UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

ANITA BAUDEAN	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. _____
	)	
PROCTER & GAMBLE PHARMACEUTICALS and AVENTIS PHARMACEUTICALS, INC.	)	**COMPLAINT**
	)	
And	)	
	)	
WARNER CHILCOTT PHARMACEUTICALS, INC.	)	
	)	
Defendants.	)	

Plaintiff Anita Baudean, by and through their undersigned counsel, and for her Complaint against Defendants, alleges as follows:

PARTIES

1. Plaintiff Anita Baudean is a resident and citizen of the City of Covington in the State of Louisiana, which is located in St. Tammany Parish, Louisiana.

2. Plaintiff was prescribed and ingested the prescription drug Actonel, in the State of Louisiana, and as a result of using Actonel, she suffered a femur fracture in the State of Louisiana.

3. For purposes of this Complaint, Actonel and its generic equivalent risdronate sodium may be used interchangeably.

4. Defendant Procter and Gamble Pharmaceuticals Inc. ("P&GP") is a corporation with its principal place of business in Cincinnati, Ohio. The Defendant's principal office is

located at One Procter and Gamble Plaza, Cincinnati, Ohio 45202.

5. Defendant Warner-Chilcott Pharmaceuticals Inc ("Warner Chilcott") is a corporation that maintains its central headquarters in Dublin, Ireland; however, its U.S. headquarters is located in Rockaway, New Jersey. On or about August 24, 2009, Ireland-based company Warner Chilcott acquired the pharmaceutical business of Procter & Gamble.

6. Defendant Aventis Pharmaceuticals, Inc. ("Aventis") is a corporation organized under the laws of Delaware, and maintains its principal place of business in Bridgewater, New Jersey.

7. At all relevant times, Defendants P&GP, Warner-Chilcott, and Aventis conducted regular and sustained business in the State of Louisiana by selling and distributing its products in the State of Louisiana and engaged in substantial commerce and business activity in St. Tammany Parish, Louisiana. Defendants P&GP, Warner-Chilcott, and Aventis and may be collectively referred to as "Defendants."

8. At all relevant times, Defendants conducted regular and sustained business in the State of Louisiana by selling and distributing its products in the State of Louisiana and engaged in substantial commerce and business activity in St. Tammany Parish, Louisiana.

9. At all relevant times, Defendants transacted and conducted business in the State of Louisiana, and derived substantial revenue in the State of Louisiana and through interstate commerce, and they continue to do so.

10. At all relevant times, Defendants expected or should have expected that their actions or omissions would have consequences within the United States of America, and in the State of Louisiana, and derived substantial revenue from interstate commerce.

11. At all relevant times, Defendants, through their agents, servants, employees

and apparent agents, were the designers, manufacturers, marketers, distributors, and sellers of the prescription drugs Actonel, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.

JURISDICTION AND VENUE

12. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiff and Defendants.

13. Plaintiff is a resident of the State of Louisiana.

14. Defendant P&GP is incorporated and have their principal place of business in the State of Ohio.

15. Defendant Warner-Chilcott is an Ireland-based company that maintains a principal place of business in the State of New Jersey.

16. Defendant Aventis is incorporated under the laws of Delaware and has its principal place of business in the State of New Jersey.

17. The amount in controversy, exclusive of interest and costs, far exceeds $75,000.00.

18. Venue lies in the Eastern District of Louisiana, as the injury sustained by the Plaintiff occurred in that district.

FACTUAL BACKGROUND

Nature of Plaintiff's Case

19. Plaintiff Anita Baudean brings this case against Defendants for injuries and damages associated with her ingestion of the pharmaceutical drug Actonel.

20. Actonel is an oral drug designed, manufactured, supplied, marketed, and distributed by the Defendants. Plaintiff Anita Baudean used Actonel for at least 9 years, during which time she was hospitalized and diagnosed with a femur fracture. Specifically, in

our about July 2011, while using Actonel, Plaintiff was diagnosed with a fracture of her right femur. As discussed herein, Plaintiff's femur fracture occurred as a direct and proximate result of her use of Actonel for at least 9 years.

