTT (US), INC., (hereinafter "Warner"), ("Merck and "Warner" are collectively known as "Defendants") upon information and belief, allege as follows:

**I. INTRODUCTION**

1. This an action for personal injury, statutory, compensatory, and punitive damages due to Plaintiff as a result of Defendants' concealment of risks associated with their drugs FOSAMAX and ACTONEL and Defendants' over promotion of the drugs for non-approved, or

"off-label," indications.

## **II. JURISDICTION AND VENUE**

2. Venue is proper within this district pursuant to Case Management Order No. 4, filed July 13, 2011, signed by Garrett E. Brown, Jr., allowing Fosamax-related cases to be filed directly into the District Court of New Jersey.

3. Jurisdiction in this action is based upon diversity of citizenship, 28 U.S.C. Section 1332 (a), and that damages exceed, exclusive of interest and costs, the sum of Seventy-five Thousand (\$75,000.00) Dollars.

4. Venue lies in the District of New Jersey as Merck's headquarters and principal place of business are located in this District.

## **III. PARTIES**

5. Plaintiffs, Dorothy H. Bozue (hereinafter "Plaintiff") and John J. Bozue, Sr. are wife and husband, and are citizens of the State of Illinois. Plaintiff was prescribed FOSAMAX and ACTONEL for the treatment and/or prevention of osteoporosis or osteopenia, and ingested Actonel from June 2001 through December 2001 and Fosamax from December 2001 through March 2012.

6. Defendant, Merck Sharp & Dohme, Corp., (hereinafter "Merck") is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business located at One Merck Drive, Whitehouse Station, NJ 08889.

7. Defendants, Warner Chilcott (US), Inc., (hereinafter "Warner") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of

business located at 100 Enterprise Drive, Suite 280, Rockaway, NJ 07866.

8. Defendant Merck was at all relevant times authorized to and regularly conducted business in the State of New Jersey and continues to do so.

9. Defendant Warner was at all relevant times authorized to and regularly conducted business in the State of New Jersey and continues to do so.

10. At all relevant times, Defendant Merck, through its agents, servants, employees and apparent agents was the designer, manufacturer, labeler, promoter, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to prevent, mitigate or reverse the effects of osteoporosis and Paget's Disease.

11. At all relevant times, Defendant Warner, through its agents, servants, employees and apparent agent was the designer, manufacturer, labeler, promoter, marketer, distributor and seller of ACTONEL, a bisphosphonate drug used primarily to prevent, mitigate or reverse the effects of osteoporosis.

12. Defendants, either directly or through its agents, apparent agents, servants or employees, at all relevant times, distributed and sold their products in the State of New Jersey.

13. Defendants derive substantial revenue from pharmaceutical products used or consumed in the State of New Jersey.

14. Defendants expected, or should have expected, that its business activities could or would have consequences within the State of New Jersey.

15. Various generic manufacturers, including the manufacturer of a generic product used by Plaintiff, marketed and sold their product with the accompanying product and label created and provided by Merck which failed to include adequate warnings about the risk of severely suppressed bone turnover and the risk of atypical femur fractures after long-term use of bisphosphonates.

16. Defendants placed their bisphosphonate products into the stream of worldwide commerce and interstate commerce in the United States. They did so without adequate testing and with no warning that the drug carried with it a risk of severely suppressed bone turnover, resulting stress fractures, or low energy femoral fractures. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product. They also did so without adequate instructions regarding the appropriate duration of use of their products.

#### **IV. SUMMARY OF THE CASE**

17. Defendants, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX and ACTONEL for the treatment and prevention of osteoporosis, Paget's Disease, and other uses.

18. As a result of the defective nature of these drugs, persons who were prescribed and ingested FOSAMAX and ACTONEL for several years, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including weakened or

brittle bones, multiple stress fractures, and low energy femoral fractures as a result of severely suppressed bone turnover caused by long-term bisphosphonate use.

19. Defendants concealed and continue to conceal its knowledge of FOSAMAX and ACTONEL'S lack of long-term benefit and unreasonably dangerous risks from Plaintiff, her physicians, other consumers, and the medical community.

20. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the well-established risks of long-term FOSAMAX and ACTONEL use including severely suppressed bone turnover and low energy femoral fractures.

21. Defendants failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX and ACTONEL after they began marketing, advertising, distributing, and selling their drugs.

22. As a result of Defendants' actions and inaction, Plaintiff was injured due to her ingestion of these drugs, which has caused and will continue to cause her various injuries and damages. Plaintiff accordingly seeks compensatory damages, statutory damages, and punitive damages to the extent allowed under New Jersey law.

## **V. FACTUAL BACKGROUND**

23. At all relevant times Defendant, MERCK was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX. Likewise, Warner Defendants were responsible for Actonel.

24. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendant Merck as FOSAMAX.

