UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

Ken and Judy Albrecht, Individually,	**§**	
and as Personal Representatives of the	**§**	
Estate of Jeffrey Carter Albrecht,	**§**	
Deceased,	**§**	
Plaintiffs,	**§**	
	§	
v.	**§**	**CIVIL ACTION NO. _____**
	§	
Pfizer, Inc.,	**§**	
Defendant.	**§**	

PLAINTIFFS' ORIGINAL COMPLAINT AND JURY DEMAND

COME NOW, Plaintiffs, by and through the undersigned counsel, and hereby brings this Complaint for damages against Defendant, and alleges the following:

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 drug varenicline, trade name Chantix® ("CHANTIX").

2. Plaintiffs bring these claims, individually and on behalf of the estate of the decedent, for personal injuries and damages.

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.

PARTIES, VENUE & JURISDICTION

5. Plaintiffs are the parents of the deceased, Jeffrey Carter Albrecht (hereinafter "Carter Albrecht"), and are the only heirs of the deceased. They are bringing this claim individually and as the estate representatives. Jeffrey Carter Albrecht left no estate upon his death; to date there has been no need for an administration. Plaintiffs Ken Albrecht and Judy Albrecht hereby request that the Court appoint them as Personal Representatives of the Estate of Jeffrey Carter Albrecht for the purposes of this litigation, and permit them to proceed on behalf of that Estate.

6. Jeffrey Carter Albrecht died on September 3, 2007, from the effects of a .357 Magnum gunshot wound. Jeffrey Carter Albrecht was a resident of Dallas County, Texas.

7. Plaintiff and Decedent may, hereinafter, collectively be referred to as "Plaintiff" and/or "Plaintiffs".

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

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

10. This Court has personal jurisdiction over Defendant because Defendant is present

and doing business within the state. Defendant is and was at all relevant times authorized to conduct business in this state and Defendant conducted such business within the state, including the performance of acts that caused or contributed to the harm, giving rise to this action.

11. This Court has diversity jurisdiction over the parties because the amount III controversy exceeds $75,000.

12. Venue is proper in this district and division. Pfizer has a registered agent located in Dallas, Texas.

FACTUAL ALEGATIONS

A.
The Decedent's Use of Chantix

13. Carter Albrecht was prescribed and/or lawfully obtained and began using CHANTIX as indicated in the last week of August, 2007, and had been using it for a period of one week prior to his death.

14. Decedent used CHANTIX in a proper and reasonably foreseeable manner.

15. Decedent used CHANTIX in a condition that was the same or substantially similar to the same condition in which the drug was manufactured, distributed and sold.

16. Decedent was not aware 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.

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

18. Decedent 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.

19. At the time of ingestion, neither the drug label, packaging insert, nor the package

containing the product provided adequate warnings that using CHANTIX carried a risk of experiencing serious injury and/or death as experienced by the Decedent.

20. Subsequent to Carter Albrecht's death, Defendant has issued warnings, including a black-box warning by the F.D.A. of the potential for violent behavior as one of the risks associated with using the drug.

B.
Injuries and Damages to Decedent, Plaintiff, and Decedent's Estate

21. As a direct and proximate result Defendant's negligence and otherwise culpable acts described herein, Carter Albrecht consumed CHANTIX which caused the Decedent to sustain injuries and damages including but not limited to those outlined below and the Decedent's wrongful death on or about September 3, 2007.

22. As a direct and proximate result of the negligence of Pfizer, and of the defective condition of CHANTIX sold by Pfizer, Carter Albrecht was killed, and his parents Ken Albrecht and Judy Albrecht suffered the loss of his companionship and society, pecuniary loss, suffered mental anguish, incurred funeral and burial expenses, and will continue to suffer such damages in the future.

23. As a further direct and proximate result of the negligence of Pfizer, Ken Albrecht and Judy Albrecht have suffered mental anguish, pain and distress, torment, suffering and emotional distress by unexpectedly and shockingly finding their son had been shot to death.

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

25. Plaintiffs' injuries and damages directly resulted from using CHANTIX.

26. 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 the Decedent.