Nature of the Drug Actonel

21. At all relevant times Defendants were responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling the prescription drugs Actonel and/or the generic risdronate sodium.

22. In March 1998, the United States Food and Drug Administration ("FDA") approved Warner Chilcott's compound risedronate sodium for various uses, including the treatment of osteoporosis and Paget's disease. Risedronate Sodium is marketed by the Defendants under the brand name Actonel.

23. Actonel falls within a class of drugs known as bisphosphonates.

24. There are two classes of bisphosphonates: the N-containing (nitrogenous) and the non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include Pamidronate (marketed as Aredia), Ibandronate (marketed at Boniva), Risedronate (marketed as Actonel), Zolendronate (marketed as Zometa), and Alendronate (marketed as Fosamax). The non-nitrogenous bisphosphonates include etridonate (marketed at Didronel), clodronate (marketed as Bonefos and Loron), and tiludronate (marketed as Skelid).

25. Actonel and other bisphosphonates are indicated for several health conditions, including treatment and prevention of osteoporosis in postmenopausal women, treatment to increase bone mass in men with osteoporosis, treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids daily with low bone mineral density, and treatment Paget's disease in men and women.

26. Osteoporosis is a condition in which the loss of living bone tissue causes the bones to become more fragile. Osteoporosis can occur when a there is a decrease in vitamin D and estrogen deprivation, which is why post-menopausal women are at an increased risk for osteoporosis.

27. More specifically, estrogen deprivation can cause an increase in the number of osteoclasts that are brought to the bone tissue. Osteoclasts are specific types of bone cells that remove bone tissue by removing its mineralized matrix and breaking up the organic bone. This process is called bone resorption. Osteoblasts, on the other hand are types of bone cells that develop bone tissue. Osteoclasts and osteoblasts work together to continuously breakdown and rebuild bone tissue. This process of continuous remodeling of the bone tissue provides bone with more durability.

28. Bisphosphonates such as Actonel are indicated for osteoporosis prevention by reducing the activity of osteoclasts in bone tissue. Actonel is considered "antiresorptive" because it decreases the activity of the osteoclasts, which consequently decreases bone breakdown.

29. However, while decreasing the activity of the osteoclasts, Actonel also increases bone mineralization. Bone mineralization in turn can increase brittleness of the bone.

30. Also, Actonel binds very tightly within bone tissue and is long-lasting, so that it is recycled as the bone is constantly being remodeled. Because Actonel binds so tightly and is so long-lasting, it remains biologically active for over 10 years after the final dose is used.

31. The labeling for Actonel states: "The safety and effectiveness of Actonel for the treatment of osteoporosis are based on clinical data of four years duration. The optimal

duration of use has not been determined."

32. Actonel has been among the Defendants' top selling drugs.

33. Although Actonel has been one of Defendants' most profitable prescription drugs, there are serious adverse health events associated with Actonel which have recently become a matter of public attention.

34. Studies, clinical trials, and other information have recently confirmed two distinct signature injuries that are associated with the use of Actonel. First, studies have demonstrated a causal connection between the use of Actonel and the onset of osteonecrosis of the jaw ("ONJ").

35. Second, and more recently, studies have confirmed a causal connection between the use of Actonel and the occurrence of atypical femur fractures.

36. These two distinct types of injuries present major health concerns to patients who have used and continue to use Actonel.

Actonel and Femur Fractures

37. Defendants knew or should have known that the use of Actonel presented an increased risk of atypical femur fractures.

38. Indeed, published reports and studies have demonstrated to the medical community and the public at large that there is a causal connection between the use of bisphosphonates such as Actonel and atypical femur fractures.

39. For example, in March 2005, an article entitled *Severely Suppressed Bone Turnover: A Potential Complication of Alendronate Therapy* was published in the Journal of Endocrinology & Metabolism detailing a report on nine patients who sustained spontaneous nonspinal fractures while on alendronate therapy. The report raised 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. The reporters concluded, "Our observations emphasize the need for increased awareness and monitoring for the potential development of excessive suppression of bone turnover during long-term alendronate therapy."