25. In March 1998, the United States Food and Drug Administration ("FDA") approved Defendant Warner's compound risedronate sodium, which is marketed by Defendant Warner as ACTONEL, for various uses, including the treatment of osteoporosis.

26. FOSAMAX and ACTONEL fall within a class of drugs known as bisphosphonates. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for the treatment of noncancerous conditions such as osteoporosis.

27. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-Ncontaining (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonate include the following: paxnidronate (Aredia); ibandronate (Boniva); risedronate (ACTONEL) and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom.

28. FOSAMAX and ACTONEL work by inhibiting bone resorption and suppressing bone turnover. Bone mineralization occurs in two phases. Primary mineralization occurs while new bone is forming. Because FOSAMAX and ACTONEL severely suppress bone turnover, bone remodeling and primary mineralization are inhibited. Secondary mineralization of existing bone however, continues to occur. This results in an increase in the tissue mineral

content of the bone which translates to an increase in bone mineral density (BMD). Increased BMD does not necessarily correspond with reduction of fracture risk. Additionally, through the bisphosphonate mechanism of action, bone becomes highly mineralized, homogenous, brittle, and more susceptible to fracture.

29. Prior to the introduction of FOSAMAX and ACTONEL, the diagnosis of osteoporosis included clinical criteria such as prior bone fracture. Through the use of the 1990's advent of BMD-based diagnosis for osteoporosis, the number of women diagnosed with osteoporosis skyrocketed. The BMD diagnostic criteria for osteoporosis has not been proven to correspond to those women who are most at risk for fracture. Upon information and belief, due to the widespread overprescription of anti-osteoporosis medications, including FOSAMAX and ACTONEL, the World Health Organization is currently investigating the prudence of the using the arbitrary standard-deviation system for the BMD-based diagnosis of osteoporosis.

30. As medical researchers have concluded: "The use of surrogate endpoints such as BMD to predict fracture reduction risk should be approached with caution, as the relationship between BMD changes and fracture risk reduction with antiresorptive therapies is uncertain." Marcus, R., et al., *Anti-Resorptive Treatment of Post-Menopausal Osteoporosis: Comparison of Study Designs and Outcomes in Large Clinical Trials with Fracture as an Endpoint*, 23 *Endocrine Rvws.* 16-37 (2002).

31. Numerous studies have confirmed that the effects of these drugs on bone continue for years after treatment is discontinued. One study showed that bone turnover was still inhibited by more than 50% 5 years after the discontinuation of FOSAMAX therapy. Strewler,

G., *Decimal Point- Osteoporosis at the 10-Year Mark*, 350 N. Engl. J. Med. 1172 (2004). Merck's own studies reveal that FOSAMAX has a half-life in bone of greater than ten years.

32. Defendants knew or should have known that by inhibiting bone turnover while at the same time allowing the secondary mineralization of old bone to continue, long term bisphosphonate therapy would result in bones becoming highly mineralized, brittle and more susceptible to fracture. This is especially true given the fact that the effects of bisphosphonate on the bone accumulate and continue for years after treatment is discontinued.

33. Defendants promoted their drugs as effective treatments for osteoporosis that significantly reduced the risk of fracture in post-menopausal women.

34. Medical researchers in the January 19, 2008, issue of the *British Medical Journal* revealed the manner in which bisphosphonates are presented to reduce fracture risk for those women who actually do have osteoporosis tends to exaggerate the actual fracture reduction benefit conferred. According to the authors, published clinical trials exaggerated the fracture-reduction benefits through the use of relative risk rather than in terms of absolute risk. As the authors state: "Impressive sounding reductions in relative risk can mask much smaller reductions in absolute risk." By using the math of "relative risk" rather than "absolute risk", the purported benefits of the drugs appear larger than they actually are in the general population. As a result, billions of dollars are being spent on a drug that has questionable utility for the ultimate goal of fracture reduction.

35. Correspondingly, when examined in a clinical setting, later observational studies revealed that the FIT study exaggerated the benefit derived from alendronate therapy in reducing the risk of fracture. The 2006 ICARO study concluded that the incidence of fractures



during treatment with antiresorptive agents, including FOSAMAX, in a clinical setting is considerably higher than that observed in randomized clinical trials, especially when therapy was not supplemented with calcium and vitamin D. Silvano et al., *Fracture Incidence and Characterization in Patients on Osteoporosis Treatment: The ICARO Study*, 21 J. Bone and Mineral Research 1565 (2006).

