IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT - LAW DIVISION

WENDY B. DOLIN, Individually and as Independent Executor of the ESTATE OF STEWART DOLIN, deceased, Plaintiff, v. SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, a Pennsylvania Corporation; MYLAN INC., a Pennsylvania Corporation; and H.D. SMITH WHOLESALE DRUG CO., a Delaware Corporation with its principal place of business in Illinois, Defendants.	)	Case No.

2012L007614
CALENDAR/ROOM Z
TIME 00:00
Product Liability

FILED LAW DIVISION
2012 JUL -9 AM 10: 04
DOROTHY BROWN
CLERK OF THE CIRCUIT COURT
COOK COUNTY, IL

COMPLAINT AT LAW

Now comes the plaintiff, Wendy B. Dolin, individually, and as Independent Executor of the Estate of Stewart Dolin, deceased, complaining against defendants, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, MYLAN INC. and H.D. SMITH WHOLESALE DRUG CO., who states:

NATURE OF ACTION AND VENUE

1. This is an unlawful misrepresentation and product liability wrongful death case arising out of the generic Paxil-induced suicide of Stewart Dolin on or about July 15, 2010, in Chicago, Illinois.

2. The transaction out of which the causes of action set forth in this complaint arise occurred in Cook County, Illinois making venue appropriate pursuant to §5/2-101(2) of the Illinois Code of Civil Procedure.

3. At the time of his suicide, Stewart was under the influence of the generic version of an antidepressant, Paxil, known generically as "paroxetine," manufactured by MYLAN Inc. and distributed by H.D. SMITH.

4. Paxil was originally designed, developed, tested, manufactured, labeled, marketed, promoted and distributed by SmithKline Beecham Corporation d/b/a GlaxoSmithKline (hereinafter referred to as "GSK").

5. Upon information and belief, GSK was either a supplier of generic paroxetine to MYLAN at the time of Stewart Dolin's death or was in a licensing agreement with MYLAN and receiving royalties from MYLAN for its sales of generic paroxetine.

6. The Circuit Court of Cook County, Illinois, Probate Division, appointed Wendy B. Dolin as Independent Executor of the Estate of Stewart Dolin, deceased, on August 19, 2010. She brings this action to recover damages and injunctive relief against defendants GSK, MYLAN and H.D. SMITH.

PARTIES

7. Plaintiff Wendy B. Dolin is a competent adult and a resident of the State of Illinois, County of Cook. At the time of her husband's death, Wendy and Stewart were residing at 721 Woodridge Lane, Glencoe, Illinois.

8. Wendy and Stewart Dolin were happily married for over 35 years.

9. On or about July 15, 2010, in Chicago, Illinois, Stewart Dolin suffered serious personal injuries and death as a result of taking the prescription drug paroxetine (generic Paxil).

10. Defendant GSK is a corporation duly existing under and by virtue of the laws of the State of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania. At all times hereinafter mentioned, defendant GSK was a pharmaceutical company involved in research,

development, design, testing, manufacture, contracting for manufacture, production, labeling, promotion, distribution, and marketing of pharmaceuticals for distribution, sale, and use by the general public, including Paxil, an antidepressant, throughout the United States and the State of Illinois. GSK regularly conducted business in Illinois, receiving substantial revenues in Illinois. This court has personal jurisdiction over GSK pursuant to Illinois' Long Arm statue and because GSK has the requisite contacts with the State of Illinois.

11. Defendant MYLAN INC. (hereinafter referred to as "MYLAN") is a corporation duly existing under and by virtue of the laws of the State of Pennsylvania with its principal place of business in Canonburg, Pennsylvania. At all times hereinafter mentioned, defendant MYLAN was and still is a generic pharmaceutical company involved in research, development, testing, manufacture, production, promotion, distribution, and marketing of pharmaceuticals for distribution, sale and use by the general public, including paroxetine, an antidepressant, throughout the United States and the State of Illinois. This court has personal jurisdiction over MYLAN pursuant to Illinois' Long Arm statute and because MYLAN has the requisite contacts with the State of Illinois.

12. Defendant H.D. SMITH WHOLESALE DRUG CO. (hereinafter referred to as "H.D. SMITH") is a corporation duly existing under and by virtue of the laws of the State of Delaware with its principal place of business in Springfield, Illinois. At all times hereinafter mentioned, defendant H.D. SMITH was a wholesale drug company involved in marketing, promoting, merchandising and distributing brand name and generic pharmaceuticals, including generic Paxil, known as paroxetine, an antidepressant, throughout the United States and the State of Illinois. H.D. SMITH regularly conducted business in Illinois, receiving substantial revenues

in Illinois. This court has personal jurisdiction over H.D.SMITH pursuant to Illinois' Long Arm statute and because H.D.SMITH has the requisite contacts with the State of Illinois.

13. At all times herein mentioned, defendants, and each of them, and their aggregates, corporates, associates, and partners, and each of them, were the agent, servant, employee, assignee, permissive user, successor in interest or joint venture of each other, and were acting within the time, purpose or scope of such agency or employment or permission; and all acts or omissions alleged herein of each such defendant were authorized, adopted, approved, or ratified by each of the other defendants.

GENERAL ALLEGATIONS

14. At the time of his death, Stewart Dolin was a 57 year old attorney and partner in the Chicago law firm of Reed Smith. He was married to Wendy Dolin with whom he had been married for over 35 years and was the father of two adult children. The Dolins were financially secure, owned their home outright, and had no pressing debts. The Dolins lived comfortably, traveled often and had an active social life.

15. In June 2010, Stewart's family doctor wrote him a prescription for Paxil to help him deal with work related anxiety and depression. Stewart's prescription was filled with the generic version of Paxil (paroxetine) manufactured by MYLAN. Rather than help him, as a result of taking the medication, Stewart's anxiety and depression got worse, he had difficulty sleeping and began having extreme thoughts.

16. On July 15, 2010, six days after beginning paroxetine, Stewart ate lunch with a business associate and returned to his office. A short time later, Stewart left the office and walked to a nearby Chicago Transit Authority Blue Line platform at the Washington/Dearborn stop.

17. As the northbound train reached the platform, Stewart leaped in front of the approaching train to his death.

18. On autopsy, Stewart's cavity blood tested positive for paroxetine.

19. Paxil (paroxetine) and other similar serotonergic antidepressants called selective serotonin reuptake inhibitors ("SSRIs") can cause an adverse reaction called akathisia, a neurobiological phenomenon marked by profound inner restlessness and agitation. The reaction often manifests itself with patients not being able to sit still, pacing or wringing their hands.

20. Akathisia has been associated with suicidal behavior for decades. For instance, a scientist working for another SSRI manufacturer, Pfizer, wrote in a 1998 medical journal article that the suicidal impulses resulting from akathisia may be explained as a feeling that "death is a welcome result" when the "acutely discomforting symptoms of akathisia are experienced on top of already distressing disorders."

21. Stewart exhibited classic symptoms of akathisia immediately before his death. A nurse who was also on the platform, noticed Stewart was very agitated, pacing back and forth and looking down the tracks.

22. The paroxetine label in existence at the time of Stewart Dolin's death did not warn of the drug's association with an increased risk of suicidal behavior in adults despite GSK's knowledge of a statistically significant 6.7 times greater risk in adults of all ages. In fact, the label stated the opposite – that the suicidality risk did not extend beyond the age of 24.

23. Paroxetine is manufactured, promoted, distributed, and marketed by GSK under the trade name Paxil, Paxil Oral Suspension, and Paxil CR. Paxil ("paroxetine") was first approved for use in the United States in 1992 for the treatment of depression in adults.

24. Paroxetine, the active ingredient in Paxil, is manufactured by GSK and generic drug companies, including MYLAN, who represent that their respective generic paroxetine products contain the same sole active ingredient as Paxil and to be bioequivalent and therapeutically equivalent to Paxil.

25. Upon information and belief, MYLAN gained FDA approval to market generic paroxetine in 2007.

26. Upon information and belief, GSK was a supplier of generic paroxetine to MYLAN at the time of Stewart Dolin's death or had an exclusive licensing agreement with MYLAN and received royalties from MYLAN for sales of generic paroxetine.

27. As set forth in more detail below, GSK has been aware of Paxil's association with an increased risk of suicidality in adults for over 20 years, but concealed the risk, and instead promoted Paxil as safe and effective.

28. MYLAN and H.D. SMITH knew or should have known of this risk.

29. In November 1989, GSK submitted its "Integrated Summary of Safety Information" to obtain approval of Paxil to treat adult depression. Amongst other adverse event statistics, the Safety Summary reported the number of suicides and suicide attempts experienced by patients who took Paxil, a placebo or a comparator drug during GSK's initial clinical trials.

30. In its presentation of the suicide attempts, GSK included in its analysis suicide attempts of placebo patients that had taken place in the placebo run-in (or wash-out) phase, **before the clinical trial actually began,** as though they had occurred after the start of the study.[1] This skewed the statistical analysis of the data presented and obscured the true risk.

[1] During the placebo run-in period (which is also called wash-out), patients participating in a clinical trial are taken off of any medications they may be taking and given a placebo (inert substance) instead. In this way, a person's system is "washed out" of other drugs and all patients

31. Adverse events that occur during run-in periods *cannot* be included when calculating adverse event ratios for clinical trials. This principle has been confirmed by both the FDA and, ultimately, GSK itself.

32. The FDA's Dr. Robert Temple, a senior figure within the FDA, and Dr. Martin Brecher, the FDA reviewer who analyzed Paxil's safety as part of the FDA approval process, confirmed that it is inappropriate to count run-in events.

