

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF SOUTH CAROLINA  
CHARLESTON DIVISION**

IN RE: LIPITOR (ATORVASTATIN CALCIUM) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL No. 2:14-mn-02502-RMG  <b>MASTER LONG FORM COMPLAINT</b>
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COMES NOW Plaintiffs in this consolidated action, collectively, and by and through the *Plaintiffs' Steering Committee*, who file this Master Long Form Complaint and Jury Demand against Defendants as an administrative device to set forth potential claims Plaintiffs, on their own behalf and/or on behalf of the estates of deceased persons and their beneficiaries, may assert against Defendants in this litigation. Plaintiffs in MDL No. 2502 bring and/or adopt this Master Long Form Complaint, and complain and allege against Defendants as follows:

**GENERALIZED ALLEGATIONS**

1. Plaintiffs herein, by and through Plaintiffs' attorneys, bring this action for personal injuries and/or wrongful death suffered by the Injured Party (the "Injured Party" and collectively the Injured Party and/or Plaintiffs are the "Plaintiff(s)"), as detailed more fully herein, suffered as a proximate result of the Injured Party's being prescribed and ingesting the defective and unreasonably dangerous prescription drug, Lipitor® (atorvastatin calcium), used primarily to lower the low-density lipoprotein ("LDL") cholesterol and triglycerides in the blood and/or as a primary prevention measure to decrease the risk of developing cardiovascular disease ("CVD") which at all times relevant hereto, was manufactured, designed, tested, packaged, labeled, marketed, advertised, distributed and sold by Defendants identified herein (collectively "Defendants"). Plaintiffs allege generally that Pfizer and/or its predecessor(s) in interest knew that the ingestion of Lipitor® (atorvastatin calcium) increased the risk of developing Type 2

Diabetes; that the risk of developing Type 2 Diabetes was higher in women than it was in men; that the Lipitor® (atorvastatin calcium) label misrepresented the incidence of hyperglycemia found in clinical trials; that Pfizer changed the Lipitor® (atorvastatin calcium) label in Japan to advise health care professionals and consumers that diabetes was a “Clinically Relevant Adverse Reaction;” and that Pfizer knew that Lipitor® (atorvastatin calcium) could not be demonstrated to benefit women as a means of primary prevention against CVD. Nevertheless, Pfizer has promoted Lipitor® (atorvastatin calcium) as safe and effective for primary prevention of CVD without regard to gender and to this day has refused to warn about the risk of developing Type 2 Diabetes in the United States despite having warned about that specific risk in the European Union labeling.

2. This Master Long Form Complaint is intended to serve the administrative functions of efficiency and economy by presenting certain common claims and common questions of fact and law for consideration by this Court within the context of this multidistrict proceeding.

3. Plaintiffs, by and through the undersigned counsel, hereby submit this Master Long Form Complaint against Defendants. Plaintiffs make the following allegations based upon personal knowledge and upon information and belief, as well as upon investigative efforts regarding events surrounding the ingestion of the prescription drug, Lipitor® (atorvastatin calcium), by Plaintiffs.

4. This Master Long Form Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court and it is not intended to consolidate for any purpose the separate claims of Plaintiffs herein. It is anticipated that individual Plaintiffs adopt this Master Long Form Complaint and the necessary causes of action herein through use of a

separate Short Form Complaint. Any separate facts and additional claims of individual Plaintiffs may be set forth in the actions filed by the respective Plaintiffs in their short form complaints. This Master Long Form Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions no Plaintiff relinquishes the right to amend their individual claims to seek any additional claims as discovery proceeds. As more particularly set forth herein, each Plaintiff maintains, among other things, that Lipitor® (atorvastatin calcium) is defective, dangerous to human health, marketed, advertised, packaged, labeled and sold in the United States and lacked proper warnings of the dangers associated with use of the drug.

5. There exists, and at all times mentioned herein there existed, a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and those Defendants are the alter ego of the other certain Defendants, and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as any entity distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction fraud and would promote injustice.

6. The injuries and damages to Plaintiffs were caused by the unreasonably dangerous condition of Lipitor® (atorvastatin calcium) and Defendants' wrongful acts and omissions.

7. Pursuant to 21 CFR §314.80 and *Wyeth v. Levine*, 555 U.S. 555 (2009): "After the FDA approves a drug, the manufacturer remains under an obligation to investigate and report any adverse events associated with the drug ... and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling of the drug." This obligation extends to post-market monitoring of adverse event

reports and re-analysis of existing information. In other words, “‘newly acquired information’ is not limited to new data, but also encompasses ‘new analyses of previously submitted data ... [because] risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments.’” Further, “a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.”

8. Had Defendants properly fulfilled their duties, their post-market surveillance would have provided evidence that Lipitor® (atorvastatin calcium) causes Type 2 Diabetes; therefore, obligating Defendants to conduct additional investigation and warn health care professionals and consumers of the risk of developing Type 2 Diabetes so that health care professionals should closely monitor patients.

9. At all times herein mentioned, Defendants were engaged in the business of, or were successors-in-interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, labeling, promoting, packaging and/or advertising for sale or selling Lipitor® (atorvastatin calcium).

10. At all times herein mentioned Defendants were authorized to do or otherwise engaged in business throughout the United States, including in the State of South Carolina, and did in fact supply the aforementioned products throughout the United States, including in the State of South Carolina and Plaintiffs’ states of residence and ingestion.

11. At all times herein mentioned, the officers and directors of Defendants authorized and directed the production and promotion of Lipitor® (atorvastatin calcium) when they knew, or with the exercise of reasonable care they should have known, of the hazards and dangerous

propensities of Lipitor® (atorvastatin calcium) and thereby actively participated in the tortious conduct which resulted in the physical injuries and/or wrongful death as described herein.

### **JURISDICTION AND VENUE**

12. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants and because the amount in controversy between Plaintiffs and Defendants exceeds \$75,000.00, exclusive of interest and costs, and because, among other reasons, Defendants have significant contacts with this District by virtue of doing business within this Judicial District.

13. Plaintiffs seek damages in excess of seventy-five thousand dollars (\$75,000.00) exclusive of interests and costs.

14. Pursuant to the Transfer Order filed on February 18, 2014, it was determined:

...that these actions involve common questions of fact, and that centralization will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. These actions share factual issues arising from common allegations that taking Lipitor can cause women to develop type 2 diabetes. Centralization will eliminate duplicative discovery, prevent inconsistent pretrial rulings (in particular with respect to class certification and *Daubert* issues), and conserve the resources of the parties, their counsel and the judiciary.

15. Pursuant to the Transfer Order and Consent of Transferee Court filed on February 18, 2014, cases are being transferred to The Honorable Richard M. Gergel in the United States District Court for the District of South Carolina, Charleston Division, as part of In Re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation (No. II) MDL No. 2502.