36. Long term studies of the effects of bisphosphonate therapy revealed that the benefits of remaining on Fosamax for longer than 5 years were limited. One study, known as the FLEX study, concluded that while women who discontinued bisphosphonates after 5 years of therapy experienced a moderate decline in BMD, their BMD remained above baseline and they did not experience a significant increase in the number of actual fractures when compared to women who continued bisphosphonate therapy for more than 5 years. Black et al., *Effects of Continuing or Stopping Alendronate After 5 Years of Treatment*, 296 JAMA 2927 (2006). The results of this study suggested that continuing bisphosphonate therapy for more than 5 years likely does not benefit the majority of women taking the drug. It was also observed in this study that during the later years of the study, the non-vertebral fracture rate of women on alendronate appeared to be the same or higher than during the first three years of alendronate therapy, despite higher bone mineral density levels.

37. Defendants have been aware of sound scientific and medical evidence that safer alternative therapies, such as vitamin D and calcium supplements, effectively reduce the risk of non-vertebral fractures without the harmful side effects that can result from long-term bisphosphonate use. For example, results of a three year study of the effect of calcium and vitamin D supplementation on bone density showed that women taking calcium and vitamin D supplements had significantly less total body bone loss and substantially fewer fractures

compared to women in the placebo group. Hughes et al., *Effects of Calcium and Vitamin D Supplementation on Bone Density in Men and Women 65 Years of Age or Older*, 337 N. Engl. J. Med. 670 (1997).

38. Despite evidence of the positive effects of vitamin D and calcium on bone health and fracture risk, along with evidence of reduced efficacy of bisphosphonates when not supplemented with vitamin D and calcium, Defendants have never done a head-to-head comparative study of treatment with bisphosphonates alone versus treatment with vitamin D and calcium alone.

39. Rather than evaluating and verifying the safety of long-term bisphosphonate use with respect to bone strength and stress fractures, Defendant Merck proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

40. Despite the wealth of information available suggesting problems with long-term use of bisphosphonates, Defendant Warner has failed to enter a study related to long-term femur fracture risk associated with its drug.

41. Over the last few years, there have been an increasing number of reports of patients suffering multiple stress fractures and low energy femoral fractures as a result of severely suppressed bone turnover caused by long-term bisphosphonate use. Severely suppressed bone turnover from long-term bisphosphonate use has also been well recognized in medical literature.

42. There is also evidence from at least one animal study that the severe suppression of bone turnover and bone remodeling that occurs with alendronate therapy, can result in the accumulation of microdamage in bone as well as a reduction in some of the biomechanical properties of bone. Mashiba et al., *Suppressed Bone Turnover by Bisphosphonates Increases Microdamage Accumulation and Reduces Some Biomechanical Properties in Dog Rib*, 15 J. Bone and Mineral Research 613 (2000). These findings were further reflected in human studies: "Our findings raise the possibility that severe suppression of bone turnover may develop during long-term alendronate therapy, resulting in increased susceptibility to, and delayed healing of, nonspinal fractures." Odvina, Clarita V., et al., *Severely Suppressed Bone Turnover: A Potential Complication of Alendronate Therapy*, 90 J. Clin. Endocrinol. Metab. 1294-1301 (2005).

43. On January 7, 2008, the FDA issued a medical advisory warning doctors and patients of the "possibility of severe and sometimes incapacitating bone, joint, and/or muscle pain," and advising physicians to discontinue prescribing bisphosphonates if such complaints occurred during therapy. One week later, the January 15, 2008, *Journal of Rheumatology* published an article concluding that Fosamax patients have a 287% higher chance of developing osteonecrosis (jaw, hip, and knee) than those not taking the drug.

44. Despite its knowledge of this dangerous side effect that can result from long-term bisphosphonate use, Defendants refused to warn patients, physicians and the medical community about the risk of severely suppressed bone turnover.

45. Consumers who have used bisphosphonates for treatment of osteoporosis, have several alternative safer products available to treat the conditions and have not been adequately

warned about the significant risks and lack of benefits associated with long-term bisphosphonate therapy.

46. Defendants knew of the significant risk of severely suppressed bone turnover, brittle bones, multiple stress fractures and low energy femoral fractures that could result from long-term bisphosphonate use, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff, her physician or the medical community, of such risks.

47. As a direct result, Plaintiff was prescribed FOSAMAX and ACTONEL for the treatment and/or prevention of osteoporosis or osteopenia, and has been permanently and severely injured, having suffered serious consequences from long-term use. Plaintiff requires, and will in the future require ongoing medical care and treatment as a result of her injuries.

48. Plaintiff has suffered from mental anguish from the knowledge that she will have life-long complications as a result of the injuries she sustained from the use of bisphosphonates.

49. Plaintiff used Actonel as prescribed and in a foreseeable manner consistently from June 2001 through December 2001; and Fosamax as prescribed and in a foreseeable manner consistently from December 2001 through March 2012.

50. As a direct and proximate result of her long-term bisphosphonate use, Plaintiff suffered severely suppressed bone turnover and sustained a severe femur fracture.