33. Dr. Brecher specifically testified that it is "scientifically illegitimate" to count placebo run-in/washout events.

34. Michael Seika, another FDA medical reviewer, explained why run-in adverse events should not be counted. According to a December 8, 1999 GSK memo of a conversation with the FDA: "Specifically, I [Thomas Kline, Assistant Director of Regulatory Affairs at GSK] asked [Michael Seika] if a patient were to die during placebo run-in, i.e. prior to randomization, should that patient be included in the calculation for placebo deaths. He clearly stated that such a patient should not be counted in our analyses, since such a patient would not comprise the 'controlled' portion of a trial."

35. GSK understood that counting adverse events during placebo run-in was improper as reflected by GSK employee Daniel Burnham's email to other GSK employees: "However, we cannot combine these placebo run-in deaths with the randomized placebo death rate for the 3 reasons above."

36. GSK's Chief Executive Officer testified that adverse side effects should only be counted after the wash-out phase is complete and the official study has begun.

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start the trial on a drug-free basis at "baseline," i.e. at the actual beginning of the clinical trial. Because people who are stopping medications during this wash-out period may be experiencing adverse events associated with withdrawing from the medication they were on, adverse events experienced during this period are not properly counted as occurring during the clinical trial.

37. An accurate reading of GSK's original safety submission to the FDA, excluding placebo run-in events, comparing the on-Paxil and on-placebo event rates to each other, **patients taking Paxil were at an 8.9 times greater risk of experiencing a suicide event than those on placebo**.

38. GSK continued the subterfuge in a 1991 submission to FDA analyzing suicidality data from its clinical trials. In response to a request from the FDA, GSK prepared a report entitled, "Suicidal Ideation and Behavior: An Analysis of the Paroxetine Worldwide Clinical Database," which was sent to the FDA by cover letter dated May 10, 1991.

39. When GSK reported the number of suicide attempts, it increased the number of suicide attempts by double and failed to disclose how many occurred during the run-in phase.

40. In fact, 5 of the 6 placebo suicide attempts identified in the May 10, 1991 report were placebo run-in events.

41. Additionally, GSK reduced the number of patients on Paxil who attempted suicide from 42 to 40.

42. By increasing the number of suicide attempts of patients taking placebo and reducing the number of Paxil patients attempting suicide, the percentages between Paxil and placebo became approximately the same, indicating a nominal increased risk for Paxil patients. (The percentage of Paxil patients attempting suicide went down from the original submission because GSK reduced the number of Paxil suicide attempts from 42 to 40.)

43. By taking out the run-in suicide attempt events, the correct number was 40 suicide attempts while on Paxil versus 1 attempt on placebo, an approximately 7.5 fold increase of suicide attempt risk for Paxil patients.

44. This does not include the number of completed suicide ratios which would provide a more complete picture of Paxil-induced suicidal behavior. Adding suicide deaths and suicide attempts together, there was an over 8 fold greater rate of suicidal acts on Paxil than on placebo.

45. The 1992 Summary Basis for Approval of Paxil shows that the FDA itself relied upon and reiterated the May 10, 1991 Suicide Report's false placebo numbers and the incorrect conclusions based on them.

46. On June 11, 2008, U.S. Senator Chuck Grassely (R-Iowa), Chairman of the Senate Committee on Finance noted in a speech to the Senate that GSK engaged in deliberate concealment of safety risks and requested an investigation into GSK's conduct.

47. In his floor statement, Sen. Grassley stated that "[e]ssentially, **it looks like GlaxoSmithKline bamboozled the FDA**."

48. Senator Grassley stated that the true data "demonstrates a causal link between the antidepressant and suicidal behavior. This has been true since 1989 although the 'bad' Paxil numbers obscured the risk for a decade-and-a-half."

49. In public, GSK continued to defend its actions. GSK spokeswoman Mary Anne Rhyne told the New Scientist in a February 2008 article that inclusion of the run-in/washout data "was intended to present the full picture of events that occurred in all phases of the clinical trials - starting from the time patients were enrolled, before they were randomised."

50. But, the New Scientist reported, "[i]ndependent researchers say it was wrong to use washout data as GSK did. '**I can't imagine circumstances in which it would be appropriate**,' says Bruce Psaty of the University of Washington in Seattle."

51. Both prior to and following Paxil's approval, GSK conducted a substantial marketing campaign regarding the benefits and safety of Paxil, reiterating in multiple arenas the

false placebo numbers from its May 10, 1991 report and the conclusions based on those false numbers.

52. For example, in September 1991, GSK employees Dr. Geoffrey Dunbar and Sarah Mewitt presented a paper entitled "Evaluation of Suicidal Thoughts and Acts with Paroxetine" at a medical conference in order to address the then recent concerns linking suicidality to SSRI antidepressants.

53. The presentation repeated the false figures from the May 10, 1991 report.

54. Dr. Dunbar presented a paper entitled, "Reduced suicidal thoughts and behavior (suicidality) with paroxetine" to the December 1991 meeting of the American College of Neuropsychopharmacology in San Juan, Puerto Rico.

55. The report asserts that "Suicides and suicide attempts occurred less frequently with paroxetine than with either placebo or active controls." However, the actual Paxil Safety Summary showed the opposite, that Paxil-treated patients attempted or committed suicide over 7 times more often than placebo-treated patients.

56. The paper falsely concluded, "This analysis shows that suicidality is inherent in depressive illness and that paroxetine is appropriate for the integrity of depressed patients."

57. After approval, GSK's promotional campaign continued and, in 1995, GSK's employee Dr. Geoffrey Dunbar and two other psychiatrists (relying upon the manipulated data) published another article in the medical journal of *European Neuropsychopharmacology*.

58. The article, titled, "Reduction of Suicidal Thoughts with Paxil in Comparison with Reference Antidepressants and Placebo" concluded that Paxil actually *reduced* suicides and suicides attempts.

59. Armed with the new "peer reviewed" article, GSK instructed its sales force to use the article with "your physicians to **alleviate any concerns they may have regarding suicidal ideation**." GSK did nothing to correct the flawed suicide data it had promulgated to the medical community.

60. On April 11, 2002, GSK submitted a Supplemental New Drug Application ("sNDA") to FDA "proposing the use of Paxil to treat children and adolescents with major depressive disorder and obsessive compulsive disorder." This Application was never approved by the FDA.

61. On October 7, 2002, Dr. Andrew Mosholder, the FDA reviewer of the pediatric sNDA for Paxil completed his review and noted that the most prominent adverse reactions in the Paxil clinical trials were "behavioral effects," but he stated "these events were coded with terms such as hostility and emotional lability. As previously noted, the sponsor's method of coding these events was potentially confusing, and thus additional information will be helpful for the purpose of definitively assessing the potential behavioral toxicity of paroxetine treatment in pediatric patients . . . Further assessment of the safety profile will have to await the sponsor's reply to requests for additional information . . ."

62. On October 21, 2002, the FDA issued a letter to GSK on its adolescent sNDA requesting additional information and clarification including "an expanded version of [a table of adverse events coded under the terms hostility, emotional lability or agitation], including all psychiatric and behavioral adverse events, and also those that occurred among placebo patients" and GSK's "rationale for coding suicide attempts and other forms of self-injurious behavior under the [ ] term 'emotional lability.'"

63. On October 25, 2002, John Davies of GSK's Biomedical Data Sciences department completed two analyses of the pediatric studies' adverse event data. The results of the first analysis showed a statistically significant difference between those children and adolescents taking Paxil compared to those taking placebo. Paxil demonstrated a relative risk 2.83 times greater than placebo. The second analysis showed a statistically significant difference between children and adolescents taking Paxil compared to those taking placebo. Paxil demonstrated a relative risk 3.0 times greater than placebo.

64. On May 21, 2003, seven months after the FDA requested additional data from GSK concerning events coded as hostility, emotional lability or agitation and seeking an explanation from GSK concerning its "rationale for coding suicide attempts and other forms of self-injurious behavior under the [ ] term 'emotional lability,'" GSK submitted a briefing document to UK regulators summarizing its pediatric clinical trial data.

65. On June 2, 2003, Dr. Russell Katz of the FDA informed FDA reviewer, Dr. Andrew Mosholder by email that the FDA had been contacted approximately one week earlier by British regulators who informed FDA that data submitted in the UK by GSK "demonstrated that use of Paxil in kids was associated with increased suicidality compared to placebo, and that the company proposed labeling changes." According to this same email, GSK "had not informed [FDA] of any of this . . ."

66. The email also states that the FDA received a "partial response" from GSK to the FDA's request for further elaboration on events subsumed under the term "Emotional Lability" and that "**almost all of these events related to suicidality**."

67. Dr. Katz also pointed out in this email that GSK "**has not proposed labeling changes**, and makes a feeble attempt to dismiss the finding." He also stated FDA's intention to

review other SSRIs to see whether or not "similar events are being **hidden by various inappropriate coding maneuvers.**"

68. As with children and adolescents, GSK coded suicide events that occurred in the adult clinical trials of Paxil as "emotional lability" as well.

69. On February 2, 2004, the FDA convened an advisory committee to discuss the relationship between Paxil and other antidepressants and suicidality in pediatric patients which ultimately recommended that the FDA issue an immediate warning concerning the potential risk of suicidality while a more in-depth analysis took place.

70. On March 22, 2004, the FDA issued a Public Health Advisory in which it asked antidepressant manufacturers to warn about a potential suicidality risk for *both* children/ adolescents and adults. Even though the FDA had not yet analyzed the adult data, the FDA asked for this added precautionary warning as to both adult and pediatric patients.