27. Upon information and belief, 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 Carter Albrecht, thereby entitling Plaintiffs to punitive and exemplary damages so as to punish Defendant and deter it from similar conduct in the future.

C.
Facts Regarding CHANTIX

28. CHANTIX, known generically as varenicline, is indicated for use as an aid to smoking cessation treatment.

29. The Defendant requested and received an "accelerated review" and/or "priority review" by the FDA for CHANTIX.

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

1.
How it Works: The Mechanism of Action

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

32. 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 smokers.[1]

[1] Bailey, William c., “Pharmacologic Therapy: Novel Approaches for Chronic Obstructive Pulmonary Disease”" Proc. Am. Thorac. Soc., Vol 4, pp 543-548, 2007. *See also*, product label:
“Varenicline binds with high affinity and selectivity at α4β2 neuronal nicotinic acetylcholine receptors. The efficacy of CHANTIX in smoking cessation is believed to be the result of varenicline's activity at a subtype of the nicotinic

33. As an "agonist" CHANTIX is supposed to reduce nicotine craving and withdrawal symptoms.

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

35. According to the information in the drug label, CHANTIX works as follows:

> Varenicline blocks the ability of nicotine to activate α4β2 receptors and thus to stimulate the central nervous mesolimbic dopamine system, believed to be the neuronal mechanism underlying reinforcement and reward experienced upon smoking. Varenicline is highly selective and binds more potently to α4β2 receptors than to other common nicotinic receptors (>500fold α3β4, >3500fold α7, >20,000fold α1βγδ), or to nonnicotinic receptors and transporters (>2000fold).

36. The receptors in the human brain affected by CHANTIX are controlled by dopamine.[2]

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

38. Smokers receive bursts of nicotine when they inhale which, coincidentally, triggers an immediate increase of dopamine; thus, creating the craving and perceived pleasure from smoking.

39. In theory, CHANTIX is supposed to work by blocking dopamine, and thus the cravings for nicotine are diminished and psychological pleasure derived from smoking is reduced.[3]

40. Essentially, CHANTIX regulates / restricts dopamine and blocks pleasure sensors

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receptor where its binding produces agonist activity, while simultaneously preventing nicotine binding to α4β2 receptors." 2/l/08 label.

[2] Wikipedia: "Dopamine has many functions in the brain, including important roles in behavior and cognition, motor activity, motovitation, and reward inhibition ... "

[3] CHANTIX activates release of 35 to 60% of the dopamine that nicotine would have caused to flow if sitting on the exact same acetylcholine receptors. J Med Chem 2005 May 19;48(10):3474-7.

to depress the normal flux of emotion experienced by humans in daily life.

2.
Failure to Adequately Study CHANTIX

41. 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.

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

43. 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.[4]
b. Intentionally ignoring any proper evaluation of depression, aggression, suicide, suicidal ideation, suicidal thoughts, suicidal tendencies, etc.
c. Failure to determine what other effect CHANTIX has on other receptors in the human brain and body.

44. 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."[5]

45. "When they tested the drug, the sample they chose simply isn't representative of the people they're targeting," says Dr. Daniel Seidman, the director of Smoking Cessation Services at Columbia University Medical Center. "By excluding drinkers, you're artificially

[4] Varenicline Study Group. Efficacy and Safety of the Novel Selective Nicotinic Acetylcholine Receptor Partial Agonist, Varenicline, for Smoking Cessation. *Arch. Intern. Med. August 2006, Vol. 166, p. 1571-1577*; Melinda Beck, "Puff Power: Drug Warnings Speak to Nicotine's Sad Grip," *Wall Street Journal,* February 19,2008, sec. D, p. 1; Deveraux, A., Mostafa, K., Laqueille, X., Efficacy of Varenicline for Smoking Cessation, *JAMA* 296 (December 6, 2006) 2555.
[5] Pfizer Press Release, January 18, 2008.

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."[6]

D.
CHANTIX Causes Serious Injury and Death

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

1.
Knowledge From Cytosine - Root Drug of Chantix

47. The active ingredient in CHANTIX is varenicline tartrate which "was derived from cytosine."[7]

48. "[Cytosine] has been around for decades as a smoking cessation drug in Eastern European Countries."[8]

49. 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.[9]

2.
Knowledge From Adverse Event Reports

50. 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).

