IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

NAOMI MALLORY	)	
	)	CASE NO. _____
Plaintiff,	)	
v.	)	
	)	COMPLAINT AND DEMAND
PFIZER INC.,	)	FOR JURY TRIAL
Defendant.	)	

The Plaintiff, Naomi Mallory ("Plaintiff"), residing in Stanwood, Washington by and through her undersigned attorneys, hereby sues the Defendant, Pfizer Inc. ("Defendant" or "Pfizer"), which has its principal place of business at 235 East 42nd Street, New York, New York 10017, and alleges as follows:

BACKGROUND

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendant's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of LIPITOR (also known as ATORVASTATIN CALCIUM and at times referred to herein as "the subject product").

PARTIES

2. Plaintiff is a natural person and resident of the State of Washington.

3. At all times relevant to this action, Plaintiff was a resident and citizen of Vernon, Connecticut and Stanwood, Snohomish County, Washington.

Thus, Snohomish County, State of Washington, is where Plaintiff is domiciled and where Plaintiff continues to reside.

4. At all times herein mentioned, Defendant was and is a corporation existing under the laws of incorporation of the State of Delaware, with its principal place of business in New York, New York, and doing business within this judicial district.

5. At all times herein mentioned, Defendant Pfizer, in interstate commerce and in this judicial district, advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public a certain pharmaceutical product, LIPITOR.

JURISDICTION AND VENUE

6. This Court has jurisdiction over Defendant and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy between Plaintiff and Defendant exceeds $150,000, exclusive of interest and cost, and because, among other reasons, Defendant has significant contacts with this district by virtue of doing business within this judicial district.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendant is subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c) and because a substantial part of the events giving rise to Plaintiff's claims occurred in this jurisdiction.

8. This action includes claims for injuries to Plaintiff caused by the use of the pharmaceutical drug Lipitor and therefore should be transferred to Multi-District Litigation No. 2502 - *In Re: Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation*, United States District Court for the District of South Carolina, the Honorable Richard M. Gergel.

FACTUAL ALLEGATIONS

9. At all times herein mentioned, Defendant, by and through its agents, servants, and/or employees failed to adequately warn physicians and consumers, including Plaintiff herein, of the risk of developing diabetes from LIPITOR.

10. LIPITOR is an HMG-CoA reductase inhibitor and a member of the drug class known as statins.

11. LIPITOR is prescribed to reduce the amount of cholesterol and other fatty substances in the blood.

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

13. Despite its knowledge of data indicating that LIPITOR is causally related to the development of type II diabetes and/or blood glucose levels diagnostic

for type II diabetes, Pfizer promoted and marketed LIPITOR as safe and effective for persons such as Plaintiff in the United States as well as in this judicial district.

14. On August 11, 2011, the Division of Metabolism and Endocrinology Products of the FDA requested that Defendant make labeling changes for LIPITOR based upon the FDA's comprehensive review, including clinical trial data.

15. In February 2012, in response to the FDA's request, Pfizer 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."

16. Until the February 2012 change, LIPITOR's label had never warned patients of any potential relation between changes in blood sugar levels and taking LIPITOR.

17. Despite the February 2012 label change, LIPITOR's label continues to fail to warn consumers of the serious risk of developing type II diabetes when using LIPITOR.

18. At all times material hereto, Defendant knew or should have known that the risks of LIPITOR included the severe and life-threatening complications of type II diabetes.

19. At all times material hereto, Defendant, by and through its agents, servants, and/or employees, negligently, recklessly and/or carelessly marketed, distributed, and/or sold LIPITOR without adequate instructions or warnings of the drug's serious side effects and unreasonably dangerous risks.

20. Plaintiff was prescribed LIPITOR and began using it as directed in approximately 1998.

21. Plaintiff was prescribed LIPITOR to lower her levels of low-density lipoprotein ("LDL") and as a primary prevention measure to decrease her risk of developing cardiovascular disease ("CVD").

22. Plaintiff was healthy prior to taking LIPITOR. She was physically active, adhered to a healthy diet, and had a total body mass index of approximately 26.1. She suffered from no chronic injuries or illnesses.

23. In keeping with her healthy and proactive lifestyle, Plaintiff agreed to initiate LIPITOR treatment in an effort to reduce her risk of developing heart disease. She relied on claims made by Pfizer that LIPITOR has been clinically shown to reduce the risk of developing heart disease.