71. In May 2004, GSK sent a "Dear Healthcare Professional" letter to doctors in the United States alerting them of the FDA's March 22, 2004 Public Health Advisory. The letter described new revised labeling that explained "patients with major depressive disorder, both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and (suicidality). . . ." The new warning recommended "close observation" of patients taking Paxil "for worsening depression or the emergence of suicidality, particularly at the beginning of treatment or at the time of dose increases or decreases." The May 2004 GSK warning provided:

> Patients with major depressive disorder, *both adult* and pediatric, may experience worsening of their depression and/or emergence of suicidal ideation and behavior (suicidality)...**patients being treated with antidepressants should be observed closely for clinical worsening and suicidality especially at the beginning of a course of drug therapy . . . Families and caregivers of patients being treated with antidepressants**

> **for major depressive disorder or other indications . . . should be alerted about the need to monitor patients for the emergence of agitation . . . as well as the emergence of suicidality . . . .**

72. On September 13 and 14, 2004, the FDA advisory committee reconvened to discuss the more in-depth analyses of antidepressant pediatric clinical trials. At the conclusion of the meeting, 25 of the experts on the FDA advisory panel voted that the data presented to them from antidepressant clinical trials in children/adolescents demonstrated a causal relationship between the antidepressants and increased suicidality. (One voted to abstain and one voted against.)

73. The FDA advisory committee recommended that a black box warning be added to antidepressant labels and the FDA agreed.

74. In January 2005, GSK updated the Paxil label to add the black box warning concerning antidepressants and the increased risk of suicidality. That warning also urged practitioners to observe their patients for signs of drug-induced suicidal behavior, including "anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania . . . ."

75. Following the child/adolescent analyses and new warnings, the FDA next sought data from manufacturers for their adult clinical trials of antidepressants. The FDA requested specific studies including those that lasted less than 17 weeks and studies involving patients with major depressive disorder.

76. Apparently recognizing that compliance with the FDA request would show that patients on Paxil had a statistically significant increased risk of suicide attempts when compared to placebo, GSK unsuccessfully lobbied the FDA to allow it to include other studies it knew were clinically different and would dilute the data and obscure the findings.

77. GSK finally accepted the FDA's request and, in late 2005, GSK began an internal analysis of the suicide data, following the FDA guidelines.

78. GSK looked specifically at all age groups of patients taking Paxil compared to patients taking placebo. GSK found that adults with Major Depressive Disorder treated with Paxil compared to placebo were at a significant increased risk of attempting suicide.

79. The results showed that the odds ratio for suicide attempt on Paxil was 6.7, a statistically significant result, meaning a patient on Paxil was about seven times more likely to attempt suicide than a patient on placebo.

80. GSK issued a "Briefing Document" on April 5, 2006, which stated: "The results provide evidence of an increase in suicide attempts in adults with MDD treated with paroxetine compared to placebo" with an "odds ratio [of] 6.7 ..."

81. Although GSK stated in the Briefing Document that the "evidence of increased suicide attempts in adults with MDD treated with paroxetine compared to placebo" was "new . . .," that statement was not true.

82. GSK changed the Paxil label in May 2006 to include this language: "In adults with MDD (all ages), there was a statistically significant increase in the frequency of suicidal behavior in patients treated with paroxetine compared with placebo (11/3,455 [0.32%] versus 1/1,978 [0.05%]); all of the events were suicide attempts."

83. Because of its adult analysis demonstrating a risk in adults, GSK deleted from its May 2006 label the following language (which had been in previous labels): "It is unknown whether the suicidality risk extends to adults."

84. The FDA did not object to GSK's label change.

85. GSK also sent a "Dear Doctor" letter to U.S. physicians in May 2006, which included this same language.

86. Meanwhile, in November 2006, the FDA completed its pooled analysis of select clinical trials (lasting less than 17 weeks) of a number of antidepressants to determine whether the suicidal risk found in the pediatric population extended to adults.

87. The data behind the FDA adult analysis involved 372 trials with 99,839 subjects and involved 18 different kinds of antidepressants, of which Paxil was but one. Of the 52,960 subjects receiving the primary antidepressants (not active control or placebo), Paxil subjects comprised 16.5% of them.

88. The 18 kinds of antidepressants which were in the analysis were classified by FDA as: SSRIs, SNRIs, Other modern antidepressants, Tricyclic antidepressants and Other antidepressants. The various SSRI drugs, of which Paxil is one, comprised eight of the 18 types of antidepressants (44.4%).

89. Thus, the analysis comprised five different neurological classes of antidepressants, including SSRIs (which are themselves different from each other), with different mechanisms of action and side effect profiles, including a propensity (or lack thereof) to induce suicidal behavior.

90. Nonetheless, the analysis showed a definite increased risk of suicidality and suicidal acts among the young adult population. Specifically, the data showed a statistically significant increased risk of both suicidality and suicidal acts for SSRI patients less than 25 years old.

91. For paroxetine, the data showed that patients under 25 taking paroxetine had a 4.36 times increased risk of a suicidal act when compared to placebo.

92. On December 13, 2006, the FDA held an advisory committee meeting to discuss its analysis of the adult data. The FDA's Dr. Thomas Laughren told the committee from the start that "there is a box warning on all antidepressant labeling, and we think that that language could be modified to extend the risk into young adults up to age 25." PDAC, December 13, 2006 transcript, p. 313.

93. Ultimately, the FDA's advisory committee agreed that "labeling changes were needed to inform health care professionals about the increased risk of suicidality in younger adults using antidepressants." May 2, 2007 FDA News Release.

94. During the meeting, Dr. Marc Stone, the FDA statistician who conducted the analysis of the adult antidepressant suicidality data, told the committee that the risk for up to age 25 "is pretty robust, and that is one reason why we stuck with it. Again, there is nothing magical about 25. You have a phenomenon that is pretty much continuous, declining with age. It is just with diminishing frequency. Yes, it's not like this goes away the day you turn 25. That's of course silly." December 13, 2006 PDAC transcript, p. 347.

95. Several months later, in May 2007, the FDA requested that manufacturers of "all antidepressant medications update the existing black box warning on their products' labeling to include warnings about increased risks of suicidal thinking and behavior, known as suicidality, in young adults ages 18 to 24 during initial treatment."

96. As illustrated above, the FDA's decision to enact class-wide labeling changes for all antidepressants, including Paxil, regarding suicidality in the adult population was based on a pooled analysis of numerous different antidepressants, not Paxil by itself.

97. In fact, Paxil was shown, in the FDA's own analysis, to increase the risk of suicidality in adult patients. Looking at Paxil alone, the FDA found an odds ratio of 2.76 for

suicidal behavior with a 95% Confidence Interval of 1.16-6.60 and a p-value of 0.02 (Table 16). What this means is that the positive association between Paxil and these suicidal events did not likely happen by chance.

98. While the FDA was in the process of implementing the class-wide labeling in 2007, GSK suggested in its exchanges with the FDA that it believed the Paxil-specific language that had been a part of Paxil's label for the previous year, should remain in the label.

99. In a June 22, 2007 email to GSK, the FDA responded to GSK's request by telling GSK that it could request a formal meeting concerning GSK's purported desire to keep the Paxil-specific language in the label.

100. Moreover, on June 21, 2007, the FDA told GSK: "We also have noted that some sponsors [drug manufacturers] have taken this opportunity to include other revisions to their labeling which are not applicable to the class labeling revision requested in our 5-1-07 letter. We are requesting that these changes be submitted as a separate supplement."

101. However, GSK never asked for a formal meeting, did not contest the class-wide labeling, nor did it seek additional labeling regarding Paxil-specific data in a separate supplement or otherwise. Instead, it chose to go along with the class-wide labeling.

102. Dr. Ronald Krall, GSK's Senior Vice President and Chief Medical Officer and the Co-Chairman of GSK's Global Safety Board testified that it was his decision not to request the meeting with the FDA because he speculated it would take a long time to get a meeting date and would not lead to a different result.

103. This is despite the fact that Dr. Krall (and GSK) felt the May 2006 analysis of Paxil clinical trials finding a 6.7 increased risk of suicidal behavior in adults of all ages was of such

importance that GSK notified physicians immediately through Dear Healthcare Professional Letters. Specifically, Dr. Krall testified:

> Q. [S]ir, would you agree that this new change to the warning section of the Paxil label GSK thought was important to get to prescribing physicians?
> A. Yes.
> Q. Okay. Now, in fact, the importance was such that GSK believed that it should notify physicians immediately through what we've described or what we've called the Dear Healthcare Professional letter?
> A. Correct.

104. GSK updated its label in August 2007 to state, inter alia:

> **Suicidality and Oral Suspension [boxed warning]**
>
> Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of PAXIL or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. **Short-term studies did not show an increase in the risk of suiciality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older.** Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. PAXIL is not approved for use in pediatric patients. (See WARNINGS: Clincial Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use.)

Emphasis added.

105. In the Warnings section, GSK's label stated, inter alia:

> Pooled analyses of short-term placebo-controlled trials of antidepressant drugs (SSRIs and others) showed that these drugs increase the risk of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults (ages 18-24) with major depressive disorder (MDD) and other psychiatric disorders. **Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24 …**

Emphasis added.

106. The emphasized language above (i.e., short-term studies did not show an increase in the risk of suicidality in adults beyond age 24) is false and misleading with respect to Paxil (paroxetine).

107. While the Warnings section of the label admitted "considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied," GSK did not disclose that, "among the selective serotonin reuptake inhibitors and newer antidepressants, only paroxetine was significantly associated with an excess risk of suicidal behavior ... (OR 2.76, 95% CI 1.16-6.60)." *See* Barbui et al., "Effectiveness of paroxetine in the treatment of acute major depression in adults: a systematic re-examination of published and unpublished data from randomized trials," CMAJ, January 29, 2008.

108. The label also stated that the use of Paxil "has been associated with the development of akathisia, which is characterized by an inner sense of restlessness and psychomotor agitation such as an inability to sit or stand still usually associated with subjective distress. This is most likely to occur within the first few weeks of treatment," **however, GSK did not warn of akathisia's association with suicidal behavior and impulses.**

109. In addition to GSK's own clinical trial data demonstrating a causal link, numerous studies published in the peer reviewed medical literature also support a causal relationship between Paxil and suicidal behavior, as the examples set forth below demonstrate.