40. A similar report entitled *Long-term risks of bisphosphonates probed* was published in the Journal of the American Medical Association in 2009. The author of the report expressed serious concerns with prolonged use of bisphosphonates, recommended that physicians discontinue bisphosphonates treatment in patients after 5 years, and stated, "until we get more data from the industry and the FDA, we are stepping back."

41. In February 2010, another report appeared in the journal Clinical Endocrinology entitled *Unusual Mid-shaft Fractures during Long-term Bisphosphonate Therapy.* The reporters studied 13 women who sustained atraumatic mid-shaft fractures, 11 of which were femur fractures. Of the 13 women, 3 had been using Actonel from 3 to 11 years. The reporters concluded that long-term use of bisphosphonates may increase the risk of unusual long bone mid-shaft fractures, and that the phenomenon was likely due to prolonged suppression of bone turnover, which could lead to accumulation of microdamage and development of hypermineralized bone.

42. Pursuant to a 2005 article entitled *Alendronate and risedronate: reports of severe bone, joint, and muscle pain* was published in the Archives of Internal Medicine, an FDA Alert was issued on January 2008 concerning serious and sometimes incapacitating bone, joint, and muscle pain associated with bisphosphonate use.

43. On March 10, 2010, in light of the many medical reports associating

bisphosphonates such as Actonel with femur fractures, the FDA issued a Safety Announcement concerning potential adverse events associated with Actonel.

44. In its announcement, the FDA acknowledged that recent reports raised the question of whether there is an increased risk of atypical subtrochanteric femur fractures (fractures in the femur bone just below the hip joint), which led to the FDA conducting an ongoing investigation.

45. However, at that time the FDA did not believe there was enough data to support such a causal connection. The FDA stated in its announcement: "At this point, the data that FDA has reviewed have not shown a clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures." The FDA further found that, based on published case reports of atypical subtrochanteric femur fractures, as well as case reports and clinical trial data obtained from bisphosphonate drug manufacturers, the current data "did not show an increase in this risk in women using these medications."

46. Nevertheless, the FDA indicated that it "is working closely with outside experts, including members of the recently convened American Society of Bone and Mineral Research Subtrochanteric Femoral Fracture Task Force, to gather additional information that may provide more insight into this issue."

47. In September of 2010, the findings of the Task Force were published in the Journal of Bone and Mineral Research in a report entitled *Atypical Subtrochanteric and Diaphyseal Femoral Fractures: Report of a Task Force of the American Society for Bone and Mineral Research*. After reviewing numerous studies, reports, articles, and other data, the Task Force concluded that "there is evidence of a relationship between long-term use of [bisphosphonate]s use and a specific type of subtrochanteric and femoral shaft fracture." The

Task Force further concluded that "physicians and patients should be made aware of the possibility of atypical femoral fractures and of the potential for bilaterality though a change in labeling of [bisphosphonate]s."

48. Based in part on the Task Force's findings, on October 13, 2010, the FDA issued another Safety Announcement concerning the class of bisphosphonates, including Actonel. The announcement stated: "The U.S. Food and Drug Administration (FDA) is updating the public regarding information previously communicated describing the risk of atypical fractures of the thigh, known as subtrochanteric and diaphyseal femur fractures, in patients who take bisphosphonates for osteoporosis. This information will be added to the *Warnings and Precautions* section of the labels of all bisphosphonate drugs approved for the prevention or treatment of osteoporosis."

49. The FDA further announced that it would be requiring a new Limitations of Use Statement in the *Indications and Usage* section of the label and would be requiring that a Medication Guide be included with all bisphosphonates medications approved for osteoporosis.

50. Thus, for the first time, Defendants included new information in their labeling indicating reports of a possible association between Actonel and atypical femur fractures. However, as with osteonecrosis of the jaw injuries, Defendants minimized the significance of the reports and indicated that there is no proof that Actonel causes femur fractures.

