

JURISDICTION

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.

OPERATIVE FACTS

5. At all times relevant hereto, Merck was engaged in the business of testing, developing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly through third parties or related entities, pharmaceuticals, including Fosamax.

6. At all times relevant hereto, Merck was responsible for, or involved in, designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing and/or selling its product, the prescription drug Fosamax.

7. 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 Merck as "Fosamax."

8. Fosamax falls within a class of drugs known as bisphosphonates, which are used for treating bone conditions such as osteopenia, osteoporosis and Paget's disease. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (Fosamax).

9. In or about 2000, Ms. Duke, then 57 years old (Birthdate August 5, 1943), was prescribed Fosamax by her physician, Dr Sudhir Khanna.

10. After over 8 years of Fosamax use, on March 11, 2009, for no apparent reason, Ms. Duke, then 65 years old, sustained a low energy fracture of the subtrochanteric area of her right femur and underwent surgery with trochanteric fixation nail at Geisinger Hospital, Danville, Pa.

11. X-rays on March 11, 2009 also showed a stress reaction in the subtrochanteric area of her left femur.

12. In or about March 2009, Ms. Duke was told by her surgeon, Dr. James C. Widmaier Jr., who recorded his causation opinion in the Geisinger Discharge Summary, that he believed her use of Fosamax had caused her femur fractures.

13. After the fracture of her right femur occurred, Dr. Widmaier discontinued Ms. Duke's use of Fosamax.

14. Ms. Duke continues to be disabled from the pain in both of her legs and is undergoing tests to determine whether she will need surgery to prevent further fracturing of her left femur.

15. It is believed and therefore averred that Ms. Duke's low energy femur fractures are due to the harmful long-term effects of Fosamax use, a consequence that was never made known to plaintiff, Ms. Duke, or her physicians by Merck.

16. It is believed and therefore averred that Merck knew or should have known and failed to warn that long term use of Fosamax was unsafe because it could cause low energy femur fractures of the type that plaintiff, Ms. Duke, suffered.

17. Merck, particularly with its heightened knowledge and experience, knew or should have known that long term use of bisphosphonates, including Fosamax, could inhibit the production of new bone cells (osteoblasts) and therefore would prevent repair of naturally occurring micro fractures in the femur which could lead to serious low energy femur fractures, and/or that prolonged suppression of bone remodeling with Fosamax could lead to serious low energy femur fractures; and

that femur fractures caused by long term Fosamax use could occur despite the apparent absence of sufficient trauma.

18. While Fosamax has been marketed, it is believed and therefore averred, that prior to plaintiff's suffering femur fractures, Merck received adverse reaction reports from different Fosamax users throughout the country that these patients were experiencing bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures after long-term use of Fosamax.

19. It is believed and therefore averred that one such report later was reported in an article written by Dr. Jennifer Schneider titled, "Should Bisphosphonates be Continued Indefinitely? An Unusual Fracture in a Healthy Woman on Long-Term Alendronate", *Geriatrics* 61(1): 31-33 (2006). Said article also reported on a fracture of a right femur after long-term use of Fosamax.

20. It is believed and therefore averred that Merck has disregarded and has refused to follow up on the reports of patients, who after using Fosamax, have experienced and reported bone brittleness, susceptibility to fractures, femoral stress fractures, and/or low energy femoral shaft fractures.

21. Merck has failed to submit these reported adverse consequences to the FDA and has failed to advise physicians and the public.

22. Merck has failed to change any of its prescribing information, package inserts or drug manuals supplied to the medical and pharmaceutical professions and the general public in order to warn of the potential for low energy femur fractures after long-term Fosamax use.

23. Fosamax is one of Merck's top selling drugs, averaging more than \$3 billion a year in sales.

24. Consumers, including Ms. Duke, who have used Fosamax had several alternative safer products available to treat their condition.

25. Merck knew of the significant risk of health complications caused by ingestion of Fosamax, but Merck did not adequately and sufficiently warn consumers, including plaintiff, Ms. Duke, or the medical community, of such risks.

26. As a direct result, Ms. Duke was prescribed Fosamax and has been permanently injured, having suffered serious injuries and damages from the ingestion of Fosamax. Ms. Duke requires and will in the future require ongoing medical care and treatment.

27. Ms. Duke has suffered mental anguish from the knowledge that she will have life-long complications as a result of the injuries she sustained from the use of Fosamax.

28. As a direct and proximate result of using Fosamax, Ms. Duke has suffered the injuries described above and is in current treatment for her condition, and has been required and will continue to be required to expend money in medical expenses to treat her injuries.

29. Ms. Duke, as a direct and proximate result of using Fosamax, has suffered, and will continue to suffer severe physical and mental pain and suffering; and has sustained permanent injuries, disability and emotional distress.

30. Ms. Duke would not have used Fosamax had Merck properly disclosed the risks associated with the drug. Alternatively, if Ms. Duke would have known of the risks of Fosamax, she would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

31. Merck, through its affirmative misrepresentations and omissions, actively concealed from Ms. Duke and her physicians the true and significant risks associated with taking Fosamax.

32. As a result of Merck's actions, Ms. Duke and her prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence, that Ms. Duke had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Merck's acts, omissions, and misrepresentations.

33. Merck is strictly liable to plaintiffs pursuant to the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 *et seq.*

34. Merck is under a duty to supply a product that is reasonably fit, suitable or safe for its intended use, such that it is not unreasonably dangerous and such that it does not cause injury to a reasonably foreseeable user.

35. Merck has failed to meet the obligation of supplying a product that is reasonably fit, suitable or safe for its intended purpose and which is not unreasonably dangerous, in that they have placed the product Fosamax into the stream of commerce when Fosamax had been defectively manufactured, defectively designed and failed to contain adequate warnings, labels or instructions.