16. Further, pursuant to Case Management Order No. 4 dated April 25, 2014:

In order to eliminate delays associated with transfer to this Court of cases filed in or removed to other federal district courts, any

Plaintiff whose case would be subject to transfer to these MDL proceedings may file his or her case directly in the District of South Carolina, in accordance with the procedures in this Order.

**PLAINTIFFS/INJURED PARTIES GENERALLY**

17. The Injured Parties are women who were prescribed and used Lipitor® (atorvastatin calcium) as described and upon direction of their health care professional(s) to lower the LDL cholesterol and triglycerides in the blood and/or as a primary prevention measure to decrease the risk of developing CVD. Ultimately, the Injured Parties suffered severe physical, economic and emotional injuries as a result of taking Lipitor® (atorvastatin calcium) (atorvastatin calcium) including but not limited to the Injured Parties being diagnosed with and treated for Type 2 Diabetes.

18. As a direct result of the ingestion of Lipitor® (atorvastatin calcium), the Injured Parties were diagnosed with Type 2 Diabetes. Had the Injured Parties or the Injured Parties' health care professional(s) been properly warned by Defendants regarding the risk of developing Type 2 Diabetes from the ingestion of Lipitor® (atorvastatin calcium) and the lack of any demonstrated benefit for women using the drug for primary prevention of CVD, the Injured Parties would not have ingested Lipitor® (atorvastatin calcium).

19. As a direct result of ingesting Lipitor® (atorvastatin calcium), the Injured Parties were permanently and severely injured, having suffered serious consequences from their ingestion of Lipitor® (atorvastatin calcium) including but not limited to the development of Type 2 Diabetes.

20. Plaintiffs, as a direct and proximate result of the Injured Parties' use of Lipitor® (atorvastatin calcium), suffered severe mental and/or physical pain and suffering along with economic loss.

21. As a proximate result of the unreasonably dangerous condition of Lipitor® (atorvastatin calcium) and Defendants' acts and omissions, Plaintiffs suffered the injuries described herein due to the Injured Parties' ingestion of Lipitor® (atorvastatin calcium). Plaintiffs accordingly seek damages associated with these injuries.

#### **DEFENDANTS GENERALLY**

22. Pfizer, Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in the State of New York. Pfizer regularly conducts business throughout the United States, including in the State of South Carolina, and derives substantial revenues from drugs it sells throughout the United States, including in the State of South Carolina. Pfizer is engaged in the business of designing, developing, manufacturing, promoting, marketing, distributing and selling pharmaceutical drugs, including the drug Lipitor® (atorvastatin calcium), throughout the United States.

23. Pfizer may be served by service of process upon its registered agent for service, CT Corporation System, 111 Eighth Avenue, New York, NY 10011.

24. Pfizer International LLC ("Pfizer International") is a corporation organized and existing under the laws of the State of New York with its principal place of business in the State of New York. Pfizer International regularly conducts business throughout the United States, including in the State of South Carolina, and derives substantial revenues from drugs it sells throughout the United States, including in the State of South Carolina. Pfizer International is engaged in the business of designing, developing, manufacturing, promoting, marketing, distributing and selling pharmaceutical drugs, including the drug Lipitor® (atorvastatin calcium), throughout the United States.

25. Pfizer International may be served by service of process upon its registered agent for service, CT Corporation System, 111 Eighth Avenue, New York, NY 10011.

26. This Court has subject matter jurisdiction based on diversity of citizenship, 28 U.S.C. §1332.

27. Pfizer, Inc. is incorporated under the laws of Delaware and has its principal place of business in New York; therefore, it is a citizen of Delaware and New York under 28 U.S.C. §1332(c)(1). Pfizer International LLC is incorporated under the laws of New York and has its principal place of business in New York; therefore, Pfizer International is a citizen of New York.

28. Hereafter Defendants Pfizer, Inc. and Pfizer International LLC will collectively be referred to as "Pfizer."

29. Greenstone LLC f/k/a Greenstone Limited ("Greenstone") is a limited liability corporation organized and existing under the laws of the State of Delaware with its principal place of business in the State of New Jersey. Greenstone may be served with process by registered mail with return receipt requested, upon The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

30. Upon information and belief, Greenstone is a wholly owned subsidiary of Pfizer. Greenstone regularly conducts business throughout the United States, including in the State of South Carolina and derives substantial revenues from drugs it sells throughout the United States, including in the State of South Carolina. Greenstone is engaged in the business of designing, developing, manufacturing, promoting, marketing, distributing and selling pharmaceutical drugs, including the drug Greenstone Atorvastatin Calcium Tablets, an authorized generic version of Lipitor® (atorvastatin calcium), throughout the United States including in the State of South Carolina.

31. Hereafter Defendants, Pfizer, Inc., Pfizer International LLC and Greenstone LLC f/k/a Greenstone Limited will collectively be referred to as "Defendants."

32. At all times herein mentioned, Defendants, in interstate commerce and in this judicial district, advertised, promoted, supplied and sold to distributors and retailers for resale to health care professionals, hospitals, medical practitioners and the general public a certain pharmaceutical product, Lipitor® (atorvastatin calcium).

#### **GENERAL FACTUAL BACKGROUND**

33. At all times herein mentioned, Defendants, by and through their agents, servants, and/or employees failed to adequately warn health care professionals and consumers, including Plaintiffs herein, of the risks of developing Type 2 Diabetes from ingesting Lipitor® (atorvastatin calcium).

34. Lipitor® (atorvastatin calcium) is an HMG-CoA reductase inhibitor and a member of the drug class known as statins.

35. Lipitor® (atorvastatin calcium) is prescribed to reduce the amount of cholesterol and other fatty substances in the blood and/or as a primary prevention measure to decrease the risk of developing CVD.

36. Parke-Davis Pharmaceutical Research, a division of Warner-Lambert Company, obtained approval from the Food and Drug Administration ("FDA") to market Lipitor® (atorvastatin calcium) on December 17, 1996. Warner-Lambert entered into a co-marketing agreement with Pfizer to sell Lipitor® (atorvastatin calcium) and thereafter those companies began distributing and selling Lipitor® (atorvastatin calcium) throughout the United States in 1997. On June 19, 2000, Pfizer acquired Warner-Lambert and all rights to Lipitor® (atorvastatin calcium).

37. Despite Defendants' knowledge of data that the use of Lipitor® (atorvastatin calcium) is causally related to the development of Type 2 Diabetes, Lipitor® (atorvastatin calcium) was promoted and marketed as safe and effective for Plaintiffs throughout the United States.

38. On August 11, 2011, the Division of Metabolism and Endocrinology Products of the FDA requested that Defendants make labeling changes for Lipitor® (atorvastatin calcium) based upon the FDA's comprehensive review, including clinical trial data.