51. Defendants did not issue a black box warning, nor did they list the new information concerning femur fractures in the WARNINGS section of the label.

52. The PRECAUTIONS section of Defendants' label does not adequately warn patients or their physicians of the potential for atypical femur fractures.

53. Thus, Defendants continue to deny in their Actonel labeling a causal relationship between the use of Actonel and atypical femur fractures.

54. Despite Defendants' continued denial of a causal relationship between Actonel and atypical femur fractures, the evidence continues to increase in support of such a relationship.

55. More recently, on February 23, 2011, the findings of a long-term study were published in the Journal of the American Medical Association entitled *Bisphosphonate Use and the Risk of Subtrochanteric or Femoral Shaft Fractures in Older Women*. The article noted that "case reports and conflicting findings from small observational studies have left clinicians and patients uncertain about whether bisphosphonates increase the risk of subtrochanteric or femoral shaft fractures." Thus, the population-based, nested case-controlled study examined the association between bisphosphonate use and fractures in postmenopausal women who used bisphosphonates between April 2002 and March 2008. The study concluded that patients on long-term bisphosphonates for osteoporosis therapy had a 274% higher chance of subtrochanteric femur fractures than similar matched patients. The researchers concluded that "our findings provide strong evidence that prolonged bisphosphonate therapy is associated with an increased risk of subtrochanteric or femoral shaft fracture[.]"

56. Thus, there is sound epidemiologic evidence that the use of Actonel can cause atypical femur fractures and that patients using Actonel for prolonged periods of time are at an increased risk of suffering such injuries.

57. Despite the causal connection between Actonel and its generic equivalent and atypical femur fractures, Defendants placed Actonel into the stream of worldwide commerce and interstate commerce in the United States. It did so without adequate testing and with no

warning that the drug carried with it a risk of causing atypical femur fractures.

58. Defendants, either directly or though their agents, apparent agents, servants, or employees, designed, manufactured, marketed, advertised, distributed, and sold Actonel for the treatment of osteoporosis, Paget's Disease, and other uses.

59. Defendants expected, or should have expected, that its business activities could or would have consequences within the State of Louisiana or any other state where its product is used.

60. As a result of the defective nature of Actonel, Plaintiff suffered and continues to suffer severe and permanent personal injuries, including femur fractures and residual effects of such injuries.

61. Defendants concealed and continue to conceal its knowledge of Actonel's unreasonably dangerous risks from Plaintiff Anita Baudean, other consumers, and the medical community.

62. Defendants failed to conduct adequate and sufficient post-marketing surveillance of Actonel after it began marketing, advertising, distributing, and selling the drug.

63. As a result of Defendants' actions and inaction, as described herein, Plaintiff Anita Baudean was injured due to her ingestion of Actonel, which has caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks compensatory damages.

Plaintiff's Use of Actonel and her Resulting Injuries

64. As a result of Defendants' claim regarding the effectiveness and safety of Actonel, Plaintiff Anita Baudean's medical provider prescribed and Anita Baudean began using Actonel. Plaintiff Anita Baudean continued to use Actonel and/or the generic

equivalent risdronate. Plaintiff Anita Baudean used Actonel and/or its generic equivalent for at least 9 years.

65. As a direct and proximate result of using Actonel, Plaintiff Anita Baudean suffered a subtrochaneric fracture in her femur.

66. Specifically, in or about July 2011, while using Actonel, Plaintiff Anita Baudean suffered a subtrochaneric femur fracture.

67. The break in Ms. Baudean's femur required surgical repair involving placement of a rod and pins.

68. Plaintiff Anita Baudean was hospitalized, underwent surgical procedures and physical rehabilitation, and has endured significant pain and suffering as a result of her femur fracture.

69. Plaintiff Anita Baudean remains at a significant increased risk for femur fractures and possibly osteonecrosis of the jaw.

70. Prior to, and during, Plaintiff's use of Actonel, Defendants knew or should have known that the use of Actonel created an unreasonable increased risk of osteonecrosis of the jaw and femur fractures, and that when taken as directed, such use of Actonel was unreasonably dangerous to consumers.