36. Plaintiffs allege that at all times, the product Fosamax was defective when it left Merck's control and the product was not substantially altered prior to reaching and being ingested by the Ms. Duke.

COUNT I
PRODUCTS LIABILITY-FAILURE TO WARN (N.J.S.A. 2A:58C-2 *et seq.*)

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

38. Merck researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, Fosamax, and in the course of same, directly advertised or marketed the product to the FDA, consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Fosamax.

39. Fosamax was under the exclusive control of Merck as aforesaid, and was unaccompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use of Fosamax, and the comparative severity, duration and the extent of the risk of injury with such use.

40. Merck has failed to timely and reasonably warn of material facts regarding the safety and efficacy of Fosamax so that no medical care provider would have prescribed Fosamax for an unlimited period of time, or no consumer would have used Fosamax for an unlimited period of time, had those facts been made known to such providers and/or consumers.

41. Merck has failed to perform or otherwise facilitate adequate testing in that such testing would have shown that Fosamax posed serious and potentially life-threatening side effects and complications with respect to which full and proper warnings accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA and the public, including plaintiffs.

42. Fosamax, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Merck, was defective due to inadequate post-marketing warnings and/or instruction because, after Merck knew or should have known of the risk of serious and potentially life-threatening side effects and complications from the use of Fosamax, Merck failed to provided adequate warnings to medical care providers, the FDA and the consuming public, including plaintiff, Ms. Duke, and continued to promote Fosamax aggressively.

43. As a direct and proximate result of the conduct of Merck as aforesaid, Ms. Duke has sustained injuries to her body including, but not limited to, low bone turnover, femoral stress fractures, low energy right femoral shaft fracture, ORIF by trochanteric fixation nail necessitating ongoing treatment and therapy, and debilitation which at times has relegated her to use of a walker and continued need of a cane for any extended ambulation, all of which have caused and are causing physical, emotional and economic injury to her, which will continue indefinitely into the future.

44. As a further direct and proximate result of the acts and omissions of Merck, Ms. Duke has been prevented from pursuing normal activities and employment, has experienced severe physical pain and suffering and mental anguish, and has been deprived of ordinary pursuits and enjoyments of life.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
PRODUCTS LIABILITY -- DEFECTIVE DESIGN (N.J.S.A. 2A:58C-2 et seq.)

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

46. Merck is a researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of Fosamax, which is defective and unreasonably dangerous to consumers.

47. The aforementioned drug is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The aforementioned drug is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than similar drugs on the market and is more dangerous than ordinary consumers can reasonably foresee.

48. The defective condition of the aforementioned drug renders it unreasonably dangerous, and it was in this defective condition at the time it left the hands of Merck. The aforementioned drug was expected to and did reach consumers, including Ms. Duke, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

49. Plaintiffs were unaware of the significant hazards and defects in the aforementioned drug. The aforementioned drug was unreasonably dangerous in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Ms. Duke was taking the aforementioned drug, the medication was being utilized in a manner that was intended by Merck. At the time she received and consumed the aforementioned drug, it was represented to be safe and free from latent defects.

50. Merck is strictly liable to Plaintiffs for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Merck because of the design defects.

51. Merck knew or should have known of the danger associated with the use of the aforementioned drug, as well as the defective nature, but has continued to design, manufacture, sell, distribute, market, promote and/or supply the aforementioned drug so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the aforementioned drug.

52. As a direct and proximate result of the conduct of Merck as aforesaid, Ms. Duke has sustained injuries to her body including, but not limited to, low bone turnover, femoral stress fractures, low energy right femoral shaft fracture, ORIF by trochanteric fixation nail necessitating ongoing treatment and therapy and debilitation which at times relegated her to use of a walker and continued need of a cane for any extended ambulation, all of which have caused and are causing physical, emotional and economic injury to her, which will continue indefinitely into the future.

53. As a further direct and proximate result of the acts and omissions of Merck, Ms. Duke has been prevented from pursuing normal activities and employment, has experienced severe physical pain and suffering and mental anguish, and has been deprived of ordinary pursuits and enjoyments of life.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
PUNITIVE DAMAGES UNDER THE PRODUCTS LIABILITY ACT (N.J.S.A.2A:58C-1)

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

55. Plaintiffs are entitled to punitive damages because Merck's failure to warn was reckless and without regard for the public's safety and welfare. Merck misled both the medical community and the public at large, including Ms. Duke, by making false representations about the safety of Fosamax. Merck downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of Fosamax despite available information demonstrating that Fosamax was likely to cause serious and potentially even fatal side effects to users.

56. It is believed and therefore averred that Merck was in possession of information that users of Fosamax were suffering low energy femur fractures and that Merck consciously disregarded that information in order to continue to reap profits from the sale of Fosamax. Merck continued to market Fosamax by providing false and misleading information with regard to safety and efficacy.

57. Merck failed to provide warnings that would have dissuaded physicians from prescribing Fosamax and consumers from purchasing and consuming Fosamax, thus depriving physicians and consumers from the true risks against the benefits of prescribing purchasing and consuming Fosamax.

WHEREFORE, Plaintiffs demand judgment against Defendant for punitive damages, together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT IV
LOSS OF CONSORTIUM

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

59. Plaintiff, Thomas Duke, has been at all time relevant to this Complaint, and still is, the husband of Plaintiff, Dolores Duke, residing together with his wife.

60. As a result of the injuries suffered by his wife as aforesaid, Plaintiff, Thomas Duke, has and will in the future suffer the loss of the usual services and consortium of his wife and has been required to provide special services and care to her.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Dated: November 9, 2009

Respectfully submitted,

POMERANTZ PERLBERGER & LEWIS, LLP

/s/ Norman Perlberger

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