24. Despite her healthy diet, Plaintiff developed type II diabetes after initiating LIPITOR treatment.

25. Plaintiff was diagnosed with type II diabetes in or about March 2003. As a result, for the rest of her life she must undergo regular testing of her blood glucose levels, adhere to a restrictive diabetic diet, and take medication to control her diabetes. Due to her diabetes, she is now at markedly increased risk of heart disease, blindness, neuropathy, and kidney disease.

26. Had Defendant properly disclosed the risks associated with LIPITOR, Plaintiff would have avoided the risk of diabetes by either not using LIPITOR at all

or by closely monitoring her blood glucose levels to see if the drug was adversely affecting her metabolism.

27. As alleged herein, as a direct, proximate, and legal result of Defendant's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug LIPITOR, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to type II diabetes. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

28. Plaintiff did not discover, nor did she have any reason to discover her diabetes was a result of a defective product and/or the wrongful conduct of Defendant, as set forth herein, until at least sometime in or about 2013.

CAUSES OF ACTION

COUNT I
CONNECTICUT PRODUCT LIABILITY ACT – STRICT LIABILITY

29. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

30. At all relevant times, Defendant was engaged in the business of designing, manufacturing, distributing and/or selling LIPITOR, a prescription statin used for the treatment of hypercholesterolemia.

31. At all relevant times, LIPITOR was associated with the increased risk of developing adverse effects, including but not limited to type II diabetes, that

could result in death, and that risk outweighed its benefit for the treatment of hypercholesterolemia.

32. At all relevant times, this risk was beyond that which would be contemplated by the ordinary physician who prescribed LIPITOR, and the ordinary consumer who purchased LIPITOR.

33. At all relevant times, Plaintiff and her treating physicians were unaware of this risks associated with LIPITOR.

34. At all relevant times, practical and medically-feasible alternate cholesterol-lowering medications that did not include an increased risk of serious adverse effects were available.

35. For these reasons, at all relevant times, Lipitor was unreasonably dangerous, and thus defective.

36. Plaintiff's treating physicians prescribed LIPITOR, to treat Plaintiff's hypercholesterolemia.

37. All of the LIPITOR that Plaintiff purchased and ingested was unreasonably dangerous and thus defective at the time she purchased it, for the reasons described above.

38. All of the LIPITOR that Plaintiff purchased and ingested was expected to and did reach Plaintiff without substantial change in the unreasonably dangerous and defective condition in which it was when it left the hands of Defendant.

39. Plaintiff took LIPITOR in the intended and prescribed manner.

40. On approximately March 3, 2003, as a direct and proximate result of taking LIPITOR, Plaintiff was diagnosed with type II diabetes.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in her favor for compensatory, treble, 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 herein contained be tried by a jury.

COUNT II
CONNECTICUT PRODUCT LIABILITY ACT – NEGLIGENCE

41. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

42. At all relevant times, Defendant was engaged in the business of designing, manufacturing, testing, studying, distributing and/or selling LIPITOR.

43. At all relevant times, Defendant had a duty to exercise reasonable care to carefully and properly design, manufacture, test, study, distribute and/or sell LIPITOR as a reasonably safe prescription drug.

44. Defendant breached that duty, because all of the LIPITOR that it designed, manufactured, tested, studied, distributed and/or sold was unreasonably dangerous and defective, for the reasons described above.

45. At all relevant times, Defendant had a duty to exercise reasonable care to conduct post-marketing studies, tests, surveillance and analyses to determine the safety profile and side effects of LIPITOR.

46. Defendant breached that duty, because it failed to timely conduct adequate studies, tests, surveillance and analyses to confirm that LIPITOR was associated with an unreasonably increased risk of developing serious adverse side effects that could result in type II diabetes and death.

47. At all relevant times, Defendant had a duty to assess the risks and adverse effects associated with LIPITOR and suspend its distribution and sale of LIPITOR if it discovered the drug to be unreasonably dangerous and defective.

48. Defendant breached that duty, because it failed to timely suspend its distribution and sale of LIPITOR once it discovered or should have discovered that LIPITOR was an unreasonably dangerous and defective drug, especially in light of the fact that safer alternatives were available.

49. If Defendant had not breached each of these duties, its LIPITOR would not have been on the market to be prescribed by Plaintiff's physician, and Plaintiff would not have been able to purchase or ingest LIPITOR, and would not have suffered type II diabetes.

50. Because the product was on the market, however, Plaintiff was prescribed LIPITOR, and purchased and ingested LIPITOR in a reasonably foreseeable manner and substantially as intended by Defendants, and as a direct and proximate result, suffered severe adverse effects.

51. At all relevant times, Defendant had a duty to assess, manage and communicate the risks, dangers and adverse effects associated with LIPITOR and its generic equivalents to the health care community and the general public.

52. At all relevant times, Defendant had a duty to distribute LIPITOR with adequate information to the general public and the health care community regarding the appropriate use of the product and its associated risks.

53. Before Plaintiff was prescribed LIPITOR, Defendant knew or should have known that it had not been adequately tested.

54. Defendant should have, but failed to, start investigating the link between LIPITOR and the development of type II diabetes before the FDA ordered such an investigation.

55. Had Defendant started to investigate the link between LIPITOR and type II diabetes on a timely basis, the associated risks would have been confirmed in time to prevent Plaintiff from being prescribed LIPITOR, from purchasing and ingesting LIPITOR, and from suffering the injuries described above.

56. Before Plaintiff was prescribed LIPITOR, Defendant knew or had reason to know that LIPITOR was associated with a greatly increased risk of developing type II diabetes.

57. Before Plaintiff was prescribed LIPITOR, Defendant knew or had reason to know that persons taking LIPITOR should be subject to more comprehensive and regular medical monitoring to ensure early discovery of potentially serious side effects.

58. Defendant failed to alert the general public and the health care community – including Plaintiff and her prescribing physicians – to the lack of adequate testing, the greatly increased risk of potential adverse effects, including

but not limited to type II diabetes, and the need for more comprehensive and regular medical monitoring that were associated with the use of LIPITOR.

59. Defendant instead downplayed the risks associated with LIPITOR in its promotional materials, instructional materials, labeling for, and communications about LIPITOR, which was especially misleading given its past and continued efforts to promote the safety and effectiveness of the drug.

60. Defendant should have anticipated that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware of the greatly increased risk of potential adverse events associated with the use of LIPITOR, absent its provision of warnings, because the general public and the health care community did not have access to the same resources as Defendant.

61. Had Defendant provided adequate warnings, Plaintiff's physicians would not have prescribed LIPITOR for her, and would have instead prescribed another treatment for hypercholesterolemia that did not include an increased risk of serious injury.

62. Had Defendant provided adequate warnings, Plaintiff would not have purchased or ingested LIPITOR, and would not have developed type II diabetes.

63. In the alternative, had Defendant provided adequate warnings, Plaintiff would have been subjected to more comprehensive and regular medical monitoring, and her injuries could have been discovered and treated in time to prevent type II diabetes.

64. The Plaintiff's injuries were the direct and proximate result of Defendant's failure to warn of the dangers associated with the use of LIPITOR.

65. It was foreseeable that persons like Plaintiff who ingested LIPITOR would, as a direct and proximate result, suffer from adverse effects, including but not limited to type II diabetes.

66. In light of this, Defendant should have anticipated that serious adverse effects were a likely result of the actions and omissions described above.

67. Defendant's actions and omissions were the direct and proximate cause of Plaintiff's type II diabetes.

68. Defendant knowingly risked the lives of the unsuspecting users of a product that it knew to be unreasonably dangerous and defective in order to continue making a profit, and its conduct thus was extreme and outrageous, and warrants an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests this Court enter judgment in her favor for compensatory, treble, 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 herein contained be tried by a jury.

COUNT III
CONNECTICUT PRODUCT LIABILITY ACT – FAILURE TO WARN

69. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

70. At all relevant times, Defendant was engaged in the business of designing, manufacturing, testing, studying, packaging, distributing, selling, marketing and/or promoting LIPITOR, a cholesterol-lowering medication.

71. At all relevant times, Defendant had a duty to assess, manage and communicate the risks, dangers and adverse effects associated with LIPITOR to the health care community and the general public.

72. At all relevant times, Defendant had a duty to distribute LIPITOR with adequate information provided to the general public and the health care community regarding the appropriate use of the product and its associated risks.

73. Before Plaintiff was prescribed LIPITOR, Defendant knew or should have known that LIPITOR had not been adequately tested.

74. Before Plaintiff was prescribed LIPITOR, Defendant knew or had reason to know that LIPITOR was associated with a greatly increased risk of potential adverse events, including but not limited to the development of type II diabetes.

75. Before Plaintiff was prescribed LIPITOR, Defendant knew or had reason to know that persons taking LIPITOR should be subject to more comprehensive and regular medical monitoring to ensure early discovery of potentially serious side effects.

76. Defendant failed to alert the general public and the health care community – including Plaintiff and her prescribing physicians – to the lack of adequate testing, the greatly increased risk of potential adverse events, and the

need for more comprehensive and regular medical monitoring that were associated with the use of LIPITOR.

77. It would have been technologically feasible, and would not have been cost-prohibitive, for Defendant to include adequate warnings and instructions in its marketing and labeling materials, and in its communications to the general public and the health care community.

78. Defendant instead used its resources to downplay the risks associated with LIPITOR in its promotional materials, instructional materials, labeling for, and communications about LIPITOR, which was especially misleading given its past and continued efforts to promote the safety and effectiveness of the drug.

79. Defendant should have anticipated that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware of the greatly increased risk of potential adverse events associated with the use of LIPITOR, absent its provision of warnings, because the general public and the health care community did not have access to the same resources as Defendant.

80. Defendant should have anticipated that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware that persons taking LIPITOR should be subject to more comprehensive and regular medical monitoring to ensure early discovery of potentially serious side effects.

81. Had Defendant provided adequate warnings, Plaintiff's physicians would not have prescribed LIPITOR for her, and would have instead prescribed another treatment for hypercholesterolemia that did not include an increased risk of serious injuries that could cause death.

82. Had Defendant provided adequate warnings, Plaintiff would not have purchased or ingested LIPITOR, and would not have developed type II diabetes.

83. In the alternative, had Defendant provided adequate warnings, Plaintiff would have been subjected to more comprehensive and regular medical monitoring, and treated in time to prevent her from developing type II diabetes.

84. The Plaintiff's injuries were the direct and proximate result of Defendant's failure to warn of the dangers of LIPITOR.

85. It was foreseeable that persons like Plaintiff who ingested LIPITOR would, as a direct and proximate result, develop type II diabetes and suffer injuries associated with the condition.

86. In light of this, Defendant should have anticipated that serious side effects that could result in the development of type II diabetes were a likely result of the actions and omissions described above.

87. Defendant's actions and omissions were the direct and proximate cause of Plaintiff's development of type II diabetes.

88. By failing to provide adequate warnings and instructions, Defendant knowingly risked the lives of the unsuspecting users of a product that it knew to be unreasonably dangerous and defective in order to continue making a profit, and its

conduct thus was extreme and outrageous, and warrants an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests this Court enter judgment in her favor for compensatory, treble, 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 herein contained be tried by a jury.

COUNT IV
CONNECTICUT PRODUCT LIABILITY ACT – STATUTORY NEGLIGENCE

89. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

90. Under the doctrine of negligence *per se,* otherwise known as statutory negligence, the duty of Defendant to exercise reasonable care included the obligation to conform its products and activities related to those products to safety standards imposed by applicable statutes or regulations.

91. An applicant such as Defendant who submits an NDA is required to fully, truthfully and accurately disclose to the FDA, with its application, and periodically at other times thereafter, data and information regarding the drug's chemistry, pharmacology, and other matters, including its proposed labeling.

92. The FDA, as a condition for approval of the NDA, must be satisfied that the proposed labeling includes data and information about risks and side effects, test results for the drug, results of animal and clinical studies, the drug's

bioavailability, and other matters, adequate to enable physicians or other foreseeable prescribers to use the drug safely.

93. Federal law requires one who owns an FDA-approved NDA to ensure at all times that the drug's labeling is and remains accurate and adequate, to conduct safety surveillance of adverse events for the drug, and to periodically and at other times report to the FDA data related to the safety of the drug and/or the accuracy of the labeling.

94. As holders of the NDA for LIPITOR, Defendant is and has been required by federal law to ensure continuously that the labeling for their product contains accurate information that would constitute adequate warnings for any medical providers who would read the labeling about the drug's intended uses, to conduct post-marketing safety surveillance, and to review all adverse drug event information.

95. Defendant was required by federal law, to report in the LIPITOR product labeling, significant information discovered in the course of the fulfillment of its obligations bearing on the risk and/or prevalence of side effects caused by the drug.

96. At all relevant times, Defendant either affirmatively decided not to engage in active investigation of the risks associated with LIPITOR so it would not have to edit its label, or failed to edit its label to include risks about which it knew or should have known.

97. Defendant also violated federal standards for the sale of prescription drugs set forth in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, because:

a. LIPITOR was adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities or controls used for its manufacture, packing, storage or installation were not in conformity with federal requirements.

b. LIPITOR was adulterated pursuant to 21 U.S.C. § 351 because, among other things, its quality fell below the standard set forth in the official compendium for LIPITOR and such deviations were not plainly stated in its label.

c. LIPITOR was misbranded pursuant to 21 U.S.C. § 352 because, among other things, its labeling was false or misleading.

d. LIPITOR was misbranded pursuant to 21 U.S.C. § 352 because words, statements or other information required by or under authority of that section were not prominently placed thereon with such conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. LIPITOR was misbranded pursuant to 21 U.S.C. § 352 because the labeling did not bear adequate directions for use, and/or the labeling did not bear adequate warnings against use where its use may have been dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as were necessary for the protection of users.

f. LIPITOR was misbranded pursuant to 21 U.S.C. § 352 because it was dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. LIPITOR did not contain adequate directions for use pursuant to 21 U.S.C. § 201.5 because, among other reasons, of omission, in whole or in part, or incorrect specification of statements of all conditions, purposes, or use for which it was intended, including conditions, purposes, or use for which it was prescribed,

recommended or suggested in its oral, written, printed or graphic advertising, and conditions, purposes or uses for which the drug was commonly used.

h. LIPITOR's labeling was not informative and accurate as required by 21 C.F.R. § 201.56.

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

j. Defendant failed to provide information that was important to the safe and effective use of LIPITOR, including the need for regular and/or consistent monitoring to ensure that a potential fatal adverse event had not developed, as required by 21 C.F.R. § 201.57.

k. Defendant failed to identify specific tests needed to select or monitor patients who took LIPITOR, as required by 21 C.F.R. § 201.57.

l. Defendant failed to state that the safety considerations for LIPITOR are such that the drug should be reserved for certain situations, as required by 21 C.F.R. § 201.57.

m. LIPITOR was mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling failed to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

n. LIPITOR was mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. Defendant failed to list the adverse reactions that occurred with LIPITOR and other drugs in the same pharmacologically active and chemically related class, as required by 21 C.F.R. § 201.57.

p. Defendant did not list the possibility that a patient could develop type II diabetes and this was not listed before other serious adverse reactions on the labeling of LIPITOR, as required by 21 C.F.R. § 201.57.

q. LIPITOR was mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. LIPITOR violated 21 C.F.R. § 210.1 because the process by which it was manufactured, processed, and/or held failed to meet the minimum current good manufacturing practices of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it met the requirements as to safety and had the identity and strength and met the quality and purity characteristics that they were purported or represented to have.

s. LIPITOR violated 21 C.F.R. § 210.122 because the labeling and packaging materials did not meet the appropriate specifications.

t. LIPITOR violated 21 C.F.R. § 211.165 because the test methods employed by Defendant were not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity and/or reproducibility of test methods had not been properly established and documented.

u. LIPITOR violated 21 C.F.R. § 211.165 because it failed to meet established standards or specifications and any other relevant quality control criteria.

v. LIPITOR violated 21 C.F.R. § 211.198 because the written procedures describing the handling of all written and oral complaints were not followed.

w. LIPITOR violated 21 C.F.R. § 310.303 because it was not safe and effective for its intended use.

x. Defendant violated 21 C.F.R. § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there were or might have been grounds for suspending or withdrawing approval of the application for LIPITOR to the FDA.

y. Defendant violated 21 C.F.R. §§ 310.305 and 314.80 by failing to report adverse events associated with LIPITOR as soon as

possible or at least within 15 days of its initial receipt of the adverse drug experience information.

z. Defendant violated 21 C.F.R. §§ 310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with LIPITOR and its cause.

aa. Defendant violated 21 C.F.R. §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed fifteen calendar days of receipt of new information or as requested by the FDA.

bb. Defendant violated 21 C.F.R. §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek information regarding serious, unexpected adverse events.

cc. Defendant violated 21 C.F.R. §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report" or "15-day Alert report follow up."

dd. Defendant violated 21 C.F.R. § 312.32 by failing to review all information relevant to the safety of LIPITOR, regardless of the source, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experiences, reports in scientific literature, unpublished scientific papers, and reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. Defendant violated 21 C.F.R. § 314.80 by failing to provide periodic reports to the FDA containing (1) a narrative summary and analysis of the information in the report and an analysis of the 15-Day Alert Reports submitted during the reporting interval, (2) an Adverse Reaction Report for each adverse drug experience not already reported under the Post-Marketing 15-Day Alert Report, and/or (3) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. Defendant violated 21 C.F.R. § 314.80 by failing to submit a copy of published articles from scientific or medical journals along with one or more 15-Day Alert Reports based on information from the scientific literature.

98. Such violations constitute a breach of duty of reasonable care toward Plaintiff that would subject Defendant to civil liability for personal injuries proximately caused by the violation.

99. As a lawful consumer of LIPITOR, Plaintiff was within the class of persons the statutes and regulations described above were designed to protect, and her injuries were the type of harm they were intended to prevent.

100. As a direct and proximate cause of the violations of these statutes and regulations by Defendant, which therefore constitute negligent *per se* acts and/or omissions, Plaintiff suffered the injuries set forth in this Complaint.

WHEREFORE, Plaintiff respectfully requests this Court enter judgment in her favor for compensatory, treble, 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 herein contained be tried by a jury.

COUNT V
CONNECTICUT PRODUCT LIABILITY ACT– NEGLIGENT MISREPRESENTATION

101. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

102. At all relevant times, Defendant was engaged in the business of designing, manufacturing, testing, studying, packaging, distributing, selling, marketing and/or promoting LIPITOR.

103. At all relevant times, Defendant had a duty to assess, manage and communicate the risks, dangers and adverse effects associated with LIPITOR to the health care community and the general public.

104. At all relevant times, Defendant had a duty to distribute LIPITOR with adequate information provided to the general public and the health care community regarding the appropriate use of the product and its associated risks.

105. Before Plaintiff was prescribed LIPITOR, Defendant knew or should have known that LIPITOR had not been adequately tested.

106. Before Plaintiff was prescribed LIPITOR, Defendant knew or had reason to know that LIPITOR was associated with a greatly increased risk of potential adverse events, including but not limited to the development of type II diabetes.

107. Before Plaintiff was prescribed LIPITOR, Defendant knew or had reason to know that persons taking LIPITOR should be subjected to more comprehensive and regular medical monitoring to ensure early discovery of potentially serious side effects.

108. Before Plaintiff was prescribed LIPITOR, Defendant knew or had reason to know that LIPITOR was no more effective for the treatment of hypercholesterolemia than other prescription medications used for this purpose.

109. Despite this, Defendant represented to the general public and the health care community that LIPITOR had been tested and found to be safe and effective for the treatment of hypercholesterolemia.

110. Despite this, Defendant also represented to the general public and the health care community that LIPITOR was more effective for the treatment of hypercholesterolemia other prescription medications.

111. These representations made by Defendant were false.

112. Defendant failed to exercise reasonable care or competence in making these misrepresentations, because it knew or should have known that LIPITOR had not been adequately tested, that LIPITOR was associated with a high risk of unreasonably dangerous side effects that outweighed the benefits, and that LIPITOR was no more effective for the treatment of hypercholesterolemia than other prescription medications.

113. Defendant should have anticipated that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware that its statements about the testing, safety and effectiveness associated with LIPITOR were false, because the general public and the health care community did not have access to the same resources as Defendant.

114. Defendant should have anticipated that the general public and the health care community – including Plaintiff and her prescribing physicians – would have reasonably and justifiably relied on Defendant's representations about the testing, safety and effectiveness associated with LIPITOR, because Defendant was the manufacturer, seller and distributor of LIPITOR, and would therefore be assumed to have superior knowledge about it.

115. Plaintiff and her treating physicians justifiably relied on Defendant's representations.

116. Had Defendant not made these misrepresentations, Plaintiff's physicians would not have prescribed LIPITOR for her, and would have instead prescribed another treatment that did not involve an increased risk of developing type II diabetes.

117. Had Defendant not made these misrepresentations, Plaintiff would not have purchased or ingested LIPITOR, and would not have developed type II diabetes.

118. In the alternative, had Defendant not made these misrepresentations, Plaintiff would have been subjected to more comprehensive and regular medical monitoring, and she could have prevented developing type II diabetes.

119. The Plaintiff's injuries were the direct and proximate result of Defendant's misrepresentations about the testing, safety and efficacy associated with LIPITOR.

120. By misrepresenting the testing, safety and efficacy associated with LIPITOR, Defendant knowingly risked the lives of the unsuspecting users of a product that it knew to be unreasonably dangerous and defective in order to continue making a profit, and its conduct thus was extreme and outrageous, and warrants an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests this Court enter judgment in her favor for compensatory, treble, 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 herein contained be tried by a jury.

COUNT VI
CONNECTICUT PRODUCT LIABILITY ACT – FRAUDULENT MISREPRESENTATION

121. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

122. At all relevant times, Defendant was engaged in the business of designing, manufacturing, testing, studying, packaging, distributing, selling, marketing and/or promoting LIPITOR.

123. At all relevant times, Defendant had a duty to assess, manage and communicate the risks, dangers and adverse effects associated with LIPITOR to the health care community and the general public.

124. At all relevant times, Defendant had a duty to distribute LIPITOR with adequate information provided to the general public and the health care community regarding the appropriate use of the product and its associated risks.

125. Before Plaintiff was prescribed LIPITOR, Defendant knew that it had not been adequately tested.

126. Before Plaintiff was prescribed LIPITOR, Defendant knew that LIPITOR was associated with a greatly increased risk of potentially fatal adverse events.

127. Before Plaintiff was prescribed LIPITOR, Defendant knew that persons taking it should be subjected to more comprehensive and regular medical monitoring to ensure early discovery of potentially serious side effects.

128. Before Plaintiff was prescribed LIPITOR, Defendant knew that LIPITOR was no more effective for the treatment of type II diabetes than other medications.

129. Despite this knowledge, Defendant represented to the general public and the health care community that LIPITOR had been tested and found to be safe and effective.

130. Despite this knowledge, Defendant also represented to the general public and the health care community that LIPITOR was more effective for the treatment of hypercholesterolemia than other medications.

131. These representations were made in reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media.

132. These representations were false and misleading, and Defendant knew that they were false and misleading, and willfully, wantonly and recklessly disregarded that they were false.

133. Defendant made these misrepresentations with the intent of inducing the general public and the health care community to rely on them, so that medical providers would prescribe LIPITOR and consumers would purchase and ingest LIPITOR.

134. Defendant knew that the general public and the health care community – including Plaintiff and her treating physicians – would justifiably rely on its misrepresentations about LIPITOR, because Defendant was the manufacturer, seller and distributor of LIPITOR, and would therefore be assumed to have superior knowledge about it, and because the general public and the health care community did not have access to the same resources as Defendant.

135. Plaintiff and her treating physicians justifiably relied and acted upon Defendant's misrepresentations.

136. Based on Defendant's misrepresentations, Plaintiff's physicians prescribed LIPITOR for Plaintiff.

137. Had Defendant not made these misrepresentations, Plaintiff's physicians would not have prescribed LIPITOR for her, and would have instead prescribed another medication for the treatment of hypercholesterolemia that did not increase the risk of developing type II diabetes.

138. Based on Defendant's misrepresentations, Plaintiff purchased and ingested LIPITOR.

139. Had Defendant not made these misrepresentations, Plaintiff would not have purchased or ingested LIPITOR, and would not have developed type II diabetes.

140. Plaintiff's injuries were the direct and proximate result of Defendant's misrepresentations about the testing, safety and efficacy associated with LIPITOR.

141. By misrepresenting the testing, safety and efficacy associated with LIPITOR, Defendant knowingly, intentionally and unconscionably risked the lives of the unsuspecting users of a product that it knew to be unreasonably dangerous and defective in order to deceive and induce the general public and the health care community to act so that it could continue making a profit, and its conduct thus was extreme and outrageous, and warrants an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests this Court enter judgment in her favor for compensatory, treble, 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 herein contained be tried by a jury.

COUNT VII
CONNECTICUT PRODUCT LIABILITY ACT – FRAUDULENT NONDISCLOSURE

142. Plaintiff incorporates each paragraph of this Complaint as if set forth fully here, and further alleges as follows.

143. At all relevant times, Defendant was engaged in the business of designing, manufacturing, testing, studying, packaging, distributing, selling, marketing and/or promoting LIPITOR.

144. At all relevant times, Defendant had a duty to assess, manage and communicate the risks, dangers and adverse effects associated with LIPITOR to the health care community and the general public.

145. At all relevant times, Defendant had a duty to distribute LIPITOR with adequate information provided to the general public and the health care community regarding the appropriate use of the product and its associated risks.

146. Before Plaintiff was prescribed LIPITOR, Defendant knew that LIPITOR had not been adequately tested.

147. Before Plaintiff was prescribed LIPITOR, Defendant knew that LIPITOR was associated with a greatly increased risk of adverse events including but not limited to the development of type II diabetes..

148. Before Plaintiff was prescribed LIPITOR, Defendant knew that persons taking LIPITOR should be subject to more comprehensive and regular medical monitoring to ensure early discovery of potentially serious side effects.

149. Defendant failed to alert the general public and the health care community – including Plaintiff and her prescribing physicians – to the lack of adequate testing, the greatly increased risk of potentially fatal adverse, and the need for more comprehensive and regular medical monitoring associated with the use of LIPITOR.

150. Defendant instead used its resources to downplay the risks associated with LIPITOR in its promotional materials, instructional materials, labeling for, and communications about LIPITOR, which was especially misleading given its past and continued efforts to promote the safety and effectiveness of the drug.

151. Defendant knew that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have

been aware of the lack of adequate testing, the greatly increased risk of potentially fatal adverse events, and the need for more comprehensive and regular medical monitoring associated with the use of LIPITOR, because the general public and the health care community did not have access to the same resources as Defendant.

152. Defendant knew that the general public and health care community, including Plaintiff and her prescribing physicians, would have reasonably and justifiably relied on Defendant to advise them about the state of testing, safety and effectiveness associated with propoxyphene-related drugs such as LIPITOR, because Defendant was the manufacturer, seller and distributor of LIPITOR, and would therefore be assumed to have superior knowledge about it.

153. Defendant failed to disclose the material information outlined above because it wanted the general public and the health care community to believe that LIPITOR was safe and effective, and wanted to induce medical providers to prescribe LIPITOR and consumers to purchase and ingest it.

154. Plaintiff and her physicians justifiably relied on the lack of information about the safety risks involved with LIPITOR, and acted upon them, by Plaintiff's physicians prescribing LIPITOR, and Plaintiff purchasing and ingesting LIPITOR.

155. Had Defendant provided adequate warnings, Plaintiff's physicians would not have prescribed LIPITOR for her, and would have instead prescribed another medication that did not include an increased risk of developing type II diabetes.

156. Had Defendant provided adequate warnings, Plaintiff would not have purchased or ingested LIPITOR, and would not have developed type II diabetes.

157. In the alternative, had Defendant provided adequate warnings, Plaintiff would have been subjected to more comprehensive and regular medical monitoring, and her injuries could have been discovered and treated in time to prevent her from developing type II diabetes.

158. The Plaintiff's injuries were the direct and proximate result of Defendant's nondisclosure of the dangers associated with LIPITOR.

159. By failing to disclose the dangers associated with LIPITOR, Defendant knowingly risked the lives of the unsuspecting users of a product that it knew to be unreasonably dangerous and defective in order to continue making a profit, and its conduct thus was extreme and outrageous, and warrants an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests this Court enter judgment in her favor for compensatory, treble, 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 herein contained be tried by a jury.

PRAYER FOR RELIEF

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

(a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For prejudgment and post judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for LIPITOR;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendant the seriousness of its conduct and to deter similar conduct in the future;

(h) For attorneys' fees, expenses, and costs of this action; and

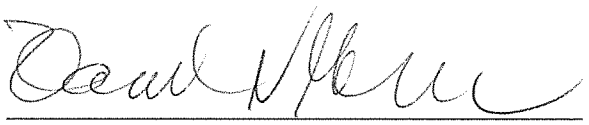
(i) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

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

Date: February 26, 2014

Respectfully Submitted,



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