71. Despite the fact that Defendants knew or should have known of the serious health risks and complications caused by the use of Actonel, Defendants failed to adequately and sufficiently warn consumers, including Plaintiff Anita Baudean, or the medical community, of such risks.

72. Had Plaintiff Anita Baudean and/or her health care providers known of the increased risk and dangers associated with Actonel, she would not have used the product and

would not have suffered a femur fracture in July of 2011.

73. At the time Plaintiff suffered the femur fracture, she did not know and had no reason to believe that her femur fracture was caused by her use of Actonel, or that her injuries could have been caused by the actions, omissions, or misconduct of Defendants.

74. Had Plaintiff Anita Baudean and/or her health care providers known of the increased risks and dangers of femur fractures associated with Actonel, she would not have used the product, would not have suffered a femur fracture, and would not have suffered the pain, injury, and economic damages described herein.

75. As a direct and proximate result of her use of Actonel, Plaintiff Anita Baudean suffered significant harm, physical injury, conscious pain and suffering, and bodily impairment, including but not limited to suffering a femur fracture, undergoing surgical procedures, enduring hospitalization, and constantly enduring pain throughout the rest of her body to this day. Plaintiff's injuries may have caused permanent effects and may continue in the future to cause her physical effects and damages which will affect her throughout her lifetime.

76. As a direct and proximate result of her use of Actonel, Plaintiff Anita Baudean has also suffered mental anguish and emotional distress in connection with her injuries and the knowledge that Plaintiff will have life-long complications as a result of her use of Actonel and resulting injuries.

77. As a direct and proximate result of her use of Actonel, Plaintiff Anita Baudean has also suffered, and will continue to suffer, economic losses in the form of medical expenses and other pecuniary losses resulting from her injuries.

FIRST CAUSE OF ACTION

DEFECT IN MANUFACTURING AND CONSTRUCTION LOUISIANA REVISED STATUTE § 9:2800.55

78. Plaintiff re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein

79. Defendants defectively in manufactured Actonel because when it left their control those prescription drugs deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards.

80. As a direct and proximate cause of Defendants' defective manufacturing, Plaintiff suffered injuries and damages, the full extent of which will be proven at trial.

SECOND CAUSE OF ACTION

PRODUCT DEFECT IN DESIGN OR FORMULATION LOUISIANA REVISED STATUTE §9:2800.56

81. Plaintiff re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

82. At all times herein mentioned, Defendants manufactured, designed, formulated, produced, created, made, constructed and/or assembled Actonel used by Plaintiff.

83. Defendants' Product was defective in that at the time the Product left the control of Defendants, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

84. The Defendants' Product was in an unsafe, defective, and inherently dangerous condition that was unreasonably dangerous to its users and, in particular, Plaintiff, Anita Baudean.

85. At all times herein mentioned, Defendants' Product was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that said Product was defective and unsafe, especially when used as instructed and in the form and manner as provided by Defendants.

86. The nature and magnitude of the risk of harm associated with the design and formulation of Defendants' Product, including femur fractures and weakening of bones, is high in light of the intended and reasonably foreseeable uses of the product as treatment of osteoporosis and Paget's disease.

87. It is highly unlikely that product users would be aware of the risks associated with Defendants' Product through either warnings, general knowledge or otherwise. Plaintiff was not aware of said risks.

88. The likelihood was high that the design or formulation would cause the harm of bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures after long-term use of Actonel in light of the intended and reasonably foreseeable use of the product.

89. The design or formulation did not conform to any applicable public or private product standard that was in effect when the Product left the control of its manufacturer.

90. The design or formulation of Defendants' Product is more dangerous than a reasonably prudent consumer would expect when used in the intended or reasonable foreseeable manner. It was more dangerous than Plaintiff expected.

91. The intended or actual utility of Defendants' Product is not of such benefit to justify the risk of bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures.