39. Pfizer maintained exclusive control over Lipitor® (atorvastatin calcium) until November 30, 2011.

40. Upon information and belief, Pfizer, Inc. entered into an exclusive agreement with Watson Pharmaceuticals, Inc. to launch an authorized generic version of Lipitor® (atorvastatin calcium/atorvastatin calcium tablets) effective from November 30, 2011 until November 30, 2016.

41. In February 2012, Defendants complied with the FDA request and added the following language to its Warnings and Precautions Section: "Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including Lipitor."

42. Despite the February 2012 label change, Lipitor® (atorvastatin calcium)'s label continues to inadequately warn consumers of the serious risks of developing Type 2 Diabetes when using Lipitor® (atorvastatin calcium).

43. Upon information and belief, on or about February 26, 2013, Greenstone, the generics arm of Pfizer, announced the launch of authorized generic atorvastatin calcium tablets, a generic version of Pfizer's drug Lipitor® (atorvastatin calcium).

44. Upon information and belief, Pfizer continues to exercise authority and control over the manufacturing, promoting, distributing, marketing and selling of atorvastatin calcium tablets, the authorized generic version of Lipitor® (atorvastatin calcium), as sold by Watson Pharmaceuticals, Inc. and Greenstone.

45. At all times material hereto, Defendants knew or should have known that the risks associated with the use of Lipitor® (atorvastatin calcium) included the severe and life-threatening diagnosis and complications of Type 2 Diabetes.

46. According to the Centers for Disease Control (“CDC”), diabetes is the seventh leading cause of death in the United States. People with diabetes can experience numerous serious and deadly complications including heart disease, stroke, blindness, chronic kidney disease and amputations. The risk for stroke is two to four times higher among people with diabetes. Adults with diabetes have heart disease death rates about two to four times higher than adults without diabetes. Diabetes is the leading cause of new cases of blindness among adults ages 20-74 and is also the leading cause of kidney failure.

47. Additionally, adults with diabetes are also at an increased risk of developing cardiovascular disease, thus Lipitor® (atorvastatin calcium) leads to the very disease that it was designed to prevent.

48. The development of Type 2 Diabetes in Plaintiffs was also preventable and resulted directly from Defendants’ refusal to conduct proper safety studies, failure to properly assess, alarming safety signals, suppression of information revealing life-threatening risks, wanton failure to provide adequate instructions and willful misrepresentations concerning the nature and safety of their product. The conduct and product defects complained of herein were

substantial factors in bringing about Plaintiffs' injuries and a reasonably foreseeable consequence of Defendants' conduct and product defects.

49. At all times material hereto, Defendants, by and through their agents, servants and/or employees, negligently, recklessly and/or carelessly marketed, distributed and/or sold Lipitor® (atorvastatin calcium) without adequate instructions or warnings of the drug's serious side effects and unreasonably dangerous risks.

50. Plaintiffs were prescribed Lipitor® (atorvastatin calcium) and used it as directed.

51. Plaintiffs were prescribed Lipitor® (atorvastatin calcium) to primarily lower the LDL cholesterol and triglycerides in the blood and/or as a primary prevention measure to decrease the risk of developing CVD.

52. Plaintiffs agreed to initiate Lipitor® (atorvastatin calcium) treatment in an effort to reduce the risk of developing heart disease. Plaintiffs relied on claims made by Defendants that Lipitor® (atorvastatin calcium) has been clinically shown to reduce the risk of developing heart disease and to lower LDL levels.

53. After beginning treatment with Lipitor® (atorvastatin calcium), Plaintiffs were subsequently diagnosed with Type 2 Diabetes.

54. As a result, for the rest of their lives, Plaintiffs must undergo regular testing of blood glucose levels, adhere to a restrictive diabetic diet and take medication to control the Type 2 Diabetes. Due to the diabetes, Plaintiffs are now at a markedly increased risk of developing heart disease, blindness, neuropathy and kidney disease.

55. Had Defendants properly disclosed the risks associated with Lipitor® (atorvastatin calcium) and the lack of any demonstrated benefit for women using the drug for primary prevention of CVD, Plaintiffs would have avoided the risk of developing diabetes by not ingesting Lipitor® (atorvastatin calcium).

56. As a direct and proximate result of Defendants' negligence, wrongful conduct and the unreasonably dangerous and defective characteristics of the drug, Lipitor® (atorvastatin calcium), Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to the development of Type 2 Diabetes. Plaintiffs have endured pain and suffering, emotional distress, loss of enjoyment of life and economic loss including incurring significant expenses for medical care and treatment which will continue in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

**ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE**

57. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

58. Plaintiffs are within the applicable statute of limitations for the claims presented hereunder because Plaintiffs did not discover the defects and unreasonably dangerous condition of Lipitor® (atorvastatin calcium) and risks associated with its ingestion, and could not reasonably have discovered the defects and unreasonably dangerous condition of Lipitor® (atorvastatin calcium) and the risks associated with its ingestion, due to the Defendants acts and omissions.

59. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, affirmative misrepresentations and omissions, which include Defendant's intentional concealment from Plaintiffs, Plaintiffs' prescribing health care professionals and the general consuming public that Lipitor®

(atorvastatin calcium) had not been demonstrated to be effective for women as a measure of primary prevention of CVD, was defective, unreasonably dangerous and carried with it the serious risk of developing Type 2 Diabetes, while aggressively and continually marketing and promoting Lipitor® (atorvastatin calcium) as a safe and effective product for women.

60. Defendants had a duty to disclose that Lipitor® (atorvastatin calcium) was not effective for women, was defective, unreasonably dangerous and that its ingestion carried with it the serious risk of developing Type 2 Diabetes.

61. Plaintiffs, Plaintiffs' prescribing health care professionals and the general consuming public, had no knowledge of, and no reasonable way of discovering, the defects found in Lipitor® (atorvastatin calcium), its unreasonably dangerous condition or the true risks associated with its ingestion at the time they purchased and ingested Lipitor® (atorvastatin calcium).

62. Defendants did not notify, inform, or disclose to Plaintiffs, Plaintiffs' prescribing health care professionals or the general consuming public that Lipitor® (atorvastatin calcium) was not effective for women, was defective and that its ingestion carried with it the serious risk of developing Type 2 Diabetes.

63. Because Defendants failed in their duty to notify Plaintiffs, Plaintiffs' prescribing health care professionals and the general consuming public that Lipitor® (atorvastatin calcium) was defective and actively attempted to conceal this fact, Defendants should be estopped from asserting defenses based on statutes of limitation or repose.

**FIRST CAUSE OF ACTION**  
**(Negligence)**

64. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

65. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiffs and Plaintiffs' health care professionals, in testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Lipitor® (atorvastatin calcium).