51. Plaintiff, as a direct and proximate result of long-term bisphosphonate use, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

52. Plaintiff used FOSAMAX and ACTONEL which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

53. Plaintiff would not have used and her physician likely would never have prescribed FOSAMAX and ACTONEL for so many years had Defendants properly disclosed the risks associated with its long-term use.

54. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with long-term FOSAMAX and ACTONEL use. The running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

55. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

## **COUNTS**

### **COUNT I: PRODUCTS LIABILITY - DEFECTIVE DESIGN** (N.J. Products Liability Act-N.J.S.A. 2A:58C-1 et seq.)

56. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

57. Defendants researched, developed, manufactured, sold, distributed, marketed, promoted and/or supplied THE DRUGS, which were defective and unreasonably dangerous, to consumers.

58. Defendants researched, developed, manufactured, sold, distributed, marketed, promoted and/or supplied THE DRUGS which were expected to reach and did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

59. Plaintiff used THE DRUGS as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendants.

60. THE DRUGS failed to perform safely when used by ordinary consumers, including Plaintiff, even when used in its intended or a reasonably foreseeable manner.

61. THE DRUGS were defective in their design and were unreasonably dangerous in that their foreseeable risks exceeded the benefits associated with its design or formulation. They are also defective in design or formulation in that they lack efficacy and/or it poses a greater likelihood of injury than other treatments for osteoporosis, osteopenia, or Paget's Disease.

62. Alternatively, THE DRUGS were defective in design or formulation in that their use posed a greater likelihood of injury than other available medications and were more dangerous than an ordinary consumer could reasonably foresee. In essence, a design posing less likelihood of injury was available with a superior mechanism of action and pharmacological design.

63. Although Defendants knew, or should have known, of the defective nature of THE DRUGS, they continued to design, manufacture, market and sell THE DRUGS so as to

maximize sales and profits at the expense of the public health and safety, in knowing, conscious and deliberate disregard of the foreseeable harm caused by THE DRUGS.

64. Plaintiff could not, through the exercise of reasonable care, have discovered THE DRUGS' defects or perceived the danger of THE DRUGS.

65. As a direct and proximate result of Defendants' failure to adequately warn or other acts and omissions of Defendants described herein, Plaintiff developed severe and permanent injuries, including severely suppressed bone turnover and a severe femur fracture, pain and mental anguish, including diminished enjoyment of life, and fear of developing other harmful conditions, including, but not limited to additional fractures resulting from severely suppressed bone turnover caused by long-term use of THE DRUGS.

66. In addition, Defendants aforementioned conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life, and the rights and safety of consumers including Plaintiff.

**COUNT II: PRODUCTS LIABILITY-FAILURE TO WARN**  
(N.J. Products Liability Act-N.J.S.A. 2A:58C-1)

67. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

68. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released the drugs into the stream of commerce, and in the course of same, directly advertised or marketed the product to

consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of THE DRUGS.

69. THE DRUGS were under the exclusive control of Defendants and were unaccompanied by appropriate warnings regarding the risk of severely suppressed bone turnover, resulting stress fractures, or low energy femoral fractures and other severe and permanent injuries associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendant further diluted or minimized the warnings given with the product.

70. Defendants downplayed the serious and dangerous side effects of THE DRUGS to encourage sales of the product; consequently, Defendants placed their profits above its customers' safety.

71. THE DRUGS were defective and unreasonably dangerous when they left the possession of Defendants in that they contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with them, including, but not limited to severely suppressed bone turnover, multiple stress fractures, and low energy femoral fractures. Even though Defendants knew or should have known of the risks and reactions associated with THE DRUGS, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

72. Plaintiff used THE DRUGS as intended or in a reasonably foreseeable manner.

73. Plaintiff could not have discovered any defect in THE DRUGS through the exercise of reasonable care.



74. Defendants, as a manufacturer of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of THE DRUGS.

75. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to her physicians.

76. Defendants had a continuing duty to warn consumers, including Plaintiff and her physicians, and the medical community of the dangers associated with THE DRUGS, and by negligently and/or wantonly failing to adequately warn of the dangers associated with their use, Defendants breached their duty.

77. Although Defendants knew, or were reckless in not knowing, of the defective nature of THE DRUGS, they continued to design, manufacture, market, and sell THE DRUGS without providing adequate warnings and instructions concerning the use of THE DRUGS so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by THE DRUGS.

78. Defendants deliberately concealed and/or intentionally withheld knowledge of harmful side effects from Plaintiff and her physicians, and the medical community. By so acting, Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by THE DRUGS

79. Although Defendants knew or should have known of the defective nature of THE DRUGS at the time Plaintiff consumed THE DRUGS, Defendants manipulated the post-market regulatory process so as to maximize sales and profits at the expense of the public

health and safety. By so acting, Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by THE DRUGS.