92. There was both technical and economic feasibility, at the time the Defendants' Products left Defendants' control, of using an alternative design or formulation that would not cause bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures.

93. The defective design or formulation of Defendants' Product was not caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person.

94. A practical and technically feasible alternative design or formulation was available that would have prevented the harm for which Plaintiff suffered.

95. By reason of the foregoing, the Defendants are liable to the Plaintiff, Anita Baudean, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a Product that is defective in design and formulation.

96. As a direct and proximate cause of Defendants' defective design and formulation, Plaintiff suffered injuries and damages, the full extent of which will be proven at trial.

THIRD CAUSE OF ACTION

PRODUCT DEFECT DUE TO INADEQUATE WARNING AND/OR INSTRUCTION LOUISIANA REVISED STATUTE § 9:2800.57

97. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

98. Defendants had a duty to warn Plaintiff of the risks associated with the Defendants' Product, namely, the risk that said product causes bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures.

99. Defendants knew, or in the exercise or reasonable care, should have known about the risk that Actonel causes bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures.

100. Defendants failed to provide warning or instruction that a manufacturer exercising reasonable care would have provided concerning the risk of bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures, in light of the likelihood that their product would cause bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures for which Plaintiff suffered.

101. Defendants' Product is defective due to inadequate post-marketing warning or instruction.

102. Defendants knew, or in the exercise or reasonable care, should have known about the risk that their Product causes bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures.

103. Defendants failed to provide post-marketing warning or instruction that a manufacture exercising reasonable care would have provided concerning the risk of bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures, in light of the likelihood that the product causes bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures for which Plaintiff suffered.

104. Defendants' Product does not contain a warning or instruction regarding bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures for normal healthy individuals.

105. The risk of bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures is not open and obvious risk or a risk that is a matter of common knowledge in regards to Actonel.

106. By reason of the foregoing, the Defendants are liable to the Plaintiff, for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling a Product that is defective due to inadequate warning or instruction.

107. As a direct and proximate cause of Defendants' defective warning, Plaintiff suffered injuries and damages, the full extent of which will be proven at trial.

FOURTH CAUSE OF ACTION

PRODUCT DEFECT IN FAILURE TO CONFORM TO EXPRESS WARRANTY LOUISIANA REVISED STATUE § 9:2800.58

108. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if fully set forth herein.

109. The Defendants' Product was defective in that, when it left the control of Defendants, the Product did not conform to representations made by Defendants.

110. Said representations are false, misleading, and inaccurate.

111. Defendants describe and represent that their Product has characteristics that simply do not conform to reality. Rather then acknowledging that Defendants' Product causes bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy

femoral shaft fractures, Defendants describe their Product as being safe for all users not specifically designated as "contraindicated."

112. These representations are in stark contrast to the bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures that Defendants' Product does actually cause.

113. While Plaintiff believes and avers that Defendants acted negligently and recklessly in making the representations, in the event Defendants are not found to have acted negligently or recklessly, Defendants are still liable for the damages and injuries suffered by Plaintiffs pursuant to Louisiana Revised Statute § 9:2800.58.

114. By reason of the foregoing, the Defendants are liable to the Plaintiff for the manufacturing, designing, formulating, producing, creating, making, constructing, and/or assembling or a Product that is defective in that it did not conform, at the time it left the control of Defendants, to representations made by Defendants.

115. As a direct and proximate result of Defendants' violation of Louisiana Revised Statute § 9:2800.58, Plaintiff has suffered injuries and damages, the full extent of which will be proven at trial.

FIFTH CAUSE OF ACTION

VIOLATION OF CONSUMER PROTECTION STATUTES LOUISIANA REVISED STATUTES §51:1401, et seq.

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

117. Defendants engaged in commercial conduct by selling Actonel.

118. Defendants misrepresented and omitted material information regarding Actonel by failing to disclose known risks, bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures.

119. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of Defendants' Product in violation of Louisiana Revised Statutes 51:1401, et seq.