66. Defendants breached their duty of reasonable care to Plaintiffs in that they negligently tested, developed, designed, manufactured, packaged, labeled, marketed and/or promoted, sold and/or distributed Lipitor® (atorvastatin calcium).

67. Plaintiffs' injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants including but not limited to one or more of the following:

- a. In its design, development, research, manufacturing, testing, packaging, monitoring, promoting, marketing, sale and/or distribution of Lipitor® (atorvastatin calcium);
- b. In its failure to warn or instruct and/or adequately warn or adequately instruct users of Lipitor® (atorvastatin calcium), including Plaintiffs, of Lipitor® (atorvastatin calcium)'s dangerous and defective characteristics;
- c. In its design, development, implementation, administration, supervision and/or monitoring of clinical trials for Lipitor® (atorvastatin calcium);
- d. In its promotion of Lipitor® (atorvastatin calcium) in an overly aggressive, deceitful and fraudulent manner despite the lack of evidence demonstrating its effectiveness in women and despite the evidence as to the product's defective and dangerous characteristics due to its propensity to cause Type 2 Diabetes;
- e. In representing that Lipitor® (atorvastatin calcium) was safe for its intended use when, in fact, the product was unsafe for its intended use;

- f. In failing to perform appropriate pre-market testing of Lipitor® (atorvastatin calcium);
  - g. In failing to perform appropriate post-market surveillance of Lipitor® (atorvastatin calcium);
  - h. In failing to adequately and properly test Lipitor® (atorvastatin calcium) before and after placing it on the market;
  - i. In failing to conduct sufficient testing on Lipitor® (atorvastatin calcium) which, if properly performed, would have shown that Lipitor® (atorvastatin calcium) has the serious risk of causing Type 2 Diabetes;
  - j. In failing to adequately warn Plaintiff, Plaintiffs' health care professionals and the consuming public that the use of Lipitor® (atorvastatin calcium) carried a risk of developing Type 2 Diabetes and that patients' blood glucose should be closely monitored;
  - k. In failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risk of diabetes associated with the use of Lipitor® (atorvastatin calcium); and
  - l. In failing to adequately and timely inform Plaintiffs and the healthcare industry of the risk of serious personal injury, namely Type 2 Diabetes, from ingestion of Lipitor® (atorvastatin calcium) as described herein.
68. Defendants knew or should have known that consumers, such as Plaintiffs, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.
69. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in favor of Plaintiffs for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**SECOND CAUSE OF ACTION**  
**(Negligent Misrepresentation)**

70. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

71. Defendants owed a duty in all of its undertakings, including the dissemination of information concerning Lipitor® (atorvastatin calcium), to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

72. Defendants disseminated to health care professionals and consumers through published labels, marketing materials and otherwise, information concerning the properties and effects of Lipitor® (atorvastatin calcium) with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest Lipitor® (atorvastatin calcium).

73. Defendants, as drug designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or ingesting Lipitor® (atorvastatin calcium), rely upon information disseminated and marketed to them regarding the product.

74. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Lipitor® (atorvastatin calcium) was accurate, complete and not misleading and, as a result,

disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false and unreasonably dangerous to consumers such as Plaintiffs.

75. Defendants, as designers, manufacturers, sellers, promoters and/or distributors, knew or reasonably should have known that patients receiving prescriptions for Lipitor® (atorvastatin calcium) written by health care professionals in reliance upon information disseminated by Defendants as the manufacturer/distributor of Lipitor® (atorvastatin calcium) would be placed in peril of developing the serious, life threatening and life-long injury of Type 2 Diabetes if the information disseminated and relied upon was materially inaccurate, misleading or otherwise false.

76. As a direct, proximate and foreseeable result of Defendants' negligence, Plaintiffs suffered grievous bodily injury and consequently economic and other losses as described above when they and/or their health care professionals, in reasonable reliance upon the negligently inaccurate, misleading and otherwise false information disseminated and marketed by Defendants, believed the information to be true and prescribed or ingested Lipitor® (atorvastatin calcium). Plaintiffs ingested Lipitor® (atorvastatin calcium) as prescribed and instructed by their health care professionals leading to the development of Type 2 Diabetes. Plaintiffs have endured pain and suffering, emotional distress, loss of enjoyment of life, economic loss including incurring significant expenses for medical care and treatment which will continue in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in favor of Plaintiffs for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**THIRD CAUSE OF ACTION**  
**(Negligent Design)**

77. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

78. Defendants are liable to Plaintiffs under common law and/or the applicable Product Liability Acts for the negligent design of Lipitor® (atorvastatin calcium).

79. At all times relevant to this lawsuit, Defendants owed a duty to consumers, including Plaintiffs and their health care professionals, to exercise reasonable care in the design of Lipitor® (atorvastatin calcium).

80. Defendants negligently and carelessly breached this duty of care to Plaintiffs because it designed Lipitor® (atorvastatin calcium) which:

- a. was not effective for women as a measure of primary prevention of CVD;
- b. was and is unreasonably defective in design because it is a compound that unreasonably increased the risks of developing Type 2 Diabetes;
- c. was and is defective in design and was not reasonably safe as intended to be used, subjecting Plaintiffs to risks with no demonstrated benefits for women using the drug for primary prevention of CVD;
- d. was and is defective in design, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with like products;
- e. was and is defective in that it contained insufficient, incorrect and defective warnings in that they failed to alert health care professionals and users, including Plaintiffs, of the risks of adverse effects and the lack of benefit for women;

- f. was and is defective in design in that it was not safe for its intended use and was inadequately tested;
- g. was and is defective in design because its risks exceeded any benefit of the drug;
- h. failed to act as a reasonable and prudent manufacturer, seller, promoter, distributor or marketer would have acted with respect to the design of Lipitor® (atorvastatin calcium); and/or
- i. defective in design because the design did not include an adequate study and testing regimen, particularly in the post-marketing period.

81. Lipitor® (atorvastatin calcium) was expected to, and did, reach the intended consumers, handlers and persons coming into contact with the product without substantial change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants.

82. At all times relevant, Lipitor® (atorvastatin calcium) was manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition which was dangerous for use by the public and in particular by Plaintiffs.

83. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common intended use.

84. At the time of Plaintiffs' use of Lipitor® (atorvastatin calcium), it was being used for its intended purpose and in a manner normally intended, to primarily lower the LDL cholesterol and triglycerides in the blood and/or as a primary prevention measure to decrease the risk of developing CVD.