[6] Derek de Koff, "This is My Brain on CHANTIX," *New York Magazine,* February 10, 2008, http://nymag.com/news/features/43892/, accessed March 2008.
[7] Etter, Jean-Francois, "Cytisine for Smoking Cessation" *Arch. Int. Med.*, Vol. 166, Aug. 14/28, 2006.
[8] *Id.*
[9] Stoyanov, S., Yanachkova, M., 1972. Tabex - therapeutic efficacy and tolerance. Savr. Med. XXIII (6), 31-33

51. 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. This large volume of reports prompted us to conduct an analysis of all adverse events for varenicline since marketing approval in 2006.

52. From May 2006 through December 2007, the FDA had 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.

53. In November 2007, the Food and Drug Administration (FDA) announced the results of its preliminary assessment of CHANTIX.[10] The FDA specifically highlighted the number of reports noting the association between suicide and attempted suicide "within days to weeks of initiating CHANTIX treatment."

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

55. 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.

[10] FDA Press Release, *Early Communication About an Ongoing Safety Review: Varenicline (marketed as CHANTIX),* http://www.fda.gov/cder/drug/early_comm/varenicline.htm (Nov. 20, 2007).

b. Vision disturbance: 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.

3.
Regulatory Action and Reviews Indicating Increased Risk

56. 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, ... "

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

58. 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."[11]

59. 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.[12] 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.[13]

60. On July 1, 2009, the F.D.A. issued a "black box" warning, requiring greater disclosure of risks in the use of Chantix.

4.
Knowledge from Other Drugs With Similar Mechanism

61. 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®).

5.
Knowledge From Clinical Trials

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

63. "Severe adverse events were experienced by 9.8% of the varenicline group and 7.3% of the NRT (nicotine patch) group."[14] Three participants experienced serious adverse

[11] FDA Public Health Advisory, FDA, "Public Health Advisory-Important Information on CHANTIX (varenicline)" (February 1,2008) at http://www.fda.gov/cder/drug/advisory/varenicline.htm.
[12] EMEA Press Release, EMEA, "European Medicines Agency concludes new advice to doctors and patients for Chantix needed" (Dec. 14, 2007) at http://www.emea.europa.eu/pdfs/genera/direct/pr/59551607en.pdf.
[13] *Id.*
[14] *Id.*

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).[15]

64. On July 5, 2006, JAMA published the results of a Pfizer sponsored study completed in February, 2004 - almost two years earlier. One of the subjects participating in the study committed suicide.[16]

65. 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 liability", "insomnia" and "abnormal dreams."[17]

E.
Poor Efficacy

66. Available data is inconclusive at best and suggests that the efficacy of CHANTIX appears to be no better than placebo or the nicotine patch.

67. Given all available data, experts remain unconvinced of relative efficacy of CHANTIX® (varenicline) and continually express concern about the potential risk associated with using the drug.[18]

68. After reviewing three clinical trials, the experts noted: "Importantly, the majority

[15] *Id.*
[16] Tonstad, S., *et al.*, Effect of Maintenance Therapy With Varenicline on Smoking Cessation - A Randomized Controlled Trial, *JAMA* 296 no. 1, (July 5, 2006) 64-71.
[17] Jorenby *et al.*, "Efficacy of Varenicline, an α4β2 Nicotinic Acetylcholine Receptor Partial Agonist, vs Placebo or Sustained-Release Bupropion for Smoking Cessation - A Randomized Controlled Trial, *JAMA* 296, No. 1 (July 5, 2006) 56-63.
[18] Kleges, *et al.*, "Varenicline for Cessation: Definite Promise But No Panacea; *JAMA* 296, No. 1 (July 5, 2006) 94-9

of participants in these three studies did not quit smoking even with varenicline."[19]

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).[20]

69. The results of a head-to-head open label trial were published, on February 8, 2008.[21] The results of the study were insignificant and only demonstrate 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%. The results after 52 weeks are worse. 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 reliable (i.e., "[T]he difference [reflecting minimally improved efficacy] was not statistically significant").[22]