80. As a direct and proximate result of Defendants' failure to adequately warn, or other acts and omissions of Defendants described herein, Plaintiff developed severe and permanent injuries, including severely suppressed bone turnover and a severe femur fracture, pain and mental anguish, including diminished enjoyment of life, and fear of developing other harmful conditions, including, but not limited to additional fractures resulting from severely suppressed bone turnover caused by long-term use of THE DRUGS.

81. In addition, Defendants' conduct in the packaging, warning, marketing, advertising, promotion, distribution, and sale of THE DRUGS was committed with knowing, conscious, willful, wanton, and deliberate disregard for the value of human life, and the rights and safety of consumers including Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for any and all damages, (including, but not limited to severe physical pain and suffering; mental anguish; severe anxiety; loss of life's pleasures; loss of enjoyment of life; and loss of future earning capacity, future earnings and income), together with interest, cost of suit and counsel fees.

### COUNT III: NEGLIGENCE

82. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

83. Defendants owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling THE DRUGS.

84. Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

- a. failing to properly and thoroughly test THE DRUGS before releasing them to market;
- b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of THE DRUGS;
- c. failing to conduct sufficient post-market testing and surveillance of THE DRUGS;
- d. designing, manufacturing, marketing, advertising, distributing, and selling THE DRUGS to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of THE DRUGS, and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drugs;
- e. failing to exercise due care when advertising and promoting THE DRUGS; and
- f. negligently continuing to manufacture, market, advertise, and distribute THE DRUGS after Defendants knew or should have known of their adverse effects.

85. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severely suppressed bone turnover and a severe femur fracture as a result. In addition, she required and will continue to require healthcare and services, and has incurred and will continue to incur medical and related expenses as a result of her injuries. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death,

aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

86. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment for damages against Defendants, costs of this action, and further demands a trial by jury of all issues so triable, and for such other and further relief as this Court deems just and proper.

#### COUNT IV: STRICT LIABILITY

87. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

88. Defendants manufactured, sold, distributed, marketed, and/or supplied THE DRUGS in a defective and unreasonably dangerous condition to consumers.

89. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted THE DRUGS, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

90. Plaintiff used THE DRUGS as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendants.

91. THE DRUGS failed to perform safely when used by ordinary consumers, including Plaintiff, including when they was used as intended and in a reasonably foreseeable manner.

92. THE DRUGS were defective in their design and were unreasonably dangerous in that their unforeseeable risks exceeded the benefits associated with their design or formulation.

93. THE DRUGS were defective in design or formulation in that they posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

94. THE DRUGS were defective in their design and were unreasonably dangerous in that they neither bore nor were packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of severely suppressed bone turnover, brittle bones, stress fractures, or low energy femoral fractures.

95. Although Defendants knew or should have known of the defective nature of THE DRUGS, they continued to design, manufacture, market, and sell THE DRUGS so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by THE DRUGS.

96. Neither Plaintiff nor her prescribing physician could not, through the exercise of reasonable care, have discovered THE DRUGS' defects or perceived the dangers posed by the drugs.

97. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severely suppressed bone turnover and severe femur fractures as a result. In addition, she required and will continue to require healthcare and services and plaintiff has incurred and will continue to incur medical and related expenses as a result of her injuries. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. She has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

98. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendants and deter they from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment for damages against Defendants, costs of this action, and further demands a trial by jury of all issues so triable, and for such other and further relief as this Court deems just and proper.

COUNT V: BREACH OF EXPRESS WARRANTY

99. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

100. Defendants expressly represented to Plaintiff, her physician, other consumers and the medical community that THE DRUGS were safe and fit for their intended purposes, that they were of merchantable quality, that they did not produce any dangerous side effects, and that they were adequately tested.

101. Defendants marketed THE DRUGS as being effective for the treatment and prevention of osteoporosis and the prevention of fractures in women with osteoporosis or osteopenia.

102. THE DRUGS do not conform to Defendants' express representations because they are not safe, have numerous and serious side effects, and cause severe and permanent injuries, including but not limited to severely suppressed bone turnover, brittle bones and low energy femoral fractures.

103. At all relevant times THE DRUGS did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

104. Plaintiff, her physician, other consumers, and the medical community relied upon Defendants' express warranties.

105. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severely suppressed bone turnover and severe femur fractures as a result. In addition, she required and will continue to require healthcare and services and has incurred and will continue to incur medical and related expenses as a result of her injuries. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of

preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

106. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling her to punitive damages as to punish Defendants and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment for damages against Defendants, costs of this action, and further demands a trial by jury of all issues so triable, and for such other and further relief as this Court deems just and proper.

#### COUNT VI: BREACH OF IMPLIED WARRANTY

107. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

108. Defendants manufactured, distributed, advertised, promoted, and sold THE DRUGS.

109. At all relevant times, Defendants knew of the use for which THE DRUGS were intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

110. Defendants were aware that consumers, including Plaintiff, would use THE DRUGS for treatment and prevention of osteoporosis and for other purposes.