85. The harm caused by Lipitor® (atorvastatin calcium) far outweighed its benefit, rendering Lipitor® (atorvastatin calcium) more dangerous and less effective than an ordinary consumer or health care professionals would expect and more dangerous than alternative products. Defendants could have designed Lipitor® (atorvastatin calcium) to make it less

dangerous. When Defendants manufactured Lipitor® (atorvastatin calcium) that caused Plaintiffs to develop Type 2 Diabetes, the state of the industry's scientific knowledge was such that a less risky design was attainable.

86. At the time Defendants' product left their control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Lipitor® (atorvastatin calcium). This was demonstrated by the existence of other statins which had a more established safety profile and a considerably lower risk profile.

87. Plaintiffs could not, in the reasonable exercise of care, have discovered the defects of Lipitor® (atorvastatin calcium) and perceived its danger.

88. The defects in Defendants' product were substantial and contributing factors in causing Plaintiffs' injuries. But for Defendants' acts and omissions Plaintiffs' would not have suffered the injuries complained of herein.

89. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in favor of Plaintiffs for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**FOURTH CAUSE OF ACTION**  
**(Strict Products Liability-Design Defect/Products Liability-Design Defect)**

90. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

91. Lipitor® (atorvastatin calcium) was expected to, and did, reach the intended consumers, handlers and persons coming into contact with the product without substantial change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants.

92. At all times relevant, Lipitor® (atorvastatin calcium) was manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition which was dangerous for use by the public and in particular by Plaintiffs.

93. Lipitor® (atorvastatin calcium), as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective in design and formulation in that when it left the hands of the Defendants' manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Lipitor® (atorvastatin calcium).

94. Lipitor® (atorvastatin calcium), as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed by Defendants was defective in design and formulation in that when it left the hands of the Defendants' manufacturers and/or suppliers, it was unreasonably dangerous and was also more dangerous than the ordinary customer would expect.

95. At all times herein mentioned, Lipitor® (atorvastatin calcium) was in a defective condition and was unsafe and Defendants knew and had reason to know that the product was defective and inherently unsafe, especially when Lipitor® (atorvastatin calcium) was used in a form and manner instructed and provided by Defendants.

96. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common intended use.

97. At the time of Plaintiffs' use of Lipitor® (atorvastatin calcium), it was being used for its intended purpose and in a manner normally intended, to primarily lower the LDL cholesterol and triglycerides in the blood and/or as a primary prevention measure to decrease the risk of developing CVD.

98. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed and/or introduced a defective product that caused an unreasonable risk to the health of consumers and to Plaintiffs in particular and Defendants are therefore strictly liable for the injuries and damages sustained by Plaintiffs.

99. The harm caused by Lipitor® (atorvastatin calcium) far outweighed its benefit, rendering Lipitor® (atorvastatin calcium) more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed Lipitor® (atorvastatin calcium) to make it less dangerous. When Defendants manufactured Lipitor® (atorvastatin calcium) that caused Plaintiffs to develop Type 2 Diabetes, the state of the industry's scientific knowledge was such that a less risky design was attainable.

100. At the time Defendants' product left their control, there was a practical, technically feasible and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Lipitor® (atorvastatin calcium).

101. At this time, there were other safe and more effective statins on the market which had a more established safety profile and a considerably lower risk profile.

102. Plaintiffs could not, in the reasonable exercise of care, have discovered the defects of Lipitor® (atorvastatin calcium) and perceived its danger.

103. The defects in Defendants' product were substantial and contributing factors in causing Plaintiffs' injuries. But for Defendants' acts and omissions Plaintiffs' would not have suffered the injuries complained of herein.

104. As a foreseeable, direct and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiffs were caused to suffer from the aforementioned injuries and damages.

105. Due to the unreasonably dangerous condition of Lipitor® (atorvastatin calcium), Defendants are strictly liable to Plaintiffs.

106. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Lipitor® (atorvastatin calcium), which is unreasonably dangerous and defective, thereby placing Lipitor® (atorvastatin calcium) into the stream of commerce.

107. At all times material hereto, Lipitor® (atorvastatin calcium) reached Plaintiff without substantial change in the condition in which Lipitor® (atorvastatin calcium) left the possession of Defendants and was used in a manner which had been contemplated by Defendants.

108. Defendants marketed and promoted Lipitor® (atorvastatin calcium) as safe for use in lowering LDL and/or preventing cardiovascular disease. When Defendants placed Lipitor® (atorvastatin calcium) into the stream of commerce, they knew it would be prescribed to lower an individual's LDL and/or as a primary prevention measure to decrease the risk of developing CVD.

109. Plaintiffs were prescribed, purchased and used Lipitor® (atorvastatin calcium) for its intended purpose.

110. Lipitor® (atorvastatin calcium) was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Type 2 Diabetes.

111. Due to its defective design, Lipitor® (atorvastatin calcium) was unreasonably dangerous to consumers including Plaintiffs.

112. Further, given the risks associated with Lipitor® (atorvastatin calcium), a reasonable manufacturer with Defendants' knowledge of the risks associated with the ingestion of Lipitor® (atorvastatin calcium) would not have marketed the product in the same condition as Defendants sold, marketed, promoted and/or distributed their products to the public including to Plaintiffs.

113. Lipitor® (atorvastatin calcium) was used as a treatment of Plaintiffs in a reasonably foreseeable manner and in accordance with the normal, intended, recommended and/or marketed use of the product.

114. Neither Plaintiff nor Plaintiffs' health care professionals could have reasonably discovered or known of the lack of efficacy in women using the drug for primary prevention or the risk of serious injury and/or death associated with Lipitor® (atorvastatin calcium).

115. The design defects in Lipitor® (atorvastatin calcium) caused Plaintiffs' injuries.

116. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

**FIFTH CAUSE OF ACTION**  
**(Strict Products Liability-Failure to Warn/Products Liability-Failure to Warn)**

117. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

118. Defendants have engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Lipitor® (atorvastatin calcium) and through that conduct has knowingly and intentionally placed Lipitor® (atorvastatin calcium) into the stream of commerce with full knowledge that it reaches consumers such as Plaintiffs who ingested it.

119. Defendants did in fact test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute Lipitor® (atorvastatin calcium) to Plaintiffs, Plaintiffs' prescribing health care professionals, and the consuming public. Additionally, Defendants expected that the Lipitor® (atorvastatin calcium) they were selling, distributing, supplying, manufacturing and/or promoting to reach, and did in fact reach, prescribing health care professionals and consumers, including Plaintiffs and Plaintiffs' prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

120. At all times mentioned herein, the aforesaid product was defective and unsafe such that it was unreasonably dangerous to the user and was so at the time it was distributed by Defendants and ingested by Plaintiffs. The defective condition of Lipitor® (atorvastatin calcium) was due in part to the fact that it was not accompanied by proper warnings regarding the possible risks of developing Type 2 Diabetes as a result of its use.