70. 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. "Severe adverse events were experienced by 9.8% of the varenicline group and 7.3% of the NRT (nicotine patch) group."[23] Three participants experienced serious adverse events during the non-treatment follow-up phase .... [One study participant] ***A woman in the varenicline group***

[19] *Id.*
[20] *Id.*
[21] "Varenicline versus transdermal nicotine patch for smoking cessation: results from a randomised open label trial." *Thorax*, published online 8 Feb 2008.
[22] *Id.*
[23] *Id.*

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.[24]

F.
Pfizer's Habit of Delaying Release of Unfavorable Data

71. Interestingly, although the results of the head-to-head comparison study referenced above were published in January 2008, the study was sponsored by Pfizer and completed on June 28, 2006.

72. Again, on July 5, 2006, JAMA published the results of a Pfizer sponsored study completed in February, 2004 - almost two years earlier - one of the subjects participating in the study committed suicide.[25]

73. Similarly, 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 liability", "insomnia" and "abnormal dreams.:[26]

74. Pfizer has previously been criticized for delaying publication of unfavorable study results. For example, Pfizer sponsored a study of one of its blockbuster Cox-2 inhibitor drugs, Bextra® (valdecoxib), which was completed in May, 2000.[27] The unfavorable results were not published until 2003.[28] Additionally, in 2004, investigative journalist, Jeanne Lenzer, reported

[24] *Id.*
[25] Tonstad, S., *et al.,* Effect of Maintenance Therapy With Varenicline on Smoking Cessation - A Randomized Controlled Trial, *JAMA* 296 No. 1, (July 5, 2006) 64-71.
[26] Jorenby *et al.*, "Efficacy of Varenicline, an α4β2 Nicotinic Acetylcholine Receptor Partial Agonist, vs Placebo or Sustained-Release Bupropion for Smoking Cessation - A Randomized Controlled Trial, *JAMA* 296, No. I (July 5, 2006) 56-63.
[27] Ott *et al.,* J Thorac Cardiovasc Surg 2003;125:1481-1492.

Pfizer's delay in releasing the results of unfavorable safety data to the FDA and consumers.[29]

75. Upon information and belief, Defendant previously illegally tested drugs without full disclosures. "In May 2006, The [Washington] Post obtained and published the Health Ministry's report, which concluded that Pfizer had violated Nigerian law, the International Declaration of Helsinki and the U.N. Convention on the Rights of the Child. The Commission concluded that Pfizer did not obtain formal government approval to conduct the trial."[30]

G.
Pfizer's Denial

76. 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, erratic and aggressive behavior.

77. 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."[31]

78. Instead, Defendant subtly shifts blame by suggesting nicotine withdrawal caused the reported changes in behavior.[32]

79. Despite its denial and shifting blame, on February 1, 2008, Pfizer revised the

[28] The safety analysis revealed, "serious adverse events occurred twice as frequently in parecoxib/valdecoxib-treated patients than in control patients. Regarding individual serious adverse events, a greater incidence in sternal wound infection was found in the parecoxib/valdecoxib patients versus control patients. The incidences of other individual serious adverse events, including cerebrovascular complications, myocardial infarction, and renal dysfunction, were proportionally greater [in parecoxib/valdecoxib treated patients]. Error! Main Document Only. Ott *et al., J Thorac Cardiovasc Surg* 2003;125:1481-1492.
[29] Jeanne Lenzer, "Pfizer criticised over delay in admitting drug's problems." *BMJ* 2004:329 (23 Oct. 2004) 935.
[30] http://www.washingtonpost.comlwp-dyn/content/article/2007/08/07/AR2007080701944-pf.html
[31] "Pfizer Statement on CHANTIX (varenicline) Labeling Update in the United States," Pfizer, Inc. press release, January 18,2008, on Pfizer website, http://www.pfizer.comlnews/press_releases/pfizer_press_releases.jsp, accessed March 2008.
[32] Press Release, Pfizer, Inc., "Pfizer Statement on CHANTIX (varenicline) Labeling Update in the United States" (Jan. 18,2008) at http://www.pfizer.comlnews/press_releases/pfizer_press_releases.jsp.