111. Plaintiff, her physician, and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell THE DRUGS only if it was indeed of merchantable quality and safe and fit for its intended use.

112. Defendants breached their implied warranty to consumers, including Plaintiff; THE DRUGS were not of merchantable quality or safe and fit for their intended use.

113. Consumers, including Plaintiff, her physician and the medical community, reasonably relied upon Defendants' implied warranty for THE DRUGS.

114. THE DRUGS reached consumers without substantial change in the condition in which they were manufactured and sold by Defendants.

115. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severely suppressed bone turnover and severe femur fractures as a result. In addition, Plaintiff required and will continue to require healthcare and services and plaintiff has incurred and will continue to incur medical and related expenses as a result of her injuries. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

116. Defendants' conduct, as described above, was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendants and deter it from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment for damages against Defendants, costs of this action, and further demands a trial by jury of all issues so triable, and for such other and further relief as this Court deems just and proper.

COUNT VII: FRAUDULENT MISREPRESENTATION

117. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

118. Defendants made fraudulent misrepresentations with respect to THE DRUGS in the following particulars:

- a. Defendants represented through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that THE DRUGS have been tested and found to be safe and effective for the treatment and prevention of osteoporosis and Paget's disease;
- b. Defendants represented that THE DRUGS were safer than other alternative medications; and
- c. Defendants represented that THE DRUGS were a pill which would prevent rather than induce osteoporotic fractures.

119. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of THE DRUGS to consumers, including Plaintiff, her physician and the medical community.

120. The representations were made by Defendants with the intent that doctors and patients, including Plaintiff and her physician, rely upon them.

121. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, her physician, other consumers, and the medical community to induce and encourage the sale of THE DRUGS.

122. Plaintiff, her physicians and others relied upon the representations.

123. Defendants' fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

124. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered severely suppressed bone turnover and severe femur fractures as a result. In addition, Plaintiff required and will continue to require healthcare and services and plaintiff has incurred and will continue to incur medical and related expenses as a result of her injuries. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

125. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of

consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demand judgment for damages against Defendants, costs of this action, and further demands a trial by jury of all issues so triable, and for such other and further relief as this Court deems just and proper.

COUNT VIII: INNOVATOR LIABILITY

126. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth and further alleges as follows:

127. Alendronate Sodium is the active ingredient in FOSAMAX, for which Defendant Merck held the patent to the formulation of the drug until 2008.

128. Beginning in or around February 2008, various generic manufacturers began manufacturing, marketing, distributing, selling and supplying Alendronate Sodium for use by consumers.

129. The label accompanying the Alendronate manufactured, marketed, distributed and sold by the generic manufacturers was created by Merck as the innovator of FOSAMAX and, in accordance with FDA regulations, provided to generic manufacturers for distribution with their Alendronate product.

130. Defendant Merck was and is responsible for the design of and language contained within its FOSAMAX label, which was absent any language related to atypical femur fractures associated with long-term use.

131. As all generic Alendronate Sodium manufacturers' product information and labels are identical to the information and label accompanying Defendant Merck's FOSAMAX, Merck is responsible and/or liable for the representations, omissions, and

misrepresentations contained in any generic manufacturer's product information and label.

132. Plaintiff reasonably relied upon the content of the product information and label of each product, for which Merck was responsible, in ingesting the bisphosphonates and thereafter suffered a serious injury.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorney's fees and such other relief as the Court deems appropriate pursuant to the common law and statutory law.

#### COUNT IX: PUNITIVE DAMAGES

133. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

134. Upon information and belief, Defendants have marketed their drugs in an unacceptable manner and not in accordance with FDA regulations.

135. In fact, Defendant Merck has been repeatedly admonished by the FDA for overstating the superiority in reducing fractures, making misleading comments about menopause as a cause of osteoporosis, and overstating the risks and minimizing the benefits of FOSAMAX in its communications to consumers and physicians.

136. In addition to the above, Defendants have repeatedly avoided FDA recommendations as to which warnings relating to public hazards should be included in materials. Defendants have engaged in other similar incidents with other drugs it sells as evidence of a pattern and practice of overstating risks and minimizing benefits.

137. Defendants' acts were willful and malicious in that Defendant's conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

#### COUNT X: LOSS OF CONSORTIUM

138. Plaintiffs repeat and incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

139. Plaintiff, John J. Bozue, Sr., has been at all time relevant to this Complaint, and still is, the husband of Plaintiff, residing together as husband and wife.

140. As a result of the injuries suffered by his wife as aforesaid, Plaintiff, John J. Bozue, Sr., has and will in the future suffer the loss of the usual services and consortium of his wife.