121. This defect caused serious injury to Plaintiffs who used Lipitor® (atorvastatin calcium) for its intended purpose and in its foreseeable manner.

122. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous risks.

123. Defendants so negligently and recklessly labeled, distributed and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

124. Defendants negligently and recklessly failed to warn of the nature and scope of the risks associated with Lipitor® (atorvastatin calcium), namely the risks of developing Type 2 Diabetes and failed to advise women or their health care professionals that there was no demonstrated benefit of the drug as a measure of primary prevention of CVD.

125. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Lipitor® (atorvastatin calcium) caused serious injuries, they failed to exercise reasonable care to warn of the dangerous risks of developing Type 2 Diabetes from Lipitor® (atorvastatin calcium) use. Even though this risk was known or reasonably scientifically knowable at the time of distribution, Defendants willfully and deliberately failed to warn of the lack of benefit for women and the potential risks associated with Lipitor® (atorvastatin calcium) and in doing so, Defendants acted with a conscious disregard to the safety of consumers, including Plaintiffs.

126. Plaintiffs could not have discovered any defect in Lipitor® (atorvastatin calcium) through the exercise of reasonable care and relied upon the skill, superior knowledge and judgment of Defendants.

127. Had Defendants properly disclosed the risks associated with Lipitor® (atorvastatin calcium) and the lack of any demonstrated benefit in women ingesting the drug for primary prevention of CVD, Plaintiffs would have avoided the risk of diabetes by not using Lipitor® (atorvastatin calcium) at all.

128. As a direct and proximate result of the carelessness, negligence, recklessness and gross negligence of Defendants alleged herein, and in such other ways to be later shown, Lipitor® (atorvastatin calcium) caused Plaintiffs to sustain injuries as alleged herein.

129. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**SIXTH CAUSE OF ACTION**  
**(Strict Products Liability-Breach of Express Warranty)**

130. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

131. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Lipitor® (atorvastatin calcium), which is unreasonably dangerous and defective, thereby placing Lipitor® (atorvastatin calcium) into the stream of commerce.

132. At all times material hereto, Lipitor® (atorvastatin calcium) reached Plaintiffs without substantial change in the condition in which Lipitor® (atorvastatin calcium) left the possession of Defendants and was used in a manner which had been contemplated by Defendants.

133. When Defendants placed Lipitor® (atorvastatin calcium) into the stream of commerce, they knew it would be prescribed to lower an individual's LDL and/or as a primary prevention measure to decrease the risk of developing cardiovascular disease and Defendants expressly warranted to Plaintiffs and Plaintiffs' health care professionals that Lipitor® (atorvastatin calcium) was of merchantable quality and safe and fit for its intended use.

134. Lipitor® (atorvastatin calcium) was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Type 2 Diabetes and there was no demonstrated benefit for women using the drug as primary prevention against developing CVD.

135. Plaintiffs, individually and through their prescribing health care professionals, reasonably relied upon the skill, superior knowledge and judgment of Defendants and upon the express warranty that Lipitor® (atorvastatin calcium) was of merchantable quality and safe and fit for its intended use.

136. Plaintiffs were prescribed, purchased and used Lipitor® (atorvastatin calcium) for its intended purpose.

137. Contrary to the express warranties for Lipitor® (atorvastatin calcium), it was not of merchantable quality and it was neither safe nor fit for its intended uses and purposes as alleged herein.

138. The harm caused by Lipitor® (atorvastatin calcium) far outweighed its benefit, rendering Lipitor® (atorvastatin calcium) more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

139. In addition, Defendants marketed and promoted Lipitor® (atorvastatin calcium) as safe and effective for use in lowering LDL and/or preventing cardiovascular disease when it was not.

140. Lipitor® (atorvastatin calcium) was used as a treatment of Plaintiffs in a reasonably foreseeable manner and in accordance with the normal, intended, recommended and/or marketed use of the product.

141. Neither Plaintiff nor Plaintiffs' health care professionals could have reasonably discovered or known of the risk of serious injury and/or death associated with Lipitor® (atorvastatin calcium) or of its lack of benefit for women.

142. As a direct and proximate result of Defendants' breach of express warranties, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss including incurring significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

143. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**SEVENTH CAUSE OF ACTION**  
**(Strict Products Liability-Breach of Implied Warranties)**

144. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

145. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Lipitor® (atorvastatin calcium), which is unreasonably dangerous and defective, thereby placing Lipitor® (atorvastatin calcium) into the stream of commerce.

146. At all times material hereto, Lipitor® (atorvastatin calcium) reached Plaintiffs without substantial change in the condition in which Lipitor® (atorvastatin calcium) left the possession of Defendants and was used in a manner which had been contemplated by Defendants.

147. When Defendants placed Lipitor® (atorvastatin calcium) into the stream of commerce, they knew it would be prescribed to lower an individual's LDL and/or as a primary prevention measure to decrease the risk of developing cardiovascular disease and Defendants impliedly warranted to Plaintiff and Plaintiffs' health care professionals that Lipitor® (atorvastatin calcium) was of merchantable quality and safe and fit for its intended purpose or use.

148. Lipitor® (atorvastatin calcium) was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Type 2 Diabetes and because it was of no demonstrated benefit for women using it a means of primary prevention of CVD.

149. Plaintiffs, individually and through their prescribing health care professionals, reasonably relied upon the skill, superior knowledge and judgment of Defendants and upon the implied warranties that Lipitor® (atorvastatin calcium) was of merchantable quality and fit for its intended purpose or use.

150. Plaintiffs were prescribed, purchased and used Lipitor® (atorvastatin calcium) for its intended purpose.

151. Contrary to the implied warranties for Lipitor® (atorvastatin calcium), it was not of merchantable quality and it was neither safe nor fit for its intended uses and purposes as alleged herein.

152. Defendants breached the warranties of merchantability and fitness for its particular purpose because Lipitor® (atorvastatin calcium) was unduly dangerous and caused undue injuries, including but not limited to Plaintiffs' developing Type 2 Diabetes.

153. The harm caused by Lipitor® (atorvastatin calcium) far outweighed its benefit, rendering Lipitor® (atorvastatin calcium) more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

154. In addition, Defendants marketed and promoted Lipitor® (atorvastatin calcium) as merchantable and safe for use in lowering LDL and/or preventing CVD when it was not.

155. Further, given the risks associated with Lipitor® (atorvastatin calcium), a reasonable manufacturer with Defendants' knowledge of the risks associated with the ingestion of Lipitor® (atorvastatin calcium) would not have marketed the product in the same condition as Defendants sold, marketed, promoted and/or distributed their products to the public including to Plaintiffs.

156. Lipitor® (atorvastatin calcium) was used as a treatment of Plaintiffs in a reasonably foreseeable manner and in accordance with the normal, intended, recommended and/or marketed use of the product.