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."[33]

H.
Failure to Warn and/or Adequately Warn of CHANTIX Risks

80. The information contained in the label for CHANTIX and package insert contains no warning and/or inadequate warning of risk for serious injury and/or death as experienced by the Decedent.

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

1.
Labeling Requirements

82. According 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.*

83. 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

[33] *Prescribing Information,* Pfizer, Inc., from FDA website, http://www.fda.gov/cder/foi/label/2008/021928s007lbl.pdf

> administration of the drug to patients known to have a hypersensitivity to it ... " *Id.* at § 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 .... " *Id*. at § 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. *Id.* 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." 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." 21 C.F.R. § 201.57 (g) (Emphasis added.)

84. At the time of ingestion, Decedent did not receive an adequate warning of the increased risk for serious injury and/or death from the CHANTIX label and package insert.

85. 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 provide inadequate information advising consumers of appropriate action if certain adverse events are experienced.

2.
Defendant Could Have Strengthened the Label Anytime

86. Defendants 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).

87. Defendants 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.

> FDA regulations explicitly permit manufacturers to unilaterally 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).

88. Such unilateral action to strengthen the label would have run contrary to the Defendant's marketing and advertising strategy: 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. This is, without exception, unacceptable.

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

89. Defendant is the world's leading manufacturer of pharmaceutical drugs.

90. In 2006, Pfizer earned $48.4 billion in revenues.

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

92. In fact, Pfizer published its 10K filing noting CHANTIX revenues rose 773 percent in one year (from $101 million in 2006 to $883 million in 2007).

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

94. Before approval by the FDA, Pfizer began marketing CHANTIX as "the first new

prescription treatment for smoking cessation in nearly a decade."[34]

95. 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."[35]

96. 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.

97. The Defendant, through its officers, agents, directors and, specifically the "Chief Executive Officer Jeffrey Kindler has been touting CHANTIX to help offset $12 billion in sales that the company [Defendant, Pfizer] ... is losing to generic competition [for Lipitor sales]" (Bloomberg. com news article 5/29/08)

98. Defendant's actions indicate a motive to pursue profits over patient safety and increase market share instead of studying the medicine.

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

100. Prior to the manufacturing, sale and distribution of CHANTIX, the Defendant,

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[34] Pfizer Corporate News, *Pfizer Delivers Strong Second-Quarter 2006 Results, Driven By Performance Of Major In-Line And New Products,* http://www.pfizer.com/news/rss_article.jsp?rssUrl=http://home.businesswire.com/portal/site/pfizer/index.jsp?ndmViewId=news_view&ndmConfigId=l006532&newsId=20070314006034&newsLang=en (July 20, 2006). Pfizer Corporate News, *Pfizer Reports Second-Quarter 2007 Results, Reconfirms Full-Year 2007 and 2008 Financial Guidance and Updates Progress on Immediate Business Priorities,* News.http://www.pfizer.com/news/rss_article.jsp?rssUrl=http://mediaroom.pfizer.com/portaUsite/pfizer/index.jsp?ndmViewId=news_view&ndmConfigId=1006533&newsId=20070718005442&newsLang=en (July 18, 2007).

[35] Pfizer Corporate News, *Pfizer Delivers Strong Second-Quarter 2006 Results, Driven By Performance Of Major In-Line And New Products,* http://www.pfizer.com/news/rss_article.jsp?rssUrl=http://home.businesswire.com/portaVsite/pfizer/index.jsp?ndmViewId=news_view&ndmConfigId=1006532&newsId=20070314006034&newsLang=en (July 20, 2006). Pfizer Corporate News, *Pfizer Reports Second-Quarter 2007 Results, Reconfirms Full-Year 2007 and 2008 Financial Guidance and Updates Progress on Immediate Business Priorities,* News.http://www.pfizer.com/news/rss_article.jsp?rssUrl=http://mediaroom.pfizer.com/portaVsite/pfizer/index.jsp?ndmViewId=news_view&ndmConfigId=1006533&newsId=20070718005442&newsLang=en (July 18, 2007).

through its respective officers, directors and managing agents, had notice and knowledge from several sources, that the product presented substantial and unreasonable risks of harm to the patients. As such, patients, including Decedent, were unreasonably subjected to risk of injury or death.

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

102. The Defendant and its respective 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.

103. The tortuous 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.

104. The Defendant sold CHANTIX by misleading users about the product and by failing to adequately warn the users of the potential serious dangers, which they knew or should have known, might result from consuming CHANTIX.

105. 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.

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

107. 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.

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

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

110. 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.

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

112. 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.

113. 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.

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

As such, CHANTIX consumers, including Decedent, were unreasonably subjected to risk of injury or death from the consumption of Defendant's product, CHANTIX.

115. 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.

116. 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.

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

118. Defendant promoted the sale of CHANTIX by misleading users about the product and by failing to warn and/or adequately warn the users of the increased risk of serious injury and/or death associated with and/or caused by CHANTIX.

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

120. 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.

121. 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.

122. 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.

123. Defendant acted with conscious and wanton disregard of the health and safety of Decedent and Plaintiffs, who request 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.

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

125. As a result, consumers, like Decedent, paid the ultimate price.

126. At all times material hereto, the Defendant proceeded to or permitted its respective drugs 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.

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

128. The Defendant failed to properly warn physicians through the package insert for CHANTIX, regarding the catastrophic, potentially fatal, risks.

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

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

COUNT I: PRODUCT LIABILITY CLAIM

131. Plaintiffs incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

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

133. At all relevant times to this action, Defendant owed a duty to properly warn Decedent and the Public of the risks, dangers and adverse side effects of CHANTIX.

134. 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.

135. 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 Decedent, 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 severe adverse skin reactions in the absence of clinical trials which cannot be conducted for this purpose, 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 Decedent, 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 severe skin reactions, 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.

136. 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 consumers, including Decedent, when safer and more effective methods of treatment were available.

137. The Defendant designed, tested, manufactured, packaged, marketed, distributed, promoted, and sold CHANTIX, placing the drug into the stream of commerce.

138. CHANTIX was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or

distributed by Defendant in a defective and unreasonably dangerous condition to consumers, including the Decedent.

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

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

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

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

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

144. CHANTIX was defective in its design in that it neither bore, nor was packaged with, nor accompanied by, warnings adequate to alert consumers, including Decedent, to the risks described herein, including, but not limited to, the risk of serious injury and/or death including, and violent behavior. 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 Decedent, of the potential risks and serious side effects associated with its use, thereby rendering Defendant liable to the Decedent.

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

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

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

148. 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 and more dangerous than an ordinary consumer would expect.

149. CHANTIX was also 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.

150. CHANTIX is unreasonably dangerous: a) in construction or composition; b) in design; c) because an adequate warning about the respective drugs was not provided; and d) because the respective drugs do not conform to an express warranty of the manufacturer about the product.

151. CHANTIX, as manufactured and supplied, was also 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. Defendants failed to perform adequate testing before exposing Decedent to CHANTIX.

152. CHANTIX, as manufactured and supplied by the Defendants, was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use and/or ingestion, they failed to provide adequate warnings to the medical community and the consumers, to whom they were directly marketing

and advertising; and, further, they continued to affirmatively promote CHANTIX as safe and effective.

153. 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.

154. Although Defendant knew or should have known of the defective nature of CHANTIX, it continued to design, manufacture, market, and sell CHANTIX so as to maximize sales and profits at the expense of the public health and safety. Defendant thus acted with conscious and deliberate disregard of the foreseeable harm caused by CHANTIX.

155. Decedent could not, through the exercise of reasonable care, have discovered the risk of serious injury and/or death associated with and/or caused by CHANTIX.

156. As a direct and proximate cause of the Defendant's defective design of CHANTIX, Decedent used the drugs rather than less expensive alternative smoking cessation therapies with better and/or similar efficacy. As a result, Decedent suffered the personal injuries described herein.

157. 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.

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

159. Defendant acted with conscious and deliberate disregard of the foreseeable harm

caused by use and ingestion of their respective drugs.