110. Aursnes et al., "Suicide attempts in clinical trials with paroxetine randomized against placebo," *BMC Medicine* (2005), found "the data strongly suggest … an increased intensity of suicide attempts per year. The two meta-analyses and our contribution taken together

make a strong case for the conclusion, at least with a short time perspective, that adults taking antidepressants have an increased risk of suicide attempts."

111. Aursnes et al., "Even more suicide attempts in clinical trials with paroxetine randomised against placebo," *BMC Medicine* (2006), based on supplemental data, the authors later concluded that their suspicion concerning Paxil and suicide attempts as set forth in their 2005 analysis "has now been confirmed."

112. Donovan et al., "Deliberate Self-Harm and Antidepressant Drugs: Investigation of a Possible Link," *British Journal of Psychiatry* (2000), found a statistically significant relative risk of 5.5 for all SSRI antidepressants, and a 4.0 relative risk for Paxil in particular.

113. Donovan et al., "The occurrence of suicide following the prescription of anti-depressant drugs," *Archives of Suicide Research* (1999), concluded "[t]he ratio between the occurrence of suicide and prescription of different classes of antidepressants ... indicated that suicide by any method (violence, gassing, poisoning by ingestion of any substance) was more likely to occur following the prescription of SSRIs than of TCAs [a different class of antide-pressants]."

114. Juurlink et al., "The Risk of Suicide With Selective Serotonin Reuptake Inhibitors in the Elderly," *The American Journal of Psychiatry* (May 2006), concluded SSRIs posed an almost five times higher risk than non-SSRIs during the first month of treatment in the elderly.

115. Barbui et al., "Antidepressants and suicide symptoms: compelling new insights from the FDA's analysis of individual patient level data," (May 2008), found "in terms of suicidal behavior ... paroxetine was associated with a statistically significant increased risk (table 1)."

116. A study published in the Journal of the Canadian Medical Association stated: "The present analysis, which suggests that paroxetine is associated with a statistically significant

increase in the risk of suicidal tendencies, expands the results of previous re-analyses of GlaxoSmithKline's data [citing GSK's 2006 analysis finding a 6.7 times increased risk] ... **The recently released re-analysis by the US food and Drug Administration ... confirmed these figures by showing that, among the selective serotonin reuptake inhibitors and newer antitdepressants, only paroxetine was significantly associated with an excess risk of suicidal behavior** ... (OR 2.76, 95% CI 1.16-6.60)." Barbui et al., "Effectiveness of paroxetine in the treatment of acute major depression in adults: a systematic re-examination of published and unpublished data from randomized trials," CMAJ, January 29, 2008, emphasis added.

117. In 2011, the suicidal behavior risk identified in GSK's 2006 retrospective analysis (i.e., finding a 6.7 odds ratio for increased suicidal behavior in adults of all ages) was reiterated in the Journal of Clinical Psychiatry (accepted for publication in May 2011, published online in February 2011 and in print in November 2011). *See*, Carpenter et al., "Meta-Analysis of Efficacy and Treatment-Emergent Suicidality in Adults by Psychiatric Indication and Age Subgroup Following Initiation of Paroxetine Therapy: A Complete Set of Randomized Placebo-Controlled Trials." Thus, in 2011, after Stewart Dolin's death, GSK essentially reconfirmed the suicidal behavior risk it had found in 2006.

118. 21 CFR § 201.57(e) mandates changes in warnings "as soon as there is reasonable evidence of an association of a serious hazard with a drug" and further admonishes that "a causal relationship need not have been proved." 21 CFR § 201.57(e) **[**effective January 2006, this CFR was re-numbered and it is now 21 CFR 201.80]. Moreover, the manufacturer of pharmaceutical drug products **"bears the responsibility for the content of its label at all times."** *Wyeth v. Levine*, 129 S.Ct. 1187, 1197-98, 173 L.Ed. 2d 51 (2009), emphasis added.

119. Thus, prior to Stewart Dolin's suicide, GSK had the knowledge, the means, and the duty to provide the medical community and the consuming public with a true and accurate warning regarding the increased risk of suicidal behavior in adults of all ages. GSK has allowed statements it knows to be false and misleading, or with reasonable care it should have known were false and misleading, to remain in the label despite its knowledge and duty to warn about Paxil's and paroxetine's risks.

COUNT I
WRONGFUL DEATH
NEGLIGENT MISREPRESENTATION/CONCEALMENT CLAIM
AS TO DEFENDANT GSK

120. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

121. In *Board of Education of City of Chicago v. A, C and S, INC.* 131 Ill. 2d 428 (1989), the Illinois Supreme Court clarified that Illinois follows § 311 of the RESTATEMENT (SECOND) OF TORTS entitled "Negligent Misrepresentation Involving Risk of Physical Harm."

122. § 311 states:

> (1) One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results
>
> (a) to the other, or
>
> (b) to such third persons as the actor should expect to be put in peril by the action taken.
>
> (2) Such negligence may consist of failure to exercise reasonable care
>
> (c) in ascertaining the accuracy of the information, or
>
> (d) in the manner in which it is communicated.

123. As a pharmaceutical company, and pursuant to § 311, GSK has and had an affirmative duty to warn the public and medical community regarding known risks associated with its pharmaceutical products.

124. GSK concealed adverse information and provided inaccurate or biased information that was material to the prescribing decisions of physicians, which misled physicians and patients who were relying on those physicians' professional judgment, including Stewart Dolin's prescribing physician. This misleading information, along with omissions of material fact related to paroxetine's safety and effectiveness, caused health care providers, patients and the general public, including Stewart Dolin and his doctor, to be misled about paroxetine's risks and benefits and deprived doctors from making a proper risk/benefit assessment as to the use of paroxetine.

125. GSK has defrauded the medical profession (including Steward Dolin's prescribing physician), the paroxetine patient population, and the general public in that it, among other acts:

(a) Negligently and carelessly concealed paroxetine's association with suicidal behavior;

(b) Negligently and carelessly misrepresented the safety and efficacy of paroxetine;

(c) Negligently and carelessly manipulated clinical trial data to obscure the suicidal behavior risk;

(d) Negligently and carelessly orchestrated the publication of medical journal articles touting the efficacy and safety of paroxetine by hiring medical communications companies to ghostwrite articles and recruiting (and paying) prominent physicians to append their names to these ghostwritten articles;

(e) Negligently and carelessly misrepresented the safety and efficacy of paroxetine through its sales force and routine visits to physicians' offices, including the prescribing physician in this case;

(f) Negligently and carelessly mischaracterized and miscoded adverse events involving self-harm with the term "emotional lability" so as to reduce the number of occurrences and hide their existence from the public and regulators;

(g) Negligently and carelessly withheld from Stewart Dolin's prescribing physician and the medical community the fact that, during the clinical trials, paroxetine patients experienced more suicidal events than patients given placebo;

(h) Falsely represented to Stewart Dolin's prescribing physician, the medical community and consumers that paroxetine was significantly more effective than placebo;

(i) Failed to inform the medical and research communities that a significant number of patients taking paroxetine during clinical trials attempted acts of self-harm at a much higher rate than in patients who took placebo;

(j) Negligently and carelessly claimed that paroxetine's characteristic side effects of insomnia, agitation and anxiety were of little or no concern when in fact these effects are known to be among the most critical and deadly of the short-term risk factors for suicide;

(k) Negligently and carelessly denied paroxetine's association with serious or deadly thoughts or acts of self-harm when its own investigators informed GSK (and GSK determined itself) that Paroxetine was associated with such conditions;

(l) Allowed the use of concomitant medications in clinical trials to lessen side effects in order to avoid the reporting of treatment-emergent adverse events, such as akathisia;

(m) Negligently and carelessly misrepresented the suicidal behavior risk, stating that it does not extend beyond age 24, when GSK's own data showed an 8.9 times greater risk for adults of all ages (1989 data), a 6.7 greater risk for patients of all ages (May 2006 analysis and publication in February 2011 reiterating these figures) and, a 2.76 greater risk according to the FDA's late 2006 analysis.

126. When said representations and/or omissions were made by GSK, it knew those representations and/or omissions to be false, or negligently disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by GSK with the intent of inducing the public to take paroxetine and the medical community (including Stewart Dolin's prescribing physician) to recommend, prescribe, and dispense paroxetine.

127. At the time the aforesaid representations and/or omissions were made by GSK, and at the time Stewart Dolin ingested paroxetine, he, Plaintiff and his medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied on GSK's assertions, promulgated through its aggressive sales tactics as set forth herein, that the drug was safe and effective when, in fact, it was not.

128. In reliance upon said representations and/or omissions, Stewart Dolin's medical provider prescribed paroxetine and Stewart Dolin was induced to take paroxetine. Had Stewart's medical provider been made aware of paroxetine's risks, he would not have prescribed the drug, or he would have warned Stewart of the risk and precursor symptoms that could lead to suicide.

129. Had Stewart known of the actual dangers of paroxetine, through his medical providers or otherwise, he would not have ingested paroxetine, or he would have ceased taking it or otherwise sought help once its side effects (which were known or should have been known to Defendant GSK, but not fully disclosed to such providers or the public) became apparent.

130. GSK's motive in failing to advise physicians and the public of paroxetine's suicide risks (and that it knew a percentage of users of the drug inevitably would experience) was for financial gain.

131. At all times herein mentioned, the actions of GSK, its agents, servants, and/or employees were negligently wanton, grossly negligent, or reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Stewart Dolin in particular and to the general public in that GSK did negligently or willfully and knowingly place the dangerous and defective drug paroxetine on the market with the specific knowledge that it would be sold to, prescribed for, and used by members of the public and without adequate instructions for use.