120. Louisiana has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that Defendants' Product was fit to be used for the purpose for which it was intended, when Defendants knew it was defective, dangerous, unsafe and by other acts alleged herein.

121. Defendants engaged in the deceptive acts and practices alleged herein in order to sell Defendants' Product to the public, including Plaintiff.

122. As a direct and proximate result of the Defendants' violations of Louisiana Revised Statutes 51:1401, et seq., Plaintiff incurred actual damages and is entitled to compensatory damages, equitable relief, punitive damages, costs and reasonable attorneys' fees.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, as follows:

a. Damages in an amount to be determined at trial, but in an amount exceeding seventy-five thousand dollars;

d. Pre-judgment and post-judgment interest at the maximum rate allowable at law;

c. The costs and disbursements incurred by Plaintiff in connection with this action, including reasonable attorneys' fees;

d. All statutory damages;

e. Disgorgement of Defendants' profits from the sale of the Product;

f. Return or refund of any purchase price paid, including, but not limited to, insurance co-payments, interest on these amounts from the date of purchase, attorneys' fees and costs, non-pecuniary damages, as well as any other legal or equitable relief to which Plaintiffs may be entitled;

g. Such other and further relief under all applicable state and federal law and any other relief the Court deems just and appropriate.

Respectfully submitted,

/s/ Lawrence J. Centola, III
Martzell & Bickford
Lawrence J. Centola, III
338 Lafayette St.
New Orleans, LA 70130
(504) 581-9065
(504) 581-7635 (fax)

-and-

Kyle S. Sclafani
4130 Canal St.
New Orleans, Louisiana 70119
(504) 875-4079
(504) 910-4324 (fax)

ATTORNEYS FOR PLAINTIFFS

JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil coversheet and the information contained herein neither replace nor supplement the filing and service of pleadngs 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 inSeptember 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
ANITA BAUDEAN

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Martzell & Bickford
338 Lafayette Street
New Orleans, LA 70130 (504) 581-9065

DEFENDANTS
PROCTOR & GAMBLE PHARMACEUTICALS, ET AL

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

Attorneys *(If Known)*

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 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) (For Diversity Cases Only) and One Box for Defendant)*

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

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

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

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

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☑ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

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

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

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

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

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

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

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

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

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*: 28 USC 1332
Brief description of cause: Drug Products Liability - Actonel leads to hip fracture

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) IF ANY *(See instructions)*: JUDGE _____ DOCKET NUMBER _____

DATE 7-3-12 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

ANITA BAUDEAN

Plaintiff

v.

PROCTOR & GAMBLE PHARMACEUTICAL, ET AL

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* AVENTIS PHARMACEUTICALS, INC.,
400 Somerset Corporate Boulevard
Bridgewater, New Jersey 08807-2867

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Lawrence J. Centola, III
Martzell & Bickford
338 Lafayette Street
New Orleans, Louisiana 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 07/03/2012

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☑ Other *(specify):* SENT VIA CERTIFIED MAIL - RETURN RECEIPT

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

ANITA BAUDEAN

Plaintiff

v.

PROCTOR & GAMBLE PHARMACEUTICAL, ET AL

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* PROCTOR & GAMBLE PHAMACEUTICALS, INC.,
One Proctor and Gamble Plaza
Cincinnati, Ohio 45202

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Lawrence J. Centola, III
Martzell & Bickford
338 Lafayette Street
New Orleans, Louisiana 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 07/03/2012

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☑ Other *(specify):* SENT VIA CERTIFIED MAIL - RETURN RECEIPT

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of Louisiana

ANITA BAUDEAN

Plaintiff

v.

PROCTOR & GAMBLE PHARMACEUTICAL, ET AL

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* WARNER-CHILCOTT PHARMACEUTICALS, INC.,
100 Enterprise Drive
Rockaway, New Jersey 07866

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Lawrence J. Centola, III
Martzell & Bickford
338 Lafayette Street
New Orleans, Louisiana 70130

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 07/03/2012

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☑ Other *(specify)*: SENT VIA CERTIFIED MAIL - RETURN RECEIPT

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: