UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
NORTHERN DIVISION

BILLY G. BEDSOLE, JR., Plaintiff, v. **PFIZER, INC.,** Defendant.	CASE NO.: 09-307 **COMPLAINT** **JURY DEMAND**

Plaintiff, by and through the undersigned counsel, hereby brings this Complaint for damages against Defendant Pfizer, Inc. and alleges:

INTRODUCTION

1. This is an action for damages relating to the Defendant's design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of the unsafe prescription drug varenicline, which is sold by Defendant under the trade name Chantix® ("CHANTIX"). Plaintiff brings these claims to recover for personal injuries and damages he suffered as a result of ingesting CHANTIX.

2. CHANTIX is associated with, and causes, an increased risk of serious injury and death including: suicide ideation, suicide attempts, and, in many instances, successful suicide. CHANTIX is also associated with, and causes, heart rhythm disturbances, seizures and muscle disorders, vision disturbances, and other dangerous conditions.

3. At all times relevant to this action, Defendant intentionally, recklessly, and/or negligently concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects, and disadvantages of CHANTIX.

4. At all times relevant to this action, Defendant intentionally, recklessly, and/or negligently, and advertised, promoted, marketed, sold, and/or distributed CHANTIX as a safe prescription medication when, in fact, Defendant had reason to know, and/or did know, that CHANTIX was not safe for its intended purposes, and that CHANTIX caused serious injury and

death.

5. At all times relevant to this action, Defendant is and was strictly liable for injuries caused by CHANTIX because the drug is unreasonably dangerous in that it was not accompanied by adequate warnings about its dangers.

PARTIES

6. At all times relevant to this action, Plaintiff, was an adult resident citizen of Demopolis, Marengo County, Alabama.

7. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York.

8. At all relevant times Defendant was engaged in the business of designing, testing, manufacturing, packaging, marketing, advertising, distributing, promoting, and selling CHANTIX.

FACTUAL ALLEGATIONS RELEVANT TO ALL CAUSES OF ACTION

The Plaintiff's Use of Chantix

9. Plaintiff was prescribed and/or lawfully obtained and began taking CHANTIX as indicated on or about the month of July, 2007.

10. Plaintiff used CHANTIX in a proper and reasonably foreseeable manner.

11. The CHANTIX that Plaintiff ingested was in the same or substantially similar condition as when it was manufactured, distributed and sold.

12. Plaintiff was not aware of, and through diligent effort was not able to discover, the risk of serious injury and/or death associated with and/or caused by using CHANTIX.

13. Plaintiff's healthcare providers were not aware of, and through diligent efforts were not able to discover, the risk of serious injury and/or death associated with and/or caused by CHANTIX.

14. Plaintiff's health care providers would not have prescribed CHANTIX had they known that CHANTIX could cause serious injury and/or death including suicide, attempted suicide, seizures, anxiety, depression, and panic attacks.

15. Plaintiff would not have purchased and used CHANTIX had Defendant properly disclosed the risks of serious injury and/or death associated with and/or caused by the drug.

16. At the time Plaintiff ingested CHANTIX, neither the drug label, the package insert, nor the package containing the product, provided adequate warnings that using CHANTIX carried a risk of experiencing serious injury and/or death including such injury as experienced by the Plaintiff.

17. Even now, as set forth below, the information in the drug label provides inadequate information and fails to properly warn consumers and medical professionals of the risks associated with using the drug.

Plaintiff's Injuries and Damages

18. As a direct and proximate result of Defendant's negligence and it otherwise culpable acts described herein, the Plaintiff consumed CHANTIX which caused Plaintiff to sustain injuries and damages including but not limited to the following: suicidal ideations, memory loss, depression, erratic behavior, mood swings, anxiety, and hospitalization.

19. As a direct and proximate result of Defendant's negligence and it otherwise culpable acts described herein, the Plaintiff consumed CHANTIX which caused him to suffer permanent injuries and, ultimately, loss of wages and loss of income earning capacity.

20. As a direct and proximate result of Defendant's negligence and its otherwise culpable acts, omissions, and/or misrepresentations, Plaintiff used CHANTIX which caused Plaintiff to suffer injuries and damages alleged herein, including severe and permanent bodily, pain, suffering, mental anguish, loss of capacity for the enjoyment of life, diminished quality of life, medical costs and expenses, health care costs and expenses, loss of wages, the loss of ability to earn money in the future.

21. Plaintiff's injuries and damages have caused, and will continue to cause, extensive pain and suffering and severe emotional distress, and have substantially reduced Plaintiff's ability to enjoy life; and have caused, and will continue to cause, Plaintiff to expend substantial sums of money.

22. Plaintiff's injuries and damages alleged more fully herein directly resulted from Defendant's negligent and otherwise culpable acts, omissions, and/or misrepresentations.

23. Plaintiff's injuries and damages directly resulted from Plaintiff's use of CHANTIX.

24. Defendant knew, should have known, or could have learned through reasonable diligence that CHANTIX caused and/or was associated with serious injury and/or death such as experienced by Plaintiff.

25. As a direct and proximate result of Defendant's conduct, Plaintiff will continue to incur damages in the future.

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

Design and Approval of CHANTIX

27. CHANTIX, known generically as varenicline, is indicated for use as an aid to quit smoking.

28. The Defendant requested and received an "accelerated review" and/or "priority review" by the federal Food and Drug Administration ("FDA") for CHANTIX.

29. In May, 2006, CHANTIX was approved for use and launched into the market for sale in the United States.

How it Works: The Mechanism of Action

30. CHANTIX is designed to work by specifically inhibiting nicotine receptors in the human brain.

31. CHANTIX employs a somewhat unique and/or novel mechanism of action that is intended to operate as a both an "agonist" and "antagonist" to decrease nicotine craving and psychological rewards associated with smoking.

32. As an "agonist," CHANTIX is supposed to reduce nicotine craving and

withdrawal symptoms.

33. As an "antagonist," CHANTIX is supposed to reduce the psychological reward associated with smoking.

34. According the information in the drug label, CHANTIX works as follows: varenicline blocks the ability of nicotine to activate α4β2 receptors in the brain and thus to stimulate the central nervous mesolimbic dopamine system, believed to be the neuronal mechanism underlying reinforcement and reward experienced as a result of smoking. Varenicline is highly selective and binds more potently to α4β2 receptors than to other common nicotinic receptors (>500-fold α3β4, >3500-fold α7, >20,000-fold α1βγδ), or to non-nicotinic receptors and transporters (>2000-fold).

35. The receptors in the human brain affected by CHANTIX are controlled by dopamine.

36. Dopamine is produced in several areas of the brain and operates as a neurotransmitter.

37. Smokers receive bursts of nicotine when they inhale which triggers an immediate increase of dopamine. This creates both the craving and the perceived pleasure from smoking.

38. In theory, CHANTIX is supposed to work by blocking dopamine so that the cravings for nicotine are diminished and the psychological pleasure derived from smoking is reduced.

39. Essentially, CHANTIX regulates / restricts dopamine and blocks pleasure sensors to depress the normal flux of emotion experienced by humans in daily life.

Failure Adequately to Study CHANTIX

40. Defendant negligently and/or intentionally failed to properly, fully and/or thoroughly study, evaluate, and/or examine the mechanism of action and the effects thereof associated with CHANTIX.

41. Defendant failed to adequately study CHANTIX to determine the risk of serious injury and/or death associated with its use.

42. Defendant's failures to conduct adequate studies of the CHANTIX include:

a. Intentionally excluding certain patients from clinical trials. For example, the Defendant excluded patients from clinical trials if they had previous history and/or diagnosis of mental / psychological disorders;

b. Intentionally ignoring any proper evaluation of depression, aggression, suicide, suicidal ideation, suicidal thoughts, suicidal tendencies, etc.; and

c. Failing to determine what other effect CHANTIX has on other receptors in the human brain and body.

43. Defendant admitted that "[p]atients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the controlled clinical trial program."

44. Dr. Daniel Seidman, the director of Smoking Cessation Services at Columbia University Medical Center, is reported to have said: "When they tested the drug, the sample they chose simply isn't representative of the people they're targeting. . . . By excluding drinkers, you're artificially inflating your results, potentially. I run a clinic, and two out of three [smokers] I see have a psychiatric or mood problem. None of these people would have been part of the original trials."

Defendant's Knowledge That CHANTIX Causes Serious Injury and Death

45. Defendant knew or should have known that CHANTIX increases the risk of causing serious injuries and death including suicide and attempted suicide.

Knowledge About Cytosine, the Root Drug of CHANTIX

46. The active ingredient in CHANTIX is varenicline tartrate which is derived from cytosine. Cytosine has been around for decades as a smoking cessation drug in Eastern European Countries.

47. Defendant knew or should have known that reports have been documented as early as 1972 linking cytosine (the derivative of the active ingredient in CHANTIX) to cases of suicide and attempted suicide.

Knowledge From Adverse Event Reports

48. According to a 2006 report by the European Medical Agency (EMEA), a 61-year-old man committed suicide less than a month after he finished taking CHANTIX. The EMEA's report found CHANTIX had six times the number of serious adverse reactions as the smoking cessation drug Zyban® (bupropion).

49. In the 4th quarter of 2007, varenicline accounted for 988 serious injuries in the U.S. reported to the FDA, more than any other individual drug in this time period. By comparison, the FDA received a median of 5 reports of serious injury for 769 different drugs in the 4th quarter. Only 35 drugs accounted for 100 or more reports.

50. From May 2006 through December 2007, the FDA received 227 domestic reports of suicidal acts, thoughts or behaviors, 397 cases of possible psychosis and 525 reports of hostility or aggression. These totals included 28 cases of suicide and 41 mentions of homicidal ideation, 60 cases of paranoia and 55 cases of hallucination. The categories were not mutually exclusive.

51. In November 2007, FDA announced the results of its preliminary assessment of CHANTIX. The FDA specifically highlighted the number of reports noting the association between suicide and attempted suicide "within days to weeks of initiating CHANTIX treatment."

52. Many of the cases received and reviewed by the FDA were reported for patients without any prior history of psychiatric illness.

53. The adverse drug event reports for varenicline describe other kinds of serious harm for which no warnings now exist. Among the most prominent are:

a. *Accidents and injuries*. A total of 173 serious events described accidental injury, including 28 road traffic accidents and 77 falls, some leading to fractures of rib, facial bones, hand, ankle, spine, and lower limbs. In these cases a variety of potential causes were identified, including loss of consciousness, mental confusion, dizziness and muscle spasms.

b. *Vision disturbances*. At least 148 reports contained medical terms

indicating vision disturbances, including 68 cases described as blurred vision and 26 terms indicating transient or other forms of blindness. This reported effect could also describe a mechanism that could or did contribute to accidents and injuries.

c. *Heart rhythm disturbances*. The FDA received 224 domestic reports classified as potential cardiac rhythm disturbances. This category, however, was dominated by reports of sudden loss of consciousness, an event that could also have non-cardiac causes. However, this category also included smaller numbers of cardiac arrests and identifiable abnormal cardiac rhythms

d. *Seizures and abnormal muscle spasms or movements*. Serious reported events included 86 cases of convulsions (seizures), 372 reports of a wide variety of movement disorders, including tremors, muscle spasms, twitching, tics, drooling, and motor hyperactivity. The extent to which these problems resolved with a reduced dose or by halting treatment could not be determined from these data.

e. *Moderate and severe skin reactions*. Reported serious events included 338 cases of hives or swelling of the tongue, face, eyes, lips or other areas. In addition, 65 cases were classified as severe and included blisters, exfoliation of the skin and lips, and Stevens-Johnson Syndrome.

f. *Diabetes*. The FDA has received 544 reports suggesting varenicline may be related to a loss of glycemic control. This category included many cases of weight loss or gain that could have alternative causes, but also identified numerous cases of symptoms and laboratory tests consistent with new onset diabetes

Regulatory Action and Reviews Indicating Increased Risk

54. On November 20, 2007 the FDA issued a Changes Being Effected ("CBE")

requiring: "Modification of the patient package insert to address possible drug adverse effects [including] depression, agitation, suicidal thoughts…"

55. On February 1, 2008, the Defendant amended the information contained in the drug label.

56. Contemporaneous with the February 1, 2008 label change, the FDA issued a Public Health Advisory alerting health care providers, patients, and caregivers to new safety warnings "related to changes in behavior, agitation, depressed mood, suicidal ideation, and actual suicidal behavior."

57. The European Medicines Agency (EMEA), "as part of the routine pharmacovigilance activities" noted receiving "cases of suicidal ideation and suicide" in July, October and November 2007. The following month, the EMEA "concluded that updated warnings to doctors and patients [were necessary] to increase awareness of cases of suicidal ideation and suicide attempts" in patients using varenicline.

Knowledge from Other Drugs with Similar Mechanism

58. Defendant knew or should have known the risks and/or potential risks of serious injury and/or death because of knowledge it had from other drugs with similar mechanisms of action. (i.e. Zoloft®).

Knowledge from Clinical Trials

59. Several clinical trials demonstrate the increased risk of serious injury and death associated with CHANTIX.

60. As reported in an EMEA press release, "Severe adverse events were experienced by 9.8% of the varenicline group and 7.3% of the NRT (nicotine patch) group." The press release asserts that "[t]hree participants experienced serious adverse events during the non-treatment follow-up phase. … [One study participant] [a] woman in the varenicline group experienced suicidal ideation which resulted in hospitalisation 11 days after completing the varenicline treatment. [She had no previously diagnosed mental and/or psychological disorder.] The study investigator considered this case to be attributable to the study drug." (emphasis

supplied)

61. On July 5, 2006, JAMA published the results of a Pfizer sponsored study in which one of the subjects participating in the study committed suicide.

62. On July 5, 2006, JAMA published the results of a randomized controlled trial completed more than a year earlier in March, 2005, which reported cases of serious adverse events associated with varenicline including acute psychosis, emotional lability, insomnia, and abnormal dreams.

Poor Efficacy of CHANTIX

63. Available data are inconclusive, but suggest that the efficacy of CHANTIX appears to be no better than placebo or the nicotine patch.

64. Given all available data, experts remain unconvinced of relative efficacy of CHANTIX and continually express concern about the potential risk associated with using the drug.

65. After reviewing three clinical trials, experts noted: "Importantly, the majority of participants in these three studies did not quit smoking even with varenicline." Additionally, the authors reviewing the studies concluded "*much research needs to be conducted to establish the effectiveness of varenicline* …." Although the efficacy evaluation was inconclusive, the greater risks associated with CHANTIX (varenicline) were clear. "*First the adverse effect profile of varenicline … reported a rate significantly higher than with either bupropion or placebo*." (emphasis added)

66. The results of a head-to-head open label trial were published on February 8, 2008. The results of the study demonstrate only slightly better efficacy associated with varenicline compared to the nicotine patch. (After 24 weeks, the efficacy of for varenicline was reported to be 32.4% compared to the nicotine patch 27.3%. After 52 weeks the efficacy of for varenicline was reported to be 26.1% compared to the nicotine patch 20.3%. Moreover, the results reflecting minimal improvement are not statistically significant and thus not reliable.

67. Despite any minimally reliable efficacy advantage, the safety analysis conducted

in the study reveals greater risks associated with varenicline as compared to the nicotine patch.

Pfizer's Pattern of Delaying Release of Unfavorable Data

68. Comparison of the dates on which Pfizer-sponsored studies of CHANTIX with unfavorable results were completed with the dates on which they were published shows a pattern in which Defendant apparently delayed releasing unfavorable data.

69. For example, the results of the head-to-head comparison study of CHANTIX and the nicotine patch were published in January 2008; the study, which was sponsored by Pfizer, was completed on June 28, 2006.

70. Similarly, the study published on July 5, 2006, in which one of the subjects participating in the study committed suicide, was completed in February, 2004.

71. In a third instance, the study published in JAMA on July 5, 2006, reported the results of a randomized controlled trial completed more than a year earlier in March, 2005.

72. This pattern of delaying the release of unfavorable studies is not limited to CHANTIX: Pfizer has previously been criticized for delaying publication of unfavorable study results in the context of other drugs. For example, Pfizer sponsored a study of one of its blockbuster Cox-2 inhibitor drugs Bextra® (valdecoxib) which was completed in May, 2000. The unfavorable results were not published until 2003. Additionally, in 2004, investigative journalist, Jeanne Lenzer, reported Pfizer's delay in releasing the results of unfavorable safety data to the FDA and consumers.

Pfizer's Denial of the Risks of CHANTIX

73. Defendant denies the mounting scientific evidence linking CHANTIX to serious injury and death including, certain psychiatric side effects and adverse events such as suicide, attempted suicide, and erratic and aggressive behavior.

74. In a press release dated January 18, 2008, Defendant stated: "A causal relationship between CHANTIX and these reported symptoms has not been established. In some reports, however, an association could not be excluded."

75. Instead, Defendant subtly shifts blame by suggesting nicotine withdrawal caused

the reported changes in behavior.

76. Despite its denial and shifting blame, on February 1, 2008, Pfizer revised the information contained in the drug label to include stronger warnings for "neuropsychiatric symptoms" advising "[a]ll patients being treated with CHANTIX should be observed for neuropsychiatric symptoms including changes in behavior, agitation, depressed mood, suicidal ideation and suicidal behavior."

Pfizer's Failure to Warn and/or Adequately Warn of CHANTIX Risks

77. The information contained in the label and package insert for CHANTIX contains no warning and/or inadequate warning of risk for serious injury and/or death.

78. Defendant knew or should have known that CHANTIX posed a risk for causing serious injury and/or death.

Labeling Requirements

79. Pursuant to federal regulations, prescription drug labels must "contain a summary of the essential scientific information needed for safe and effective use." The label "shall be informative and accurate and neither promotional in tone nor false and misleading …." *See* generally 21 C.F.R. § 201.56. Furthermore, every drug label must "contain specific information required under § 201.57 under certain headings, including in this order: Contraindication, Warnings, Precautions, Adverse Reactions." *Id*.

80. More specifically, § 201.57 requires the following information in each of the four respective sections:

> 1) *Contraindications*: "Under this section heading, the labeling shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. These situations include administration of the drug to patients known to have a hypersensitivity to it …" 21 C.F.R. § 201.57(d)
>
> 2) *Warnings*: "Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. ..."

21 C.F.R. § 201.57(e)

3) *Precautions*: "This subsection of the labeling shall contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug. 21 C.F.R. at § 201.57(f)(1)

4) *Adverse Reactions*: "An adverse reaction is an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." 21 C.F.R. § 201.57(g). For clarification the section further reads: "*The 'Warnings' section of the labeling or, if appropriate, the 'Contraindications' section of the labeling shall identify any potentially fatal adverse reaction*." *Id.* (emphasis supplied).

81. The CHANTIX label and package insert in use when Plaintiff's physician prescribed the drug did not provide Plaintiff's physician with an adequate warning about the increased risk of serious injury and/or death from CHANTIX.

82. The CHANTIX label and package insert in use when Plaintiff purchased and ingested the drug did not provide Plaintiff with an adequate warning about the increased risk of serious injury and/or death from CHANTIX.

83. The information contained in the product label and package insert is insufficient for many reasons, including but not limited to the following: a) the label fails to explicitly warn of increased risk for serious injury and/or death; and, b) the label fails to reference the severity of such serious injuries; and/or c) the label fails to provide adequate information advising consumers of appropriate action if certain adverse events are experienced.

Defendant Could Have Strengthened the Label at Any Time

84. Defendant could have strengthened the label for CHANTIX at any time without the approval of the FDA. *See generally Witczak v. GSK*, 377 F.Supp.2d 729 (2005) *interpreting* 21 C.F.R. § 314.70(c)(6)(iii)(A).

85. Defendant should have been poised to strengthen the label and notify consumers of any potential problems at the first reports of adverse reactions - particularly life-threatening reactions, and the risk of serious injury and/or death.

86. FDA regulations explicitly permit manufacturers unilaterally to strengthen a

warning label at any time without regulatory pre-approval. 21 C.F.R. § 314.70(c)(6)(iii)(A). This particular regulation was promulgated precisely to allow drug-makers to quickly strengthen label warnings when evidence of new side effects is discovered. *See* 30 Fed.Reg. 993 (Jan. 30, 1965). Thus, as the FDA has noted, the regulation "permits the addition to the drug's labeling or advertising of information about a hazard without advance approval" by the FDA. 44 Fed.Reg. 37447 (June 26, 1979); *see also Witczak v. GSK*, 377 F.Supp.2d 726, 729 (2005).

Defendant's Motivation: Market Share Not Medicine and Profit Over Patient Safety.

87. Unilateral action to strengthen the label would, however, have run contrary to the Defendant' marketing and advertising strategy, which was to study the market, not the medicine, and pursue profit over patient safety. Defendant's efforts focused on increasing profits and market share while turning a blind eye to consumer safety.

88. Defendant is the world's leading manufacturer of pharmaceutical drugs. In 2006, Pfizer earned $48.4 billion in revenues.

89. CHANTIX has quickly become one of Pfizer's best-selling new drugs.

90. As reported by Pfizer in SEC filings, CHANTIX revenues rose 773 percent in one year (from $101 million in 2006 to $883 million in 2007).

91. Pfizer earned $241 million in the 3rd quarter of 2007 alone from CHANTIX sales.

92. Before approval by the FDA, Pfizer began marketing CHANTIX as "the first new prescription treatment for smoking cessation in nearly a decade."

93. Pfizer described CHANTIX as a "key new product, deliver[ing] strong revenues …. CHANTIX® (varenicline) continues its strong performance, with nearly 2.5 million U.S. patients having filled a prescription as of June 15, 2007."

94. On or about June 15, 2006, within a year after being launched onto the open market in the United States, nearly 2.5 million U.S. consumers purchased CHANTIX.

95. As reported by Bloomberg news on May 29, 2008, Pfizer (through its officers, agents, directors and, specifically the Chief Executive Officer Jeffrey Kindler) touted CHANTIX as helping the company offset $12 billion in sales that the Pfizer was losing to generic

competition for Lipitor.

96. Upon information and belief, the Defendant, as a result of the manufacturing and marketing of CHANTIX, has reaped huge profits while failing adequately to warn of the potential hazard associated with the ingestion.

97. Prior to the manufacture, sale and distribution of CHANTIX, the Defendant, through its officers, directors and managing agents, had notice and knowledge from several sources, that the products presented substantial and unreasonable risks of harm to the patients.

98. Despite such knowledge, the Defendant, through its officers, directors and managing agents, for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to properly warn the Plaintiff, patients, consumers, physicians, and the public of the serious risk of serious injury and/or death caused by CHANTIX.

99. The Defendant and its officers, agents and managers intentionally proceeded with the manufacturing, sale and marketing of CHANTIX, knowing that patients and consumers would be exposed to serious injury and death.

100. The tortious actions and misdeeds of the Defendant as alleged herein are ongoing and at all times relevant hereto were ongoing and continuous and constituted ongoing and continuous torts.

101. The Defendant sold CHANTIX by misleading doctors and users about the product and by failing adequately to warn prescribing doctors and users of the potential serious dangers, which Pfizer knew or should have known, might result from ingesting CHANTIX.

102. The Defendant widely and successfully marketed CHANTIX throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of their respective drugs, in order to induce widespread use and consumption.

103. The Defendant made misrepresentations by means including but not limited to: media advertisements, and statements contained in sales literature.

104. At the time Defendant manufactured, advertised, and distributed CHANTIX, Defendant intentionally ignored and/or withheld information regarding the increased risks of

serious injury and death associated with and/or caused by CHANTIX including, behavior changes, agitation, depressed mood, suicidal ideation, and actual suicidal behavior.

105. Defendant knew that if such increased risks of serious injury and/or death were disclosed, doctors would not prescribe and consumers would not purchase CHANTIX.

106. At all times relevant herein, Defendant engaged in a marketing campaign with the intent that consumers would request prescriptions and, thereby, purchase CHANTIX.

107. Defendant widely and successfully marketed CHANTIX throughout the United States by, among other things, conducting promotional campaigns that misrepresented the safety and efficacy of CHANTIX in order to induce widespread use and consumption.

108. Defendant made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiff's prescribing physician.

109. As a result of the manufacturing and marketing of the Defendant's product CHANTIX, Defendant has reaped huge profits, while concealing from the public, knowledge of the potential hazards associated with the drug.

110. The Defendant should have taken appropriate measures to ensure that CHANTIX would not be placed into the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

111. Defendant, through its officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of CHANTIX.

112. Defendant and its officers, agents and managers intentionally proceeded with the manufacturing, marketing, advertising, promotion, distribution and sale of CHANTIX, knowing that persons would be exposed to serious injury and death, in order to advance their own pecuniary interests.

113. Defendant's conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiff.

114. Defendant negligently and/or intentionally failed to adequately monitor post-marketing adverse event reports.

115. Defendant negligently and/or intentionally failed to monitor, analyze and/or report the data generated by the testing it conducted and adverse event reports identifying CHANTIX.

116. In promoting CHANTIX to the medical community, the FDA, and the general public, Defendant negligently and/or intentionally minimized the risks of serious injury and/or death associated with and/or caused by CHANTIX.

117. Defendant instead engaged in a pattern of reckless behavior and manipulation in a successful effort to enhance profits at the expense of the public health.

118. Defendant acted with conscious and wanton disregard of the health and safety of Plaintiff, who requests an award of additional damages for the sake of example and for the purpose of punishing such entities for its conduct, in an amount sufficiently large to be an example to others and to deter Defendant and others from engaging in similar conduct in the future. The above-described wrongful conduct was done with knowledge, authorization, and ratification of officers, directors, and managing agents of Defendant.

119. The Defendant actions and/or lack thereof demonstrate gross negligence, if not reckless disregard for human live or, worse, intentional misconduct.

120. At all times material hereto, the Defendant proceeded to or permitted its drug to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold without adequate warnings of the serious injuries and death associated with and/or caused by using CHANTIX.

121. The Defendant failed adequately to warn the Plaintiff and other consumers, of the potential serious dangers which they knew or should have known might result from consuming CHANTIX.

122. The Defendant failed to properly warn physicians through the package insert for CHANTIX or otherwise regarding the catastrophic, potentially fatal, risks associated with the drug.

123. The Defendant's failure to include warnings regarding the risks of serious injury and death was done with full knowledge of such risks.

124. Prior to the Plaintiff's injuries caused by CHANTIX, the Defendant was aware of published medical literature which demonstrated an association and/or causal relationship between CHANTIX and such serious injuries and death.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

125. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

126. Defendant owed Plaintiff a duty to exercise reasonable care when designing, testing, manufacturing, marketing, advertising, promoting, distributing, and/or selling CHANTIX.

127. At all relevant times to this action, Defendant owed a duty to properly warn Plaintiff, physicians, consumers, and the public of the risks, dangers and adverse side effects of CHANTIX including the increased risk of serious injury and death.

128. Defendant breached its duty by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of CHANTIX, as set forth below.

129. Defendant failed to exercise due care under the circumstances and therefore breached this duty in numerous ways, including the following:

a. failing to test CHANTIX properly and thoroughly before releasing the drug to the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of CHANTIX;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of CHANTIX which indicated risks associated with its use;

d. failing to conduct adequate post-market monitoring and surveillance of CHANTIX;

e. failing to conduct adequate analysis adverse event reports;

f. designing, manufacturing, marketing, advertising, distributing, and selling CHANTIX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of CHANTIX and without proper instructions to avoid the harm which could foresee ably occur as a result of using the drug;

g. failing to exercise due care when advertising and promoting CHANTIX;

h. negligently continuing to manufacture, market, advertise, and distribute CHANTIX after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. failing to use due care in the preparation and development of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

j. failing to use due care in the design of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

k. failing to conduct adequate pre-clinical testing and research to determine the safety of CHANTIX;

l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CHANTIX, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of CHANTIX for causing serious injury and/or death in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant to the need to change the drug's warnings or to withdraw

m. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, his doctors, other consumers, the medical community, and the FDA;

n. failing to accompany CHANTIX with proper warnings regarding all possible adverse side effects, including serious injury (e.g., suicide, attempted suicide, seizure, diabetes, SJS reactions, etc.) associated with the use of the same;

o. failing to use due care in the manufacture, inspection, and labeling of CHANTIX to prevent the aforementioned risk of injuries to individuals who used the drugs;

p. failing to use due care in the promotion of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

q. failing to use due care in the sale and marketing of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

r. failing to use due care in the selling of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

s. failing to provide adequate and accurate training and information to the sales representatives who sold the drugs;

t. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of CHANTIX;

u. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing serious injury and

death as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reaction;

v. failing to educate healthcare providers and the public about the safest use of the drug;

w. failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and

x. being otherwise reckless, careless and/or negligent.

130. Despite the fact that Defendant knew or should have known that CHANTIX increased the risk of serious injury and/or death, Defendant continued to promote and market CHANTIX to doctors and to consumers, including Plaintiff, when safer and more effective methods treatment were available.

131. As a direct and proximate consequence of Defendant's negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiff sustained injuries and damages alleged herein including specifically those alleged in this Complaint under the heading "Plaintiff's Injuries and Damages."

132. By reason of the foregoing, Defendant is liable to Plaintiff as a result of its negligence for damages, including compensatory damages and exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees, in an amount to be proved at trial.

COUNT II: ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE

133. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

134. At all times relevant to this action, the Defendant designed, tested, manufactured, packaged, marketed, distributed, promoted, and sold CHANTIX, placing the drug into the stream of commerce.

135. At all times relevant to this action, CHANTIX was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendant in a condition that was defective and unreasonably dangerous to consumers, including the Plaintiff.

136. CHANTIX was expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

137. Plaintiff used CHANTIX as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

138. CHANTIX was unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

139. CHANTIX was unreasonably dangerous in that, as designed, the risks of serious injury and/or death, including suicidal ideation, attempted suicide and suicide, posed by its consumption exceeded any benefit the drug was designed to or might in fact bestow.

140. CHANTIX was unreasonably dangerous in that, as designed, it was dangerous to an extent beyond that contemplated by ordinary consumers, including Plaintiff.

141. CHANTIX was unreasonably dangerous in that it neither bore, nor was packaged with, nor accompanied by, warnings adequate to alert physicians, including the doctors who prescribed it to Plaintiff, or consumers, including Plaintiff, to the risks described herein, including, but not limited to, the risk of serious injury and/or death including, suicidal ideation, attempted suicide and suicide. The drug was not accompanied by adequate labeling, instructions for use and/or warnings to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, of the potential risks and serious side effects associated with its use, thereby rendering Defendant liable to the Plaintiff.

142. There were safer alternative methods and designs for the like product.

143. CHANTIX was insufficiently tested and caused harmful side effects that outweighed any potential utility.

144. CHANTIX was unsafe for normal or reasonably anticipated use.

145. CHANTIX was defective in design or formulation because when the drug left the hands of the respective manufacturer and/or supplier, it was unreasonably dangerous, more dangerous than an ordinary consumer would expect, and not accompanied by adequate warnings.

146. CHANTIX was defective and unreasonably dangerous in that the foreseeable risk of injuries from CHANTIX exceeded the benefits associated with the design and/or formulation of the product.

147. CHANTIX, as manufactured and supplied, was defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

148. Defendant failed to perform adequate testing before exposing Plaintiff to CHANTIX.

149. CHANTIX as manufactured and supplied by the Defendant was defective due to inadequate post-marketing warnings or instructions because, after Defendant knew or should have known of the risk of injuries from use and/or ingestion, it failed to provide adequate warnings to the medical community and the consumers, to whom it was directly marketing and advertising; and, further, it continued to affirmatively promote CHANTIX as safe and effective.

150. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that CHANTIX should not have been marketed in that condition.

151. As a direct and proximate cause of the Defendant' defective design of CHANTIX, including the lack of appropriate warnings, Plaintiff used the drug rather than less expensive alternative smoking cessation therapies with better and/or similar efficacy. As a result, Plaintiff suffered the damages and injuries described herein.

152. Information given by Defendant to the medical community and to the consumers

concerning the safety and efficacy of CHANTIX, especially the information contained in the advertising and promotional materials did not accurately reflect the serious and potentially fatal side effects.

153. Had adequate warnings and instructions been provided, Plaintiff would not have been prescribed or taken CHANTIX, and would not have been at risk of the harmful side effects described herein.

154. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious of serious injury and/or death associated with and/or caused by CHANTIX.

155. As a direct and proximate consequence of the defective nature of CHANTIX and the Defendant's failure to provide adequate warnings about the dangers associated with the drug, the Plaintiff sustained injuries and damages alleged herein including specifically those alleged in this Complaint under the heading "Plaintiff's Injuries and Damages."

156. By reason of the foregoing, Defendant is strictly liable to Plaintiff for damages, including compensatory damages, and exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees, in an amount to be proved at trial.

COUNT III: BREACH OF EXPRESS WARRANTY

157. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

158. Defendant expressly represented to Plaintiff (and to other consumers and the medical community) that CHANTIX was safe, efficacious and fit for its intended purposes, that it was of merchantable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested.

159. Defendant breached expressed warranties with respect to CHANTIX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice

letters, and regulatory submissions that CHANTIX was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associate with using CHANTIX;

b. Defendant represented that CHANTIX was as safe, and/or safer than other alternative medications and fraudulently concealed information, which demonstrated that CHANTIX was not safer than alternatives available on the market; and

c. Defendant represented that CHANTIX was as more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the drug.

160. CHANTIX does not conform to Defendant's express representations because it is not safe, efficacious, it has numerous and serious unwarned-of side effects, causes severe and permanent injuries and was not adequately tested.

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

162. Plaintiff, his physician, other consumers, and the medical community relied upon Defendant's express warranties, resulting in Plaintiff's ingestion of the drug.

163. As a direct and proximate consequence of Defendant's breach of its warranties, the Plaintiff sustained injuries and damages alleged herein including specifically those alleged in this Complaint under the heading "Plaintiff's Injuries and Damages."

164. By reason of the foregoing, Defendant is liable to Plaintiff as a result of its breach of warranty for damages, including compensatory damages, and exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees, in an amount to be proved at trial.

COUNT IV: BREACH OF IMPLIED WARRANTY

165. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

166. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold CHANTIX.

167. At all relevant times, Defendant intended that CHANTIX be used in the manner that Plaintiff in fact used it.

168. Defendant impliedly warranted CHANTIX to be of merchantable quality, safe and fit for the use for which Pfizer intended it and Plaintiff in fact used it.

169. Defendant was aware that consumers, including Plaintiff, would use CHANTIX as an aid to quit smoking; which is to say that Plaintiff was a foreseeable user of Defendant's product CHANTIX.

170. The drug was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

171. Defendant breached various implied warranties with respect to CHANTIX including the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CHANTIX was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using CHANTIX;

b. Defendant represented that CHANTIX was as safe, and/or safer than other alternative medications and fraudulently concealed information, which demonstrated that CHANTIX was not safer than alternatives available on the market; and

c. Defendant represented that CHANTIX was as more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the drug.

172. In reliance upon Defendant's implied warranty, Plaintiff used CHANTIX as

prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

173. Defendant breached its implied warranty to Plaintiff in that CHANTIX was not of merchantable quality, safe and fit for its intended use, or adequately tested.

174. As a direct and proximate consequence of Defendant's breach of its warranty, the Plaintiff sustained injuries and damages alleged herein including specifically those alleged in this Complaint under the heading "Plaintiff's Injuries and Damages."

175. By reason of the foregoing, Defendant is liable to Plaintiff as a result of its breach of warranty, for damages, including compensatory damages, and exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees in an amount to be proved at trial.

COUNT V: FRAUDULENT MISREPRESENTATION

176. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

177. At all relevant times, Defendant knew of the use for which CHANTIX, was intended and expressly and/or impliedly warranted their respective drug was of merchantable quality and safe and fit for such use.

178. Defendant's superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and dangers of CHANTIX and its intentional dissemination of promotional and marketing information about CHANTIX for the purpose of maximizing its sales, each gave rise to the affirmative duty meaningfully to disclose and provide all material information about the risks and harms associated with the drugs.

179. Defendant fraudulently represented to Plaintiff, Plaintiff's physicians, and other persons and professionals on whom Defendant knew that Plaintiff would rely, as well as the public at large, that CHANTIX was safe to ingest and that the utility of this product outweighed any risk in use for their intended purposes. Also, by failing to disclose to Plaintiff, and others for

the benefit of and Plaintiff, important safety and injury information, thereby suppressing material facts about the drug, while having a duty to disclose such information, which duty arose from their actions of making, marketing, promoting, distributing and selling pharmaceutical products to Plaintiff and others, Defendant further led Plaintiff to rely upon the safety of the product.

180. Defendant's false representations were fraudulently made, in that the subject drug in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.

181. Defendant knew or should have known that its representations were false. Defendant made such false representations with the intent or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations, leading to the use of the subject drugs by Plaintiff.

182. Defendant made fraudulent misrepresentations with respect to CHANTIX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CHANTIX had been tested and found to be safe and effective as an aid to smoking cessation; and

b. Defendant represented that CHANTIX was as safe and/or safer and/or more efficacious than other alternative medications.

183. Defendant knew that these representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of CHANTIX to consumers, including Plaintiff, and to the medical community.

184. Defendant made these misrepresentations with the intent that doctors and patients, including the Plaintiff, rely upon them.

185. Defendant's misrepresentations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of CHANTIX.

186. Plaintiff's doctors, and others, relied upon the representations to the detriment of the Plaintiff.

187. Defendant's fraudulent representations evince its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

188. Defendant made these misrepresentations at a time when Defendant knew or had reason to know that CHANTIX had defects and was unreasonably dangerous and was not what Defendant had represented to the medical community, the FDA and the consuming public, including Plaintiff.

189. The misrepresentations were made by Defendant with an intent that patients and doctors, including Plaintiff and his doctor, rely upon them.

190. Defendant's misrepresentations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of CHANTIX.

191. Defendant's fraudulent representations evinced their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

192. In selecting treatment, Plaintiff's physician and Plaintiff relied on and were induced by Defendant's misrepresentations concerning the dangers of CHANTIX.

193. Plaintiff and the treating medical community did not know that the representations made by Defendant were false and were justified in relying upon Defendant's representations.

194. Had Plaintiff been aware of the increased risks of serious injury and/or death associated with CHANTIX and the relative efficacy of CHANTIX compared with other readily available alternative smoking cessation therapies, Plaintiff would not have purchased and used CHANTIX.

195. As a direct and proximate result of Defendant's fraudulent misrepresentations, upon which Plaintiff and his doctors reasonably relied, Plaintiff suffered injuries and sustained damages for which Defendant is liable.

196. As a direct and proximate consequence of Defendant's fraudulent misrepresentations, the Plaintiff sustained injuries and damages alleged herein including specifically those alleged in this Complaint under the heading "Plaintiff's Injuries and Damages."

197. By reason of the foregoing, Defendant is liable to Plaintiff as a result of its fraudulent misrepresentations, for damages, including compensatory damages, and exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees, in an amount to be proven at trial.

COUNT VI: FRAUDULENT CONCEALMENT

198. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

199. Defendant fraudulently concealed information with respect to CHANTIX in the following particulars:

a. Defendant fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using CHANTIX;

b. Defendant fraudulently concealed information demonstrating that CHANTIX was not safer than alternatives available on the market; and

c. Defendant fraudulently concealed information regarding the true efficacy of the drug.

200. Defendant had sole access to material facts concerning the dangers and unreasonable risks of CHANTIX.

201. Defendant omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of CHANTIX including, serious injury and/or death.

202. Furthermore, Defendant's purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of

CHANTIX in order to increase sales.

203. The concealment of information by Defendant about the substantial risks of serious injury and/or death associated with CHANTIX was intentional.

204. The information that Defendant concealed about CHANTIX was material to the risk benefit analysis that Plaintiffs' physicians undertook in deciding to prescribe CHANTIX to Plaintiff.

205. Plaintiff and his doctors were unaware of the substantial risks of serious injury and/or death associated with and/or caused by CHANTIX, which Defendant concealed from them.

206. Had they known the truth, Plaintiff's doctors would not have prescribed, and Plaintiff would not have ingested, CHANTIX.

207. Had Defendant not fraudulently concealed such information, Plaintiff would not have ingested CHANTIX and suffered resulting harm. Because of Defendant's fraudulent concealment Plaintiff ingested CHANTIX.

208. As a direct and proximate consequence of Defendant's fraudulent concealment, the Plaintiff sustained injuries and damages alleged herein including specifically those alleged in this Complaint under the heading "Plaintiff's Injuries and Damages."

209. By reason of the foregoing, Defendant is liable to Plaintiff as a result of its fraudulent concealment, for damages, including compensatory damages, and exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees, in an amount to be proven at trial.

COUNT VII: RECKLESS AND/OR NEGLIGENT MISREPRESENTATION AND CONCEALMENT

210. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

211. At all relevant times, Defendant designed, tested, manufactured, packaged, marketed, distributed, promoted, and sold CHANTIX.

212. At all relevant times, Defendant knew of the use for which CHANTIX was intended and expressly and/or impliedly warranted that the drug was of merchantable quality and safe and fit for such use.

213. Defendant's superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and dangers of CHANTIX and its intentional dissemination of promotional and marketing information about CHANTIX for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the drugs.

214. Defendant recklessly, and/or negligently represented to Plaintiff, Plaintiff's physicians, and other persons and professionals on whom it was known by Defendant that they would rely, that the CHANTIX was safe to ingest and that the utility of this product outweighed any risk in use for their intended purposes.

215. Defendant recklessly and/or negligently failed to disclose to Plaintiff, and others, important safety and efficacy information, thereby suppressing material facts about the drug, while having a duty to disclose such information, which duty arose from their actions of making, marketing, promoting, distributing and selling pharmaceutical products to Plaintiff and others.

216. Defendant led Plaintiff to rely upon the safety of the product in its use.

217. The false representations of the of Defendant were recklessly and/or negligently made in that the subject drug products in fact caused injury, were unsafe, and the benefits of their use were far outweighed by the risk associated with use thereof.

218. Defendant committed acts of reckless and/or negligent misrepresentation and reckless and/or negligent concealment by suppressing material facts relating to the dangers and injuries associated with, and caused by, the use of the subject drug.

219. Defendant knew or should have known that its representations and/or omissions were false. Defendant made such false, negligent and/or reckless representations with the intent or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations, leading

to the use of the subject drugs by Plaintiff.

220. Defendant recklessly and/or negligently misrepresented and/or omitted information with respect to CHANTIX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that CHANTIX was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using CHANTIX;

b. Defendant represented that CHANTIX was as safe and/or safer than other alternative smoking cessation therapies and fraudulently concealed information, which demonstrated that CHANTIX was not safer than alternatives available on the market; and

c. Defendant represented that CHANTIX was as more efficacious than other alternative smoking cessation therapies and fraudulently concealed information, regarding the true efficacy of the drug.

221. Defendant made affirmative misrepresentations; and recklessly and/or negligently omitted material adverse information regarding the safety and effectiveness of CHANTIX.

222. Defendant made these misrepresentations and/or omissions at a time when Defendant knew or had reason to know that CHANTIX had defects and was unreasonably dangerous and was not what Defendant had represented to the medical community, the FDA and the consuming public, including Plaintiff.

223. Defendant omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of CHANTIX including, serious injury and death. Furthermore, Defendant's purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of CHANTIX in order to increase sales.

224. Defendant's misrepresentations and/or omissions were undertaken by Defendant

with an intent that doctors and patients, including Plaintiff, rely upon them.

225. Defendant's misrepresentations and/or omissions were undertaken with the intent of defrauding and/or deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of CHANTIX.

226. Defendant's misrepresentations and/or omissions evinced the Defendant's callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

227. Plaintiff's physician and Plaintiff relied on and were induced by Defendant's misrepresentations, omissions, and/or active concealment of the dangers of CHANTIX in selecting treatment.

228. Plaintiff and his doctors did not know that the representations made by Defendant were false and were justified in relying upon Defendant's representations.

229. Had Plaintiff been aware of the increased risk of side effects associated with CHANTIX and the relative efficacy of CHANTIX compared with other readily available alternative smoking cessation therapies, Plaintiff would not have taken CHANTIX.

230. As a direct and proximate consequence of Defendant's misrepresentations, Plaintiff sustained injuries and damages alleged herein including specifically those alleged in this Complaint under the heading "Plaintiff's Injuries and Damages."

231. By reason of the foregoing, Defendant is liable to Plaintiff for damages, including compensatory damages, and exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees, in an amount to be proven at trial.

COUNT VIII: GROSS NEGLIGENCE

232. Plaintiff repeats and re-alleges each and every allegation in paragraphs 1 through 128 of this Complaint as if set forth in full in this cause of action.

233. Defendant had a duty to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of CHANTIX, including a duty to ensure that Defendant's product, CHANTIX, did not cause users to suffer from

unreasonable and dangerous side effects.

234. Defendant failed to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's product, CHANTIX, in that Defendant knew or should have known that taking Defendant's product, CHANTIX, caused unreasonable and life-threatening injuries, as alleged herein.

235. Defendant was grossly negligent under the circumstances and breached its duty of care in numerous ways, including the following:

a. failing to test CHANTIX properly and thoroughly before releasing the drug to the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of CHANTIX;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of CHANTIX which indicated risks associated with its use;

d. failing to conduct adequate post-market monitoring and surveillance of CHANTIX;

e. failing to conduct adequate analysis adverse event reports;

f. designing, manufacturing, marketing, advertising, distributing, and selling CHANTIX to consumers, including and Plaintiff, without an adequate warning of the significant and dangerous risks of CHANTIX and without proper instructions to avoid the harm which could foresee ably occur as a result of using the drug;

g. failing to exercise due care when advertising and promoting CHANTIX;

h. recklessly continuing to manufacture, market, advertise, and distribute CHANTIX after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. failing to use due care in the preparation and development of CHANTIX

to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

j. failing to use due care in the design of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

k. failing to conduct adequate pre-clinical testing and research to determine the safety of CHANTIX;

l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CHANTIX, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of CHANTIX for causing serious injury and death as alleged herein in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant to the need to change the drug's warnings or to withdraw it from the market altogether;

m. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, his doctors, other consumers, the medical community, and the FDA;

n. failing to accompany CHANTIX with proper warnings regarding all possible adverse side effects associated with the use of the same;

o. failing to use due care in the manufacture, inspection, and labeling of CHANTIX to prevent the aforementioned risk of injuries to individuals who used the drugs;

p. failing to use due care in the promotion of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

q. failing to use due care in the sale and marketing of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

r. failing to use due care in the selling of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

s. failing to provide adequate and accurate training and information to the sales representatives who sold the drugs;

t. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of CHANTIX;

u. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing such serious injury and death as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reaction;

v. failing to educate healthcare providers and the public about the safest use of the drug;

w. failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and

x. was otherwise grossly negligent.

236. Although Defendant knew, or recklessly disregarded, the fact that Defendant's product, CHANTIX, caused potentially lethal side effects, Defendant continued to market Defendant's product, CHANTIX, to consumers, including Plaintiff, without disclosing these side effects including the risks of serious injury and/or death.

237. Defendant knew and/or consciously or recklessly disregarded the fact that consumers such as Plaintiff would suffer injury as a result of Defendant's failure to exercise

reasonable care as described above.

238. Defendant knew of, or recklessly disregarded the defective nature of Defendant's product, CHANTIX, as set forth herein, but continued to design, manufacture, market, and sell Defendant's product, CHANTIX, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by Defendant's product, CHANTIX.

239. As a direct and proximate consequence of Defendant's gross negligence, the Plaintiff sustained injuries and damages alleged herein including specifically those alleged in this Complaint under the heading "Plaintiff's Injuries and Damages."

240. By reason of the foregoing, Defendant is liable to Plaintiff as a result of its gross negligence for damages, including compensatory damages, and exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees, in an amount to be proven at trial.

COUNT IX: WILLFUL, WANTON, AND MALICIOUS CONDUCT

241. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

242. Pfizer directly or indirectly, maliciously and wantonly made, created, manufactured, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold CHANTIX.

243. Pfizer breached its duty and was wanton and malicious in its actions, misrepresentations, and omissions in that it:

a. failed to test CHANTIX properly and thoroughly before releasing the drug to the market;

b. failed to analyze properly and thoroughly the data resulting from the pre-marketing tests of CHANTIX;

c. failed to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of CHANTIX which indicated risks associated with its use;

d. failed to conduct adequate post-market monitoring and surveillance of CHANTIX;

e. failed to conduct adequate analysis adverse event reports;

f. designed, manufactured, marketed, advertised, distributed, and sold CHANTIX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of CHANTIX and without proper instructions to avoid the harm which could foresee ably occur as a result of using the drug;

g. failed to exercise due care when advertising and promoting CHANTIX;

h. willfully and wantonly continued to manufacture, market, advertise, and distribute CHANTIX after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. willfully and wantonly failed to use due care in the preparation and development of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

j. willfully and wantonly failed to use due care in the design of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

k. failed to conduct adequate pre-clinical testing and research to determine the safety of CHANTIX;

l. failed to conduct adequate post-marketing surveillance and exposure studies to determine the safety of CHANTIX, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of CHANTIX for causing such serious injury and death as alleged herein in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant to the need to change the drug's warnings or to

withdraw it from the market altogether;

m. failed to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, his doctors, other consumers, the medical community, and the FDA;

n. failed to accompany CHANTIX with proper warnings regarding all possible adverse side effects associated with the use of the same;

o. willfully and wantonly failed to use due care in the manufacture, inspection, and labeling of CHANTIX to prevent the aforementioned risk of injuries to individuals who used the drugs;

p. willfully and wantonly failed to use due care in the promotion of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

q. willfully and wantonly failed to use due care in the sale and marketing of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

r. willfully and wantonly failed to use due care in the selling of CHANTIX to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;

s. failed to provide adequate and accurate training and information to the sales representatives who sold the drugs;

t. failed to provide adequate and accurate training and information to healthcare providers for the appropriate use of CHANTIX;

u. failed to conduct or fund research into the development of medications of this type which would pose the least risk of causing serious injury and death as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better

remedies and treatment for those who experience these tragic adverse reaction;

v. failed to educate healthcare providers and the public about the safest use of the drug;

w. failed to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and

x. otherwise behaved willfully, wantonly, and maliciously.

244. Pfizer knew or should have known that CHANTIX was unreasonably dangerous and could cause serious injuries, including death.

245. As a direct and proximate result of the wanton and malicious acts and omissions of Pfizer, the Plaintiff sustained injuries and damages alleged herein including specifically those alleged in this Complaint under the heading "Plaintiff's Injuries and Damages."

246. By reason of the foregoing, Pfizer is liable to Plaintiff as a result of its willful, wanton and malicious conduct, for damages, including compensatory damages, and exemplary and punitive damages together with interest, and the costs of suit and attorneys' fees, in an amount to be proven at trial..

COUNT X: UNJUST ENRICHMENT

247. Plaintiff repeats and re-alleges each and every allegation of this Complaint as if set forth in full in this cause of action.

248. At all times relevant to this action, Defendant designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold CHANNTIX.

249. Plaintiff purchased CHANTIX for the purpose of stopping smoking.

250. Defendant has accepted payment from Plaintiff for the purchase of CHANTIX.

251. Plaintiff did not receive the safe and effective pharmaceutical product for which Plaintiff intended to purchase.

252. It is inequitable and unjust for Defendant to retain this money because the Plaintiff did not in fact receive the product Defendant represented CHANTIX to be.

253. By reason of the foregoing, Plaintiff is entitled to equitable relief against Defendant an account of its unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant as follows:

A. Compensatory damages, including without limitation past and future medical expenses; past and future lost wages and loss of earning capacity; past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; and consequential damages;

B. Punitive damages in an amount sufficient to punish Defendant and set an example;

C. Disgorgement of profits;

D. Restitution;

E. Costs and fees of this action, including reasonable attorney's fees;

F. Prejudgment interest and all other interest recoverable; and

G. Such other additional and further relief as Plaintiff may be entitled to in law or in equity.

Dated: this the 2nd day of June, 2009.

/s/ Elizabeth Ellis Chambers

Elizabeth Ellis Chambers
ASB-3521-A63E
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PLAINTIFF DEMANDS A TRIAL OF ALL ISSUES BY STRUCK JURY.

/s/ Elizabeth Ellis Chambers
Elizabeth Ellis Chambers