132. As a direct and proximate result of GSK's negligent actions, omissions and misrepresentations, Plaintiff and the Estate of Stewart Dolin suffered physical injury, harm, damages, economic and non-economic loss, and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant GSK for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT II
WRONGFUL DEATH
FRAUDULENT MISREPRESENTATION/CONCEALMENT CLAIM
AS TO DEFENDANT GSK

133. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

134. As a pharmaceutical company, GSK has an affirmative duty to warn the public and medical community regarding known risks associated with its pharmaceutical products. GSK concealed adverse information and provided inaccurate or biased information that was material to the prescribing decisions of physicians, which misled physicians and patients who were relying on those physicians' professional judgment, including Stewart Dolin's prescribing physician. This misleading information, along with omissions of material fact related to paroxetine's safety and effectiveness, caused health care providers, patients and the general public, including Stewart Dolin and his doctor, to be misled about paroxetine's risks and benefits and deprived doctors from making a proper risk/benefit assessment as to the use of paroxetine.

135. GSK has defrauded the medical profession (including Steward Dolin's prescribing physician), the paroxetine patient population, and the general public in that it, among other acts:

(a) Fraudulently concealed paroxetine's association with suicidal behavior;

(b) Fraudulently misrepresented the safety and efficacy of paroxetine;

(c) Fraudulently manipulated clinical trial data to obscure the suicidal behavior risk;

(d) Fraudulently orchestrated the publication of medical journal articles touting the efficacy and safety of paroxetine by hiring medical communications companies to ghostwrite articles and recruiting (and paying) prominent physicans to append their names to these ghost-written articles;

(e) Fraudulently misrepresented the safety and efficacy of paroxetine through its sales force and routine visits to physicians' offices, including the prescribing physician in this case;

(f) Fraudulently mischaracterized and miscoded adverse events involving self-harm with the term "emotional lability" so as to reduce the number of occurrences and hide their existence from the public and regulators;

(g) Fraudulently withheld from Stewart Dolin's prescribing physician and the medical community the fact that, during the clinical trials, paroxetine patients experienced more suicidal events than patients given placebo;

(h) Fraudulently represented to Stewart Dolin's prescribing physician, the medical community and consumers that paroxetine was significantly more effective than placebo;

(d) Failed to inform the medical and research communities that a significant number of patients taking paroxetine during clinical trials attempted acts of self-harm at a much higher rate than in patients who took placebo;

(e) Fraudulently claimed that paroxetine's characteristic side effects of insomnia, agitation and anxiety were of little or no concern when in fact these effects are known to be among the most critical and deadly of the short-term risk factors for suicide;

(f) Fraudulently denied paroxetine's association with serious or deadly thoughts or acts of self-harm when its own investigators informed GSK (and GSK determined itself) that Paroxetine was associated with such conditions;

(g) Allowed the use of concomitant medications in clinical trials to lessen side effects in order to avoid the reporting of treatment-emergent adverse events, such as akathisia;

(h) Fraudulently misrepresented the suicidal behavior risk, stating that it does not extend beyond age 24, when GSK's own data showed an 8.9 times greater risk for adults of all ages (1989 data), a 6.7 greater risk for patients of all ages (May 2006 analysis and publication in

February 2011 reiterating these figures) and, a 2.76 greater risk according to the FDA's late 2006 analysis.

136. When said representations and/or omissions were made by GSK, it knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by GSK with the intent of defrauding and deceiving the public in general and the medical community and with the intent of inducing the public to take paroxetine and the medical community (including Stewart Dolin's prescribing physician) to recommend, prescribe, and dispense paroxetine.

137. At the time the aforesaid representations and/or omissions were made by GSK, and at the time Stewart Dolin ingested paroxetine, he and his medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied on GSK's assertions, promulgated through its aggressive sales tactics as set forth herein, that the drug was safe and effective when, in fact, it was not.

138. In reliance upon said representations and/or omissions, Stewart Dolin's medical provider prescribed paroxetine and Stewart Dolin was induced to take paroxetine. Had Stewart's medical provider been made aware of paroxetine's risks, he would not have prescribed the drug, or he would have warned Stewart of the risk and precursor symptoms that could lead to suicide. Had Stewart known of the actual dangers of paroxetine, through his medical providers or otherwise, he would not have ingested paroxetine, or he would have ceased taking it or otherwise sought help once its side effects (which were known or should have been known to Defendant GSK, but not fully disclosed to such providers or the public) became apparent.

139. GSK's motive in failing to advise physicians and the public of paroxetine's suicide risks (and that it knew a percentage of users of the drug inevitably would experience) was for financial gain.

140. At all times herein mentioned, the actions of GSK, its agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Stewart Dolin in particular and to the general public in that GSK did willfully and knowingly place the dangerous and defective drug paroxetine on the market with the specific knowledge that it would be sold to, prescribed for, and used by members of the public and without adequate instructions for use.

141. As a direct and proximate result of GSK's deliberate actions, omissions and misrepresentations, Plaintiff and the Estate of Stewart Dolin suffered physical injury, harm, damages, economic and non-economic loss, and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant GSK for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT III
VIOLATION OF ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT CLAIM AS TO DEFENDANT GSK

142. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

143. At all times pertinent hereto, Stewart Dolin was a "consumer" and "person" as those terms are defined in the Illinois Consumer Fraud and Deceptive Business Practices Act (the "Consumer Fraud Act") 815 ILCS 505/1.

144. At all times pertinent hereto, Defendant GSK was engaged in providing "advertisements" and "merchandise" in "trade" and "commerce" as those terms are defined in the Consumer Fraud Act, 815 ILCS 505/1.

145. GSK (a) engaged in unfair and deceptive acts and practices by providing unfair, false, deceptive, and unconscionable representations and statements in its label, advertisements, telemarketing, public relations and other promotional materials, as outlined in this Complaint; (b) with the intent on GSK's part that Stewart Dolin and other consumers would rely on this deception; and (c) which all occurred in a course of conduct involving trade and commerce.

146. As set forth above, GSK has known that Paxil can increase the risk of suicidal behavior in adults for more than 20 years. GSK re-confirmed the risk in 2006 (prior to Stewart Dolin's death) and warned of the risk at that time. However, in August 2007, after making a feeble attempt to keep the Paxil-specific suicide risk data in the label, GSK stripped this risk language from the label and changed the label to conform with class-wide labeling concerning antidepressants generally.

147. Despite its clear knowledge of a suicidal behavior risk and its previous warnings, since August 2007, GSK has allowed an affirmative misrepresentation to exist in the label that there is no risk beyond the age of 24. This is false and misleading and resulted in Stewart Dolin's death.

148. GSK failed to ensure that the content of its label was/is true and correct and adequately warns the medical community and consuming public of Paxil's risks.

149. The above and foregoing unfair and deceptive acts and practices constitute violations of the Consumer Fraud Act, 815 ILCS 505/2.

150. As a direct and proximate result of GSK's unfair and deceptive acts and practices, Stewart Dolin, Plaintiff and the public were deceived.

151. Plaintiff is entitled to damages and other statutory relief provided in the Act including but not limited to, appropriate injunctive and equitable relief.

152. The policies, acts and practices alleged herein were substantial, were not outweighed by any countervailing benefits to Plaintiff and caused damages to Plaintiff and Stewart Dolin that could have been avoided. Such conduct is unethical, unscrupulous and against public policy.

153. The above-described unfair and unconscionable acts and practices conducted by GSK continue to this day and will likely result in damages in the future.

154. As a result of the conduct described herein, GSK has been unjustly enriched at Plaintiff and decedent's expense.

155. Plaintiff seeks an order of this court declaring such deceptive acts and practices to be a violation of the Act, requiring GSK to immediately cease such unfair methods of competition and enjoining GSK from continuing to conduct business via the unfair and unconscionable acts and practices as complained herein. Plaintiff additionally requests an order disgorging GSK's ill-gotten gains and awarding Plaintiff full damages, plus attorney's fees and costs.

WHEREFORE, Plaintiff respectfully requests that she be awarded her actual economic damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division, her attorney's fees and costs and for injunctive relief in the form of an order a) declaring GSK's conduct to be deceptive and a violation of the Consumer Fraud Act; b)

directing GSK to cease and desist from engaging in such unfair and deceptive conduct; c) enjoining GSK from further violations of the Consumer Fraud Act; d) directing GSK to include in its Paxil label data showing the increased rate of suicidality for adult patients of all ages taking paroxetine or be enjoined from receiving royalties from generic paroxetine sales and from the manufacture, production, promotion, distribution and marketing of Paxil/paroxetine for distribution, sale, and use by the general public.

COUNT IV
WRONGFUL DEATH
STRICT PRODUCT LIABILITY DESIGN DEFECT CLAIM AS TO DEFENDANT GSK

156. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

157. Defendant GSK is the manufacturer, designer, distributor, seller, and/or supplier of paroxetine.

158. The paroxetine manufactured and supplied by Defendant GSK was unreasonably dangerous in design or formulation in that, when it left the control of the Defendant GSK, it was unsafe when put to its reasonably foreseeable use considering the nature and function of the drug defeating ordinary consumer expectations.

159. The paroxetine manufactured and supplied by Defendant GSK was unreasonably dangerous in design or formulation in that the risk of danger inherent in the design outweighs the benefits of the design when the product is put to a use that is reasonably foreseeable considering the nature and function of the product.