160. Neither Decedent nor his 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.

161. 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, Decedent, Decedent's heirs and Decedent's estate sustained injuries and damages alleged herein.

162. As a further direct and proximate result of the acts of Defendant, Ken and Judy Albrecht suffered emotional distress by unexpectedly and shockingly finding that their son had been shot to death.

WHEREFORE, Plaintiffs, both individually and as Personal Representatives of the Estate of Jeffrey Carter Albrecht, demands judgment against Defendant and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT II: BREACH OF EXPRESS WARRANTY

163. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

164. Defendant expressly represented to Decedent (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.

165. 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.

166. 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.

167. At all relevant times, including during the period that Decedent ingested and suffered injury, CHANTIX did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

168. Decedent, other consumers, and the medical community relied upon Defendant's express warranties, resulting in Decedent's ingestion of the drug.

169. Plaintiff, after ascertaining that the product violated express warranties, hereby supply notice to manufacturer of same through the filing of this lawsuit.

170. As a direct and proximate consequence of Defendant's breach of express warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiffs, Decedent, Decedent's heirs and Decedent's estate sustained injuries and damages alleged herein.

171. As a further direct and proximate result of the acts of Defendant, Ken and Judy Albrecht suffered emotional distress by unexpectedly and shockingly finding that their son had been shot to death.

WHEREFORE, Plaintiffs, both individually and as Personal Representative of the Estate of Jeffrey Carter Albrecht, demands judgment against Defendant and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT III: BREACH OF IMPLIED WARRANTY

172. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

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

174. At all relevant times, Defendant intended that CHANTIX be used in the manner that Decedent in fact used it and Defendant impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

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

176. Decedent was at all relevant times in privity with Defendant.

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

178. 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.

179. In reliance upon Defendant's implied warranty, Decedent used CHANTIX as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

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

181. Plaintiffs, after ascertaining that the product violated express warranties, supply notice to manufacturer of same through the filing of this lawsuit.

182. As a direct and proximate consequence of Defendant's breach of implied warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiffs, Decedent, Decedent's heirs and Decedent's estate sustained injuries and damages alleged herein.

183. As a further direct and proximate result of the acts of Defendant, Ken and Judy Albrecht suffered emotional distress by unexpectedly and shockingly finding that their son had been shot to death.

WHEREFORE, Plaintiffs, both individually and as Personal Representative of the Estate of Jeffrey Carter Albrecht, demand judgment against Defendant and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT IV: UNJUST ENRICHMENT

184. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

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

186. Decedent purchased CHANTIX for the purpose of stopping smoking.

187. Defendant has accepted payment from Decedent for the purchase of CHANTIX.

188. Decedent did not receive the safe and effective pharmaceutical product for which Decedent intended to purchase.

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

WHEREFORE, Plaintiffs, both individually and as Personal Representative of the Estate of Jeffrey Carter Albrecht, demand judgment against Defendant and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and issues so triable.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court appoint Ken Albrecht and Judy Albrecht as Personal Representatives of the Estate of Jeffrey Carter Albrecht for the purposes of this litigation, and demand judgment against Defendant on each count as follows:

a. Compensatory damages for the described injuries and losses with respect to each cause of action;

b. Funeral and burial expenses;

c. Pecuniary loss, including the loss of the care, maintenance, support, services, advise, counsel, and reasonable contributions of a pecuniary value;

d. Past and future mental anguish, including emotional pain, torment, and suffering experienced by Plaintiffs Ken and Judy Albrecht because of the death of their son, Jeffrey Carter Albrecht;

e. Past and future emotional distress;

f. Loss of companionship and society, including the loss of the positive benefits flowing from the love, comfort, companionship and society of their son Jeffrey Carter Albrecht to Ken & Judy Albrecht;

g. Reasonable attorney's fees where recoverable;

h. Punitive damages;

i. Costs of this action;

j. Prejudgment and all other interest recoverable in this action;

k. Postjudgment interest from date of judgment until paid; and,

l. Such other additional and further relief to which Plaintiffs may be justly entitled, in law or in equity.

Respectfully submitted,

LAW FIRM OF BARRETT W. STETSON

/s/ Barrett W. Stetson

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