#### COUNT XI: ALTERNATE STATE LAW THEORIES OF RECOVERY

141. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

142. In the event that New Jersey law is found not to apply, Plaintiff alleges the following Illinois state law causes of action including but not limited to:

- a. Products liability, defective design: Plaintiff alternatively pleads the analogous Illinois common law product liability cause of action for defective design under *Restatement of Torts (Second)* against Defendants.
- b. Products liability, failure to warn: Plaintiff alternatively pleads the analogous Illinois common law product liability cause of action for failure to warn under *Restatement of Torts (Second)* against Defendants.

- c. Negligence: Plaintiff alternatively pleads the analogous Illinois common law cause of action for negligence.
- d. Strict liability: Plaintiff alternatively pleads the analogous Illinois common law cause of action for strict liability product liability claims under *Section 402A of the Restatement of Torts (Second)* against Defendants.
- e. Breach of Express Warranty: Plaintiff alternatively pleads the analogous Illinois statute, Ill. Comp. Stat. Ann. Ch. 810, 5/2-313 *et seq.* and any common law causes of action for Breach of Express Warranty.
- f. Breach of Implied Warranty: Plaintiff alternatively pleads the analogous Illinois statutes, Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.* and any common law causes of action for Breach of Implied Warranty.
- g. Fraudulent Misrepresentation: Plaintiff alternatively pleads the analogous Illinois statute and/or common law cause of action for Fraudulent Misrepresentation.
- h. Negligent Misrepresentation: Plaintiff pleads the Illinois statute and/or common law cause of action for Negligent Misrepresentation.
- i. Violation of Consumer Protection Laws: Plaintiff pleads a Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act under Ill. Comp. Stat. Ann ch. 815, 505/1 *et seq.* against all Defendants.

WHEREFORE, Plaintiff prays for judgment against Defendant, as follows:

- a. For general damages in an amount to be proven at the time of trial;
- b. For special damages in an amount to be proven at the time of trial;
- c. For statutory damages as set forth above, in an amount to be proven at the time of trial;

- d. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;
- e. For pre judgment and post judgment interest on the above general and special damages;
- f. For costs of this suit and attorneys' fees; and
- g. All other relief that this Court deems necessary, proper, and just.

**DEMAND FOR JURY TRIAL**

Demand is hereby made for a trial by jury.

MOTLEY RICE, LLC

By: /s/Carmen S. Scott  
Carmen S. Scott  
Fred Thompson, III  
MOTLEY RICE, LLC  
28 Bridgeside Boulevard  
Mt. Pleasant, SC 29465  
Tele. (843) 216-9000  
Fax: (843) 216-9430

*Attorneys for Plaintiffs*

Dated: October 31, 2012



JS 44 (Rev. 12/07, NJ 5/08)

## 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 THE REVERSE OF THE FORM.)

## I. (a) PLAINTIFFS

DOROTHY H. BOZUE AND JOHN J. BOZUE, SR.,

(b) County of Residence of First Listed Plaintiff Will County, IL

(c) Attorney's (Firm Name, Address, Telephone Number and Email Address)

Carmen S. Scott  
Motley Rice, LLC  
28 Bridgeside Blvd.  
Mt. Pleasant, SC 29464

843-216-9160  
cscott@motleyrice.com

## DEFENDANTS

Merck, Sharp &amp; Dohme, Corp., and Warner Chilcott (US), Inc.

County of Residence of First Listed Defendant \_\_\_\_\_

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE 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)

- |   |                                       |                            |   |                            |                                       |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
|   | PTF                                   | DEF                        |   | PTF                        | DEF                                   |
| Citizen of This State                   | <input type="checkbox"/> 1            | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State                | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5            |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |

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

<b>CONTRACT</b>		<b>TORTS</b>		<b>FORFEITURE/PENALTY</b>	<b>BANKRUPTCY</b>	<b>OTHER STATUTES</b>
<input type="checkbox"/> 110 Insurance	<input type="checkbox"/> 310 Airplane	<input type="checkbox"/> 362 Personal Injury - Med. Malpractice	<input type="checkbox"/> 610 Agriculture	<input type="checkbox"/> 422 Appeal 28 USC 158	<input type="checkbox"/> 400 State Reapportionment	
<input type="checkbox"/> 120 Marine	<input type="checkbox"/> 315 Airplane Product Liability	<input checked="" type="checkbox"/> 365 Personal Injury - Product Liability	<input type="checkbox"/> 620 Other Food & Drug	<input type="checkbox"/> 423 Withdrawal 28 USC 157	<input type="checkbox"/> 410 Antitrust	
<input type="checkbox"/> 130 Miller Act	<input type="checkbox"/> 320 Assault, Libel & Slander	<input type="checkbox"/> 368 Asbestos Personal Injury Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881		<input type="checkbox"/> 430 Banks and Banking	
<input type="checkbox"/> 140 Negotiable Instrument	<input type="checkbox"/> 330 Federal Employers' Liability	<b>PERSONAL PROPERTY</b>	<input type="checkbox"/> 630 Liquor Laws	<b>PROPERTY RIGHTS</b>	<input type="checkbox"/> 450 Commerce	
<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment	<input type="checkbox"/> 340 Marine	<input type="checkbox"/> 370 Other Fraud	<input type="checkbox"/> 640 R.R. & Truck	<input type="checkbox"/> 820 Copyrights	<input type="checkbox"/> 460 Deportation	
<input type="checkbox"/> 151 Medicare Act	<input type="checkbox"/> 345 Marine Product Liability	<input type="checkbox"/> 371 Truth in Lending	<input type="checkbox"/> 650 Airline Regs.	<input type="checkbox"/> 830 Patent	<input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations	
<input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans)	<input type="checkbox"/> 350 Motor Vehicle	<input type="checkbox"/> 380 Other Personal Property Damage	<input type="checkbox"/> 660 Occupational Safety/Health	<input type="checkbox"/> 840 Trademark	<input type="checkbox"/> 480 Consumer Credit	
<input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits	<input type="checkbox"/> 355 Motor Vehicle Product Liability	<input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 690 Other	<b>SOCIAL SECURITY</b>	<input type="checkbox"/> 490 Cable/Sat TV	
<input type="checkbox"/> 160 Stockholders' Suits	<input type="checkbox"/> 360 Other Personal Injury		<b>LABOR</b>	<input type="checkbox"/> 861 HIA (1395ff)	<input type="checkbox"/> 810 Selective Service	
<input type="checkbox"/> 190 Other Contract			<input type="checkbox"/> 710 Fair Labor Standards Act	<input type="checkbox"/> 862 Black Lung (923)	<input type="checkbox"/> 850 Securities/Commodities/Exchange	
<input type="checkbox"/> 195 Contract Product Liability			<input type="checkbox"/> 720 Labor/Mgmt. Relations	<input type="checkbox"/> 863 DIWC/DIWW (405(g))	<input type="checkbox"/> 875 Customer Challenge 12 USC 3410	
<input type="checkbox"/> 196 Franchise			<input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act	<input type="checkbox"/> 864 SSID Title XVI	<input type="checkbox"/> 890 Other Statutory Actions	
			<input type="checkbox"/> 740 Railway Labor Act	<input type="checkbox"/> 865 RSI (405(g))	<input type="checkbox"/> 891 Agricultural Acts	
<b>REAL PROPERTY</b>	<b>CIVIL RIGHTS</b>	<b>PRISONER PETITIONS</b>	<input type="checkbox"/> 790 Other Labor Litigation	<b>FEDERAL TAX SUITS</b>	<input type="checkbox"/> 892 Economic Stabilization Act	
<input type="checkbox"/> 210 Land Condemnation	<input type="checkbox"/> 441 Voting	<input type="checkbox"/> 510 Motions to Vacate Sentence	<input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)	<input type="checkbox"/> 893 Environmental Matters	
<input type="checkbox"/> 220 Foreclosure	<input type="checkbox"/> 442 Employment	<b>Habeas Corpus:</b>		<input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 894 Energy Allocation Act	
<input type="checkbox"/> 230 Rent Lease & Ejectment	<input type="checkbox"/> 443 Housing/Accommodations	<input type="checkbox"/> 530 General	<b>IMMIGRATION</b>		<input type="checkbox"/> 895 Freedom of Information Act	
<input type="checkbox"/> 240 Torts to Land	<input type="checkbox"/> 444 Welfare	<input type="checkbox"/> 535 Death Penalty	<input type="checkbox"/> 462 Naturalization Application		<input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice	
<input type="checkbox"/> 245 Tort Product Liability	<input type="checkbox"/> 445 Amer. w/Disabilities - Employment	<input type="checkbox"/> 540 Mandamus & Other	<input type="checkbox"/> 463 Habeas Corpus - Alien Detainee		<input type="checkbox"/> 950 Constitutionality of State Statutes	
<input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 446 Amer. w/Disabilities - Other	<input type="checkbox"/> 550 Civil Rights	<input type="checkbox"/> 465 Other Immigration Actions			
	<input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 555 Prison Condition				

## 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 ☐ 7 Appeal to District Judge from Magistrate Judgment

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
28 USC Section 1391 and USC Section 1392Brief description of cause:  
Product Liability and Diversity

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

## VIII. RELATED CASE(S)

(See instructions):

JUDGE Joel A. PisanoDOCKET NUMBER MDL 2243; 3:08-CV-0008

Explanation:

DATE 10/31/12

SIGNATURE OF ATTORNEY OF RECORD

**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.C.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; 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 clerks 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 seven 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.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

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

**VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

**VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases. Provide a brief explanation of why the cases are related.

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