160. As a direct and proximate result of decedent's reasonably anticipated use of paroxetine as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendant GSK, Plaintiff and the Estate of Stewart Dolin suffered serious injury,

harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant GSK for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT V
WRONGFUL DEATH
STRICT PRODUCT LIABILTY DEFECT CLAIM DUE TO FAILURE TO WARN AS TO DEFENDANT GSK

161. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

162. The paroxetine manufactured and/or supplied by Defendant GSK was unreasonably dangerous due to inadequate warning or instruction because Defendant GSK knew or should have known that the product created significant risks of serious bodily harm and death to consumers and it failed to adequately warn health care providers of such risks.

163. The paroxetine manufactured and/or supplied by Defendant GSK was unreasonably dangerous due to inadequate post-marketing warning or instruction because, after Defendant GSK knew or should have known of the risk of serious bodily harm and death from the use of paroxetine, Defendant GSK failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

164. As a direct and proximate result of decedent's reasonably anticipated use of paroxetine as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendant GSK, Plaintiff and the Estate of Stewart Dolin suffered serious injury,

harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant GSK for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq.*, and/or other applicable laws.

COUNT VI
WRONGFUL DEATH
NEGLIGENCE CLAIM AS TO DEFENDANT GSK

165. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

166. Defendant GSK had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of paroxetine into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

167. Defendant GSK failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of paroxetine into interstate commerce in that GSK knew or should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

168. The injuries described herein were caused by the negligence and misrepresentations of GSK through its agents, servants and/or employees acting within the course and scope of their employment including among other things:

(a) Carelessly and negligently researching, designing, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing paroxetine;

(b) Failing to properly and adequately test paroxetine for its intended use for the treatment of depression;

(c) Failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions to paroxetine;

(d) Being careless and negligent in that GSK knew or should have known that paroxetine was a substance known to be associated with producing life-threatening effects upon certain users including but not limited to suicidal behavior;

(e) Negligently and carelessly failing to adequately warn the medical community, the general public, Plaintiff and Stewart Dolin in particular, of the dangers, contra-indications, and side effects from the use of paroxetine;

(f) Negligently and carelessly representing that paroxetine was safe for use for the purposes intended when, in fact, it was unsafe for certain users;

(g) Negligently and carelessly failing to act as a reasonably prudent drug manufacturer and/or distributor;

(h) Negligently and carelessly over promoting paroxetine in a zealous and unreasonable way;

(i) Failing to revise paroxetine's label to issue specific warnings regarding the adult suicide risks associated with paroxetine;

(j) Negligently and carelessly continuing to manufacture, distribute and market paroxetine for use by consumers notwithstanding the fact that it knew or should have

known that paroxetine posed a serious risk of bodily harm to consumers, that it contained inadequate warning and was defectively design;

(k) Negligently and carelessly failing to cease manufacturing, distribution, promotion and sales of the defectively designed and labeled paroxetine.

169. Before Stewart Dolin first took paroxetine, GSK, based upon the state of knowledge as it existed at the time, knew or should have known that paroxetine could be dangerous and unsafe, and knew or should have known that it was a substance associated with acts of self-harm.

170. Defendant GSK knew or should have known that consumers such as decedent would suffer injury as a result of GSK's failure to exercise ordinary care as described above.

171. As a direct and proximate result of Stewart Dolin's reasonably anticipated use of paroxetine as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by GSK, Plaintiff and the Estate of Stewart Dolin suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant GSK for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT VII
WRONGFUL DEATH
BREACH OF EXPRESS WARRANTY CLAIM
AS TO DEFENDANT GSK

172. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

173. Defendant GSK expressly warranted that paroxetine was a safe and effective prescription antidepressant and that it did not induce suicidal behavior in adult patients.

174. At all times herein mentioned, GSK utilized packaging, labeling, journal articles, advertising media, and an outside sales force to urge the use, purchase, and utilization of paroxetine and expressly warranted to physicians, plaintiffs, and other members of the general public that paroxetine was safe and effective.

175. GSK represented to the consumer who would use paroxetine and to the physicians who would prescribe it, without a complete disclosure of paroxetine's side effects, that paroxetine was safe and efficacious for people suffering from depression, which amounted to an express warranty of paroxetine's safety and efficacy.

176. GSK knew or in the exercise of reasonable diligence should have known that paroxetine could cause the serious side effects set forth herein.

177. Plaintiff and the medical community, including the doctors who prescribed paroxetine to Stewart Dolin, relied on GSK's express warranty representations in the use of paroxetine, but paroxetine was not effective, safe, and proper for its intended use as warranted in that paroxetine failed and was dangerous when put to its intended use.

178. As a direct and proximate result of the aforesaid conduct of GSK, Stewart Dolin suffered serious physical, emotional, and mental injuries, as well as economic injuries (to himself as well as to the Estate of Stewart Dolin) in excess of the jurisdictional minimum of this Court.

179. Timely notice was tendered to GSK pursuant to the applicable provisions of the Uniform Commercial Code and pursuant to 810 ILCS 5/2-607(3)(a) by the filing of this complaint and the service of the same upon said Defendant.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant GSK for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT VIII
WRONGFUL DEATH
BREACH OF IMPLIED WARRANTY OF
MERCHANTABILITY CLAIM AS TO DEFENDANT GSK

180. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

181. At the time GSK designed, manufactured, marketed, sold, and/or distributed paroxetine for use by Plaintiff, GSK knew of the use for which paroxetine was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

182. GSK represented and warranted to physicians, including Stewart Dolin's physician, and the public in general (the prescribers and users of the product) that paroxetine was safe and efficacious.

183. Stewart Dolin used paroxetine in accordance with his physician's recommendations and in the manner GSK intended.

184. As a result of GSK's manufacture and sale of paroxetine, there arose certain implied warranties running from GSK to Stewart Dolin as a purchaser and user of paroxetine. Among the implied warranties were that:

(a) Paxil/paroxetine was of merchantable quality;

(b) Paxil/paroxetine was fit for its primary purpose;

(c) Paxil/paroxetine was fit for the particular purpose for which it was intended;

(d) Paxil/paroxetine was not defective; and

(e) Paxil/paroxetine was safe and efficacious.

185. Stewart Dolin reasonably relied upon the skill and judgment of GSK as to whether paroxetine was of merchantable quality and safe for its intended use and upon GSK's implied warranty as to such matters.

186. Contrary to such implied warranty, paroxetine was not of merchantable quality or safe or fit for its intended use, because the product was unreasonably dangerous as described above.

187. Timely notice was tendered to GSK pursuant to the applicable provisions of the Uniform Commercial Code and pursuant to 810 ILCS 5/2-607(3)(a) by the filing of this complaint and the service of the same upon said Defendant.

188. As a direct and proximate result of GSK's breach of warranty, Plaintiff and the Estate of Stewart Dolin suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant GSK for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT IX
WRONGFUL DEATH
NEGLIGENT MISREPRESENTATION CLAIM
AS TO DEFENDANT MYLAN

189. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

190. As a pharmaceutical company, Defendant MYLAN has an affirmative duty to warn the public and medical community regarding known risks associated with its pharmaceutical products. MYLAN concealed adverse information and provided inaccurate or biased information that was material to the prescribing decisions of physicians, which misled physicians and patients who were relying on those physicians' professional judgment, including Stewart Dolin's prescribing physician. This misleading information, along with omissions of material fact related to paroxetine's safety and effectiveness, caused health care providers, patients and the general public, including Stewart Dolin and his doctor, to be misled about paroxetine's risks and benefits and deprived doctors from making a proper risk/benefit assessment as to the use of paroxetine.

191. Defendant MYLAN has defrauded the medical profession (including Steward Dolin's prescribing physician), the paroxetine patient population, and the general public in that it, among other acts:

(a) Negligently and carelessly concealed paroxetine's association with suicidal behavior;

(b) Negligently and carelessly misrepresented the safety and efficacy of paroxetine;

(c) Negligently and carelessly withheld from Stewart Dolin's prescribing physician and the medical community the fact that, during the clinical trials, paroxetine patients experienced more suicidal events than patients given placebo;

(d) Negligently and carelessly represented to Stewart Dolin's prescribing physician, the medical community and consumers that paroxetine was significantly more effective than placebo;

(e) Failed to inform the medical and research communities that a significant number of patients taking paroxetine during clinical trials attempted acts of self-harm at a much higher rate than in patients who took placebo;

(f) Negligently and carelessly claimed that paroxetine's characteristic side effects of insomnia, agitation and anxiety were of little or no concern when in fact these effects are known to be among the most critical and deadly of the short-term risk factors for suicide;

(g) Negligently and carelessly denied Paroxetine's association with serious or deadly thoughts or acts of self-harm;

(h) Negligently and carelessly misrepresented the suicidal behavior risk, stating that it does not extend beyond age 24;

(i) MYLAN had actual knowledge based upon studies, published reports and clinical experience that its product paroxetine created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information, yet MYLAN negligently omitted this information in its product labeling, promotions and advertisements and instead labeled, promoted and advertised its product as safe in order to avoid losses and sustain profits in sales to consumers.

192. When said representations and/or omissions were made by MYLAN, it knew those representations and/or omissions to be false, or negligently disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by MYLAN with the intent of inducing the public to take paroxetine and the medical community

(including Stewart Dolin's prescribing physician) to recommend, prescribe, and dispense paroxetine.

193. At the time the aforesaid representations and/or omissions were made by MYLAN, and at the time Stewart Dolin ingested paroxetine, he, Plaintiff and his medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied on MYLAN's assertions that the drug was safe and effective when, in fact, it was not.

194. In reliance upon said representations and/or omissions, Stewart Dolin's medical provider prescribed paroxetine and Stewart Dolin was induced to take paroxetine. Had Stewart's medical provider been made aware of paroxetine's risks, he would not have prescribed the drug, or he would have warned Stewart of the risk and precursor symptoms that could lead to suicide. Had Stewart known of the actual dangers of paroxetine, through his medical providers or otherwise, he would not have ingested paroxetine, or he would have ceased taking it or otherwise sought help once its side effects (which were known or should have been known to MYLAN, but not fully disclosed to such providers or the public) became apparent.