157. Neither Plaintiffs nor Plaintiffs' health care professionals could have reasonably discovered or known of the risk of serious injury and/or death associated with Lipitor® (atorvastatin calcium) or its lack of benefit for women as a measure of primary prevention of CVD.

158. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss including incurring significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

159. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue

to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**EIGHTH CAUSE OF ACTION**  
**(Fraud and Misrepresentation)**

160. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

161. Defendants misrepresented to Plaintiffs, Plaintiffs' prescribing health care professionals, the healthcare industry and consumers the safety and effectiveness of Lipitor® (atorvastatin calcium) and/or fraudulently, intentionally and/or negligently concealed material information including adverse information regarding the safety and efficacy of Lipitor® (atorvastatin calcium).

162. Defendants made representations and actively concealed adverse information when they knew or should have known that Lipitor® (atorvastatin calcium) had defects, dangers and characteristics that were other than what they had represented to Plaintiffs and the healthcare industry generally.

163. Specifically, Defendants actively concealed from Plaintiffs, Plaintiffs' prescribing health care professionals, the healthcare industry and consumers that:

- a. Defendants and/or their predecessors were in possession of data demonstrating that Lipitor® (atorvastatin calcium) increases the risk of Type 2 Diabetes, increases the risk of increased blood glucose rising to levels diagnostic for Type 2 Diabetes and that the incidence of increased blood glucose was higher in women;

- b. The incidence of hyperglycemia found in the NDA clinical trials was at least three times higher in users of Lipitor® (atorvastatin calcium) as compared to placebo subjects but the labeling actively misrepresented the true incidence;
- c. There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Lipitor® (atorvastatin calcium) in women before and after its product launch;
- d. Lipitor® (atorvastatin calcium) was not fully and adequately tested by Defendants and/or their predecessor(s) for the risk of developing Type 2 Diabetes;
- e. Testing and studies by other entities as reported in the scientific literature have shown that the use of Lipitor® (atorvastatin calcium) increases the risk of Type 2 Diabetes;
- f. Although Pfizer relied on results from the ASCOT-LLA trial to obtain an indication for Lipitor® (atorvastatin calcium) as a means of primary prevention of CVD, that study did not demonstrate that the drug was effective for women and in fact showed that women who used Lipitor® (atorvastatin calcium) had a higher risk of CVD;
- g. Data from the ASCOT-LLA and TNT trials showed there was higher overall mortality in women using Lipitor® (atorvastatin calcium) and the TNT trial showed that in women who had never smoked (about a third of the women in the study) and women who used the higher dose of the drug had an eight-fold higher risk of non-cardiovascular mortality;
- h. In Japan, Pfizer changed the Lipitor® (atorvastatin calcium) label to advise health care professionals and consumers that diabetes was a “Clinically Significant Adverse Reaction” to the drug and that health care professionals should monitor their patients.
- i. Pfizer has warned about an increased risk of diabetes in its European labeling for Lipitor® (atorvastatin calcium) but has refused to warn about that risk in the United States.

164. These misrepresentations and/or the active concealment alleged were perpetuated directly and/or indirectly by Defendants.

165. Defendants knew or should have known that these representations were false and made the representations with the intent or purpose of deceiving Plaintiffs, Plaintiffs' prescribing health care professionals, the healthcare industry and consumers.

166. Defendants made these false representations with the intent or purpose that Plaintiffs, Plaintiffs' prescribing health care professionals, the healthcare industry and consumers would rely on these representations leading to the use of Lipitor® (atorvastatin calcium) by Plaintiffs as well as the general public.

167. At all times mentioned herein, neither Plaintiffs nor Plaintiffs' health care professionals were aware of the falsity of the statements being made by Defendants and believed them to be true. Had Plaintiffs or Plaintiffs' health care professionals been aware of said facts, Plaintiffs' health care professionals would not have prescribed Lipitor® (atorvastatin calcium) or Plaintiffs' health care professionals would have provided said facts to Plaintiffs and Plaintiffs would not have ingested Lipitor® (atorvastatin calcium).

168. Plaintiffs justifiably relied on, to their detriment, Defendants' fraudulent misrepresentations and/or the active concealment of safety information.

169. Defendants had a post-sale duty to warn Plaintiffs, Plaintiffs' prescribing health care professionals and the general public about the potential risks and complications associated with Lipitor® (atorvastatin calcium) in a timely manner.

170. Defendants made the misrepresentations and actively concealed information about the defects and dangers of Lipitor® (atorvastatin calcium) with the intent and specific desire that Plaintiffs' prescribing health care professionals and the consuming public would rely on such information, or the absence of information, in selecting Lipitor® (atorvastatin calcium) as a treatment.

171. As a result of Defendants' misrepresentations, concealment and/or suppression of information, Plaintiffs ingested Lipitor® (atorvastatin calcium) and suffered injuries as set forth herein.

172. As a direct and proximate result of Defendants' fraud and misrepresentation, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**NINTH CAUSE OF ACTION**  
**(Constructive Fraud)**

173. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

174. Defendants committed constructive fraud by knowingly making false and material representations with reckless disregard for the truth or falsity of such material representations and with the intent Plaintiffs and Plaintiffs' prescribing health care professionals and consumers would rely on those material representations.

175. Plaintiffs and Plaintiffs' prescribing health care professionals were unaware of the falsity of Defendants' material representations. Plaintiffs were injured as a direct and proximate result of the reliance on Defendants' material representations.

176. Additionally, Defendants knowingly omitted material information and remained silent despite the fact that they had a duty to inform Plaintiffs, Plaintiffs' prescribing health care professionals and the general public of the inaccuracy of these misrepresentations. This

omission constitutes a positive misrepresentation of material fact with the intent that Plaintiffs and Plaintiffs' prescribing health care professionals would rely on Defendant's misrepresentations. In fact, Plaintiffs and Plaintiffs' prescribing health care professionals acted with actual and justifiable reliance on Defendants' representations and Plaintiffs were injured as a result.

177. At all times herein mentioned, Defendants had a duty to Plaintiffs, Plaintiffs' prescribing health care professionals and the general public to accurately inform them of the risks associated with Lipitor® (atorvastatin calcium) and the lack of any demonstrated benefit for women using the drug for primary prevention because Defendant, as the manufacturer of Lipitor® (atorvastatin calcium), was in a position of superior knowledge and judgment regarding any potential risks associated with Lipitor® (atorvastatin calcium).

178. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiffs related to the use of Lipitor® (atorvastatin calcium) because of their propensity to deceive others or constitute an injury to public interests or public policy.

179. In breaching their duties to Plaintiffs, Defendants used their position of trust as the manufacturer of Lipitor® (atorvastatin calcium) to increase sales of the drug at the expense of informing Plaintiffs that, by ingesting Lipitor® (atorvastatin calcium), they were placing themselves at a significantly increased risk of developing Type 2 Diabetes.

180. As a direct and proximate result of Defendants' carelessness, negligence and fraud, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue

to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**TENTH CAUSE OF ACTION**  
**(Loss of Consortium)**

181. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

182. At all times herein mentioned, certain Plaintiffs were and are legally married as husband and wife.

183. As a direct and proximate result of the aforementioned conduct of Defendants and as a result of the injuries and damages to the Injured Plaintiffs, certain Plaintiffs have been deprived of the love, companionship, comfort, affection, society, solace or moral support, protection, loss of enjoyment of sexual relations and loss of physical assistance in the operation and maintenance of the home, of their spouse and has thereby sustained and will continue to sustain damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**ELEVENTH CAUSE OF ACTION**  
**(Wrongful Death)**

184. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

185. The Injured Party/Decedent was survived by heirs/beneficiaries at the time of her death.

186. As a result of the above-referenced negligent acts and omissions by Defendants, the Injured Party/Decedent suffered injuries, including but not limited to Type 2 Diabetes, which proximately caused Injured Party's/Decedent's wrongful death.

187. Further, as a result of the above-referenced negligent acts and omissions by Defendants, Injured Party/Decedent experienced conscious pain and suffering, trauma and wrongful death.

188. But for the above-referenced negligent acts and omissions by Defendants which proximately caused Injured Party's/Decedent's wrongful death, the Injured Party/Decedent would have alleged the above-referenced and foregoing causes of action on her own behalf.

189. Therefore, Plaintiff as the Administrator/Personal Representative/Executor of the Estate of the Injured Party/Decedent brings this action on behalf of Injured Party/Decedent for all of the above-referenced and foregoing causes of action.

190. Plaintiff as the Administrator/Personal Representative/Executor of the Estate of the Injured Party/Decedent further alleges that as a result of the death of the Injured Party/Decedent, Decedent's heirs/beneficiaries have suffered and will continue to suffer pecuniary loss, mental shock and suffering, wounded feelings, grief and sorrow, loss of companionship, deprivation of use and comfort of decedent's society; and economic losses including funeral expenses and other compensatory damages, all in addition to the

beneficiary's/heirs actual damages, and further are entitled to punitive damages in an amount to be determined by a jury for the unconscionable conduct as alleged herein.

191. All of the above-referenced acts and omissions are in violation of the common law and state statutes.

192. Plaintiff as the Administrator/Personal Representative/Executor of the Estate of the Injured Party/Decedent seeks recovery for conscious suffering, emotional pain, torment, trauma and wrongful death incurred as a result of the above-referenced acts and/or omissions.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

**TWELFTH CAUSE OF ACTION**  
**(Unjust Enrichment)**

193. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

194. Plaintiffs conferred a benefit on Defendants by purchasing Lipitor® (atorvastatin calcium).

195. Plaintiffs, however, did not receive the safe and effective drug for which Plaintiffs paid.

196. It would be inequitable for Defendants to retain this money because Plaintiffs did not, in fact, receive a safe and efficacious drug.

197. By virtue of the conscious wrongdoing alleged in this Master Long Form Complaint, Defendants have been unjustly enriched at the expense of Plaintiffs who hereby seek the disgorgement and restitution of Defendants' wrongful profits, revenue and benefits to the

extent and in the amount deemed appropriate by the Court and for such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

198. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

#### **PUNITIVE DAMAGES**

199. Plaintiffs repeat and re-allege all of the above paragraphs and all subsequent paragraphs as if each were set forth herein verbatim.

200. At all times material hereto, Defendants knew or should have known that Lipitor® (atorvastatin calcium) was inherently dangerous with respect to the risk of diabetes.

201. At all times material hereto, Defendants attempted to misrepresent and did misrepresent the facts concerning the safety and efficacy of Lipitor® (atorvastatin calcium).

202. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs, concerning the safety of Lipitor® (atorvastatin calcium).

203. At all times material hereto, Defendants knew and recklessly disregarded the fact that Lipitor® (atorvastatin calcium) causes the chronic illness, Type 2 Diabetes.

204. Notwithstanding the foregoing, Defendants continued to aggressively market Lipitor® (atorvastatin calcium) to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

205. Defendants knew of the lack of warnings regarding the risk of Type 2 Diabetes associated with the use of Lipitor® (atorvastatin calcium), but Defendants intentionally concealed and/or recklessly failed to disclose that risk and continued to manufacture, package, label, market/promote, distribute and sell Lipitor® (atorvastatin calcium) without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious and/or negligent disregard of the foreseeable harm caused by Lipitor® (atorvastatin calcium).

206. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using Lipitor® (atorvastatin calcium) against its benefits.

207. Lipitor® (atorvastatin calcium) represented twenty-five (25) percent of Pfizer's annual revenue between 2001 and 2011.

208. Pfizer spent approximately \$1.5 billion in advertising directly to consumers, such as Plaintiffs.

209. Prior to the expiration of the patent for Lipitor® (atorvastatin calcium), Pfizer spent over \$600 million annually to market the drug.

210. Had Defendants fulfilled their obligations to health care professionals and consumers, including Plaintiffs, by accurately providing the risks and efficacy of Lipitor® (atorvastatin calcium), Defendants would have lost revenue and market share.

211. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiffs suffered severe and permanent physical and emotional injuries including but not limited to Type 2 Diabetes. Plaintiffs have endured pain and suffering, have suffered economic loss (including incurring significant expenses for medical care and treatment) and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

212. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton and deliberate disregard for the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues contained herein be tried by a jury.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

- a. For compensatory and general damages in a sum in excess of the jurisdictional minimum of this Court;
- b. For past and future medical, incidental and hospital expenses according to proof;
- c. For past and future pain and suffering, mental anguish and diminished enjoyment of life;

- d. For pre-judgment and post-judgment interest as provided by law;
- e. For full refund of all purchase costs Plaintiff paid for Lipitor® (atorvastatin calcium);
- f. For past and future loss of earnings and/or earning capacity, according to proof;
- g. For consequential damages in excess of the jurisdictional minimum of this Court;
- h. For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
- i. For attorneys' fees, expenses and costs of this action;
- j. Damages for loss of consortium;
- k. Damages for wrongful death; and
- l. For such further relief as this Court deems necessary, just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs demand a trial by jury on all counts and as to all issues.

Respectfully Submitted:  
*Plaintiffs' Executive and Steering Committees*

/s/ H. Blair Hahn  
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Dated: May 30, 2014.

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was served electronically upon all counsel via the Court's electronic case filing system, CM/ECF, on May 30, 2014.

s/ H. Blair Hahn

H. Blair Hahn