195. At all times herein mentioned, the actions of MYLAN, its agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Stewart Dolin in particular and to the general public in that MYLAN did willfully and knowingly place the dangerous and defective drug paroxetine on the market with the specific knowledge that it would be sold to, prescribed for, and used by members of the public and without adequate instructions for use.

196. As a direct and proximate result of MYLAN's negligent actions, omissions and misrepresentations, Plaintiff and the Estate of Stewart Dolin suffered physical injury, harm,

damages, economic and non-economic loss, and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant GSK for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT X
VIOLATION OF ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT CLAIM AS TO DEFENDANT MYLAN

197. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

198. At all times pertinent hereto, Stewart Dolin was a "consumer" and "person" as those terms are defined in the Illinois Consumer Fraud and Deceptive Business Practices Act (the "Consumer Fraud Act") 815 ILCS 505/1.

199. At all times pertinent hereto, Defendant MYLAN was engaged in providing "advertisements" and "merchandise" in "trade" and "commerce" as those terms are defined in the Consumer Fraud Act, 815 ILCS 505/1.

200. MYLAN (a) engaged in unfair and deceptive acts and practices by providing unfair, false, deceptive, and unconscionable representations and statements in its label, advertisements, telemarketing, public relations and other promotional materials, as outlined in this Complaint; (b) with the intent on the MYLAN's part that the Stewart Dolin and other consumers would rely on this deception; and (c) which all occurred in a course of conduct involving trade and commerce.

201. The above and foregoing unfair and deceptive acts and practices constitute violations of the Consumer Fraud Act, 815 ILCS 505/2.

202. As a direct and proximate result of MYLAN's unfair and deceptive acts and practices, Stewart Dolin, Plaintiff and the public were deceived.

203. Plaintiff is entitled to damages and other statutory relief provided in the Act including but not limited to, appropriate injunctive and equitable relief.

204. The policies, acts and practices alleged herein were substantial, were not outweighed by any countervailing benefits to Plaintiff and caused damages to Plaintiff and her decedent that could have been avoided. Such conduct is unethical, unscrupulous and against public policy.

205. The above-described unfair and unconscionable acts and practices conducted by MYLAN continue to this day and will likely result in damages in the future.

206. As a result of the conduct described herein, MYLAN has been unjustly enriched at Plaintiff and decedent's expense.

207. Plaintiff seeks an order of this court declaring such deceptive acts and practices to be a violation of the Act, requiring MYLAN to immediately cease such unfair methods of competition and enjoining MYLAN from continuing to conduct business via the unfair and unconscionable acts and practices as complained herein. Plaintiff additionally requests an order disgorging MYLAN's ill-gotten gains and awarding Plaintiff full damages, plus attorney's fees and costs.

WHEREFORE, Plaintiff respectfully requests that she be awarded her actual economic damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division; her attorney's fees and costs; and for injunctive relief in the form of an order

declaring MYLAN's conduct to be deceptive and a violation of the Consumer Fraud Act, and an order directing MYLAN to cease and desist from engaging in such unfair and deceptive advertising and enjoining it from further violations of the Consumer Fraud Act.

COUNT XI
WRONGFUL DEATH
STRICT PRODUCTS LIABILITY DESIGN DEFECT CLAIM AS TO DEFENDANT MYLAN

208. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

209. Defendant MYLAN is the manufacturer, designer, distributor, seller, and/or supplier of paroxetine.

210. The paroxetine manufactured and supplied by Defendant MYLAN was unreasonably dangerous in design or formulation in that, when it left the control of the Defendant GSK, it was unsafe when put to its reasonably foreseeable use considering the nature and function of the drug defeating ordinary consumer expectations.

211. The paroxetine manufactured and supplied by Defendant MYLAN was unreasonably dangerous in design or formulation in that the risk of danger inherent in the design outweighs the benefits of the design when the product is put to a use that is reasonably foreseeable considering the nature and function of the product.

212. As a direct and proximate result of Stewart Dolin's reasonably anticipated use of paroxetine as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by MYLAN, Plaintiff and the Estate of Stewart Dolin, suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant MYLAN for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT XII
WRONGFUL DEATH
STRICT PRODUCTS LIABILTY DEFECT CLAIM DUE TO FAILURE TO WARN AS TO DEFENDANT MYLAN

213. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

214. The paroxetine manufactured and/or supplied by Defendant MYLAN was defective due to inadequate warning or instruction because MYLAN knew or should have known that the product created significant risks of serious bodily harm and death to consumers and it failed to adequately warn consumers and/or their health care providers of such risks.

215. The paroxetine manufactured and/or supplied by MYLAN was defective due to inadequate post-marketing warning or instruction because, after MYLAN knew or should have known of the risk of serious bodily harm and death from the use of paroxetine, MYLAN failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

216. As a direct and proximate result of Stewart Dolin's reasonably anticipated use of paroxetine as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by MYLAN, Plaintiff and the Estate of Stewart Dolin suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant MYLAN for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT XIII
WRONGFUL DEATH
NEGLIGENCE CLAIM AS TO DEFENDANT MYLAN

217. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

218. Defendant MYLAN had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of paroxetine into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

219. MYLAN failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of paroxetine into interstate commerce in that MYLAN knew or should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

220. The injuries described herein were caused by the negligence and misrepresentations of MYLAN through its agents, servants and/or employees acting within the course and scope of their employment including among other things:

(a) Carelessly and negligently researching, designing, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing paroxetine;

(b) Failing to properly and adequately test paroxetine for its intended use for the treatment of depression;

(c) Failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions of paroxetine;

(d) Being careless and negligent in that MYLAN knew or should have known that paroxetine was a substance known to be associated with producing life-threatening effects upon certain users including but not limited to suicidal behavior;

(e) Negligently and carelessly failing to adequately warn the medical community, the general public, Plaintiff and Stewart Dolin in particular, of the dangers, contra-indications, and side effects from the use of paroxetine;

(f) Negligently and carelessly representing that paroxetine was safe for use for the purposes intended when, in fact, it was unsafe for certain users;

(g) Negligently and carelessly failing to act as a reasonably prudent drug manufacturer and/or distributor;

(h) Negligently and carelessly over promoting paroxetine in a zealous and unreasonable way;

(i) Failing to send a "Dear Doctor" letter to physicians to warn regarding the adult suicide risks associated with paroxetine;

(j) Failing to ask GSK to make labeling changes to Paxil's label to warn regarding the adult suicide risks associated with Paxil/paroxetine;

(k) Failing to ask the FDA to issue enhanced warnings regarding the adult suicide risks associated with paroxetine;

(l) Negligently and carelessly continuing to manufacture, distribute and market paroxetine for use by consumers notwithstanding the fact that it knew or should have known that paroxetine posed a serious risk of bodily harm to consumers, that it contained inadequate warning and was defectively design;

(m) Negligently and carelessly failing to cease manufacturing, distribution, promotion and sales of the defectively designed and labeled paroxetine.

221. Before Stewart Dolin first took paroxetine, MYLAN, based upon the state of knowledge as it existed at the time, knew or should have known that paroxetine could be dangerous and unsafe, and knew or should have known that it was a substance associated with acts of self-harm.

222. MYLAN knew or should have known that consumers such as decedent would suffer injury as a result of MYLAN's failure to exercise ordinary care as described above.

223. As a direct and proximate result of Stewart Dolin's reasonably anticipated use of paroxetine as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by MYLAN, Plaintiff and the Estate of Stewart Dolin suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant MYLAN for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws

COUNT XIV
WRONGFUL DEATH
BREACH OF EXPRESS WARRANTY CLAIM
AS TO DEFENDANT MYLAN

224. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

225. Defendant MYLAN expressly warranted that paroxetine was a safe and effective prescription antidepressant and that it did not induce suicidal behavior in adult patients.

226. At all times herein mentioned, MYLAN utilized packaging, labeling, journal articles, advertising media, and/or an outside sales force to urge the use, purchase, and utilization of paroxetine and expressly warranted to physicians, plaintiffs, and other members of the general public that paroxetine was safe and effective.

227. MYLAN represented to the consumer who would use paroxetine and to the physicians who would prescribe it, without a complete disclosure of paroxetine's side effects, that paroxetine was safe and efficacious for people suffering from depression, which amounted to an express warranty of paroxetine's safety and efficacy.

228. MYLAN knew or in the exercise of reasonable diligence should have known that paroxetine could cause the serious side effects set forth herein.

229. Plaintiff and the medical community, including the doctors who prescribed paroxetine to Stewart Dolin, relied on MYLAN's express warranty representations in the use of paroxetine, but paroxetine was not effective, safe, and proper for its intended use as warranted in that paroxetine failed and was dangerous when put to its intended use.

230. As a direct and proximate result of the aforesaid conduct of MYLAN, Stewart Dolin suffered serious physical, emotional, and mental injuries, as well as economic injuries (to

himself as well as to the Estate of Stewart Dolin) in excess of the jurisdictional minimum of this Court.

231. Timely notice was tendered to MYLAN pursuant to the applicable provisions of the Uniform Commercial Code and pursuant to 810 ILCS 5/2-607(3)(a) by the filing of this complaint and the service of the same upon said Defendant.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant MYLAN for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT XV
WRONGFUL DEATH
BREACH OF IMPLIED WARRANTY OF
MERCHANTABILITY CLAIM AS TO DEFENDANT MYLAN

232. 1Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

233. At the time Defendant MYLAN designed, manufactured, marketed, sold, and/or distributed paroxetine for use by Stewart Dolin, MYLAN knew of the use for which paroxetine was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

234. MYLAN represented and warranted to physicians, including Stewart Dolin's physician, and the public in general (the prescribers and users of the product) that paroxetine was safe and efficacious.

235. Stewart Dolin used paroxetine in accordance with his physician's recommendations and in the manner Defendant MYLAN intended.

236. As a result of MYLAN's manufacture and sale of paroxetine, there arose certain implied warranties running from MYLAN to Stewart Dolin as a purchaser and user of paroxetine. Among the implied warranties were that:

(a) Paxil/paroxetine was of merchantable quality;

(b) Paxil/paroxetine was fit for its primary purpose;

(c) Paxil/paroxetine was fit for the particular purpose for which it was intended;

(d) Paxil/paroxetine was not defective; and

(e) Paxil/paroxetine was safe and efficacious.

237. Stewart Dolin reasonably relied upon the skill and judgment of MYLAN as to whether paroxetine was of merchantable quality and safe for its intended use and upon MYLAN's implied warranty as to such matters.

238. Contrary to such implied warranty, paroxetine was not of merchantable quality or safe or fit for its intended use, because the product was unreasonably dangerous as described above.

239. Timely notice was tendered to Defendant MYLAN pursuant to the applicable provisions of the Uniform Commercial Code and pursuant to 810 ILCS 5/2-607(3)(a) by the filing of this complaint and the service of the same upon said Defendant.

240. As a direct and proximate result of MYLAN'S breach of warranty, Plaintiff and the Estate of Stewart Dolin suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant MYLAN for compensatory damages exceeding the minimum jurisdictional amount in the Circuit

Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq.*, and/or other applicable laws.

COUNT XVI
VIOLATION OF ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT CLAIM AS TO DEFENDANT H.D. SMITH

241. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

242. At all times pertinent hereto, Stewart Dolin was a "consumer" and "person" as those terms are defined in the Illinois Consumer Fraud and Deceptive Business Practices Act (the "Consumer Fraud Act") 815 ILCS 505/1.

243. At all times pertinent hereto, Defendant H.D. SMITH was engaged in providing "advertisements" and "merchandise" in "trade" and "commerce" as those terms are defined in the Consumer Fraud Act, 815 ILCS 505/1.

244. H.D. SMITH (a) engaged in unfair and deceptive acts and practices by providing unfair, false, deceptive, and unconscionable representations and statements in its labeling, advertisements, telemarketing, public relations and other promotional materials, as outlined in this Complaint; (b) with the intent on H.D. SMITH's part that Stewart Dolin and other consumers would rely on this deception; and (c) which all occurred in a course of conduct involving trade and commerce.

245. That the above and foregoing unfair and deceptive acts and practices constitute violations of the Consumer Fraud Act, 815 ILCS 505/2.

246. As a direct and proximate result of H.D. SMITH's unfair and deceptive acts and practices, Stewart Dolin, Plaintiff and the public were deceived.

247. Plaintiff is entitled to damages and other statutory relief provided in the Act, including but not limited to, appropriate injunctive and equitable relief.

248. The policies, acts and practices alleged herein were substantial, were not outweighed by any countervailing benefits to Plaintiff and caused damages to Plaintiff and her decedent that could have been avoided. Such conduct is unethical, unscrupulous and against public policy.

249. 1The above-described unfair and unconscionable acts and practices conducted by H.D. SMITH continue to this day and will likely result in damages in the future.

250. As a result of the conduct described herein, H.D. SMITH has been unjustly enriched at Plaintiff and decedent's expense.

251. Plaintiff seeks an order of this court declaring such deceptive acts and practices to be a violation of the Act, requiring H.D. SMITH to immediately cease such unfair methods of competition and enjoining H.D. SMITH from continuing to conduct business via the unfair and unconscionable acts and practices as complained herein. Plaintiff additionally requests an order disgorging H.D. SMITH's ill-gotten gains and awarding Plaintiff full damages, plus attorney's fees and costs.

WHEREFORE, Plaintiff respectfully requests that she be awarded her actual economic damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division; her attorney's fees and costs; and for injunctive relief in the form of an order declaring H.D. SMITH's conduct to be deceptive and a violation of the Consumer Fraud Act, and an order directing H.D. SMITH to cease and desist from engaging in such unfair and deceptive advertising and enjoining it from further violations of the Consumer Fraud Act.

COUNT XVII
WRONGFUL DEATH
STRICT PRODUCTS LIABILITY DESIGN DEFECT CLAIM AS TO DEFENDANT H.D. SMITH

252. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

253. Defendant H.D. SMITH is the wholesale distributor, seller, and/or supplier of paroxetine.

254. The paroxetine distributed and supplied by Defendant H.D. SMITH was unreasonably dangerous in design or formulation in that, when it left the control of the Defendant GSK, it was unsafe when put to its reasonably foreseeable use considering the nature and function of the drug defeating ordinary consumer expectations.

255. The paroxetine distributed and supplied by Defendant H.D. SMITH was unreasonably dangerous in design or formulation in that the risk of danger inherent in the design outweighs the benefits of the design when the product is put to a use that is reasonably foreseeable considering the nature and function of the product.

256. As a direct and proximate result of Stewart Dolin's reasonably anticipated use of paroxetine as sold, supplied, marketed and/or introduced into the stream of commerce by H.D. SMITH, Plaintiff and the Estate of Stewart Dolin, suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant MYLAN for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compen-

sate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT XVIII
WRONGFUL DEATH
STRICT PRODUCTS LIABILTY DEFECT CLAIM DUE TO FAILURE TO WARN AS TO DEFENDANT H.D. SMITH

257. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

258. The paroxetine distributed and/or supplied by Defendant H.D. SMITH was defective due to inadequate warning or instruction because H.D. SMITH knew or should have known that the product created significant risks of serious bodily harm and death to consumers and it failed to adequately warn consumers and/or their health care providers of such risks.

259. The paroxetine distributed and/or supplied by H.D. SMITH was defective due to inadequate post-marketing warning or instruction because, after H.D. SMITH knew or should have known of the risk of serious bodily harm and death from the use of paroxetine, H.D. SMITH failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

260. As a direct and proximate result of Stewart Dolin's reasonably anticipated use of paroxetine as distributed, sold, supplied, marketed and/or introduced into the stream of commerce by H.D. SMITH, Plaintiff and the Estate of Stewart Dolin suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant H.D. SMITH for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly

compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNT XIX
WRONGFUL DEATH
NEGLIGENCE CLAIM AS TO DEFENDANT H.D. SMITH

261. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

262. Defendant H.D. SMITH had a duty to exercise reasonable care in the labeling, design, sale and/or distribution of paroxetine into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

263. H.D. SMITH failed to exercise ordinary care in the sale, quality assurance, quality control, labeling, marketing, promotion and distribution of paroxetine into interstate commerce in that H.D. SMITH knew or should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

264. The injuries described herein were caused by the negligence and misrepresentations of H.D. SMITH through its agents, servants and/or employees acting within the course and scope of their employment including among other things:

(a) Carelessly and negligently selling, merchandising, advertising, promoting, labeling, distributing, and marketing paroxetine;

(b) Being careless and negligent in that H.D. SMITH knew or should have known that paroxetine was a substance known to be associated with producing life-threatening effects upon certain users including but not limited to suicidal behavior;

(e) Negligently and carelessly failing to adequately warn the medical community, the general public, Plaintiff and Stewart Dolin in particular, of the dangers, contra-indications, and side effects from the use of paroxetine;

(f) Negligently and carelessly representing that paroxetine was safe for use for the purposes intended when, in fact, it was unsafe for certain users;

(g) Negligently and carelessly failing to act as a reasonably prudent drug distributor;

(h) Negligently and carelessly over promoting paroxetine in a zealous and unreasonable way;

(i) Negligently and carelessly continuing to distribute and market paroxetine for use by consumers notwithstanding the fact that it knew or should have known that paroxetine posed a serious risk of bodily harm to consumers, that it contained inadequate warning and was defectively designed;

(j) Negligently and carelessly failing to cease distribution, promotion and sales of the defectively designed and labeled paroxetine.

265. Before Stewart Dolin first took paroxetine, H.D. SMITH, based upon the state of knowledge as it existed at the time, knew or should have known that paroxetine could be dangerous and unsafe, and knew or should have known that it was a substance associated with acts of self-harm.

266. H.D. SMITH knew or should have known that consumers such as decedent would suffer injury as a result of H.D. SMITH's failure to exercise ordinary care as described above.

267. As a direct and proximate result of Stewart Dolin's reasonably anticipated use of paroxetine as sold, supplied, marketed and/or introduced into the stream of commerce by H.D.

SMITH, Plaintiff and the Estate of Stewart Dolin suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

WHEREFORE, Plaintiff respectfully requests that judgment be entered against Defendant H.D. SMITH for compensatory damages exceeding the minimum jurisdictional amount in the Circuit Court of Cook County, Illinois Law Division and in an amount that will fully and fairly compensate each of the next of kin pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1 *et seq*., and/or other applicable laws.

COUNTS XX-XXXVIII
SURVIVAL CAUSES OF ACTION

268. Plaintiff incorporates all of the allegations in Count I through XIX by reference as if pleaded herein in full as Counts XX through XXXVIII, in that same order.

269. As a direct and proximate result of one or more of Defendant's foregoing deliberate, careless and negligent acts and/or omissions, Stewart Dolin was injured and suffered damages of a personal and pecuniary nature, including pain and suffering, prior to his death, damages for which had he survived he would have been entitled to maintain an action; and such an action has survived him and accrued to the benefit of his estate.

270. Plaintiff brings the same substantive causes of action as set forth in Counts I through XIX of this action as Counts XX through XXXVIII with the only difference that these claims are made under 755 ILCS 5/27-6, commonly known as the Survival Act of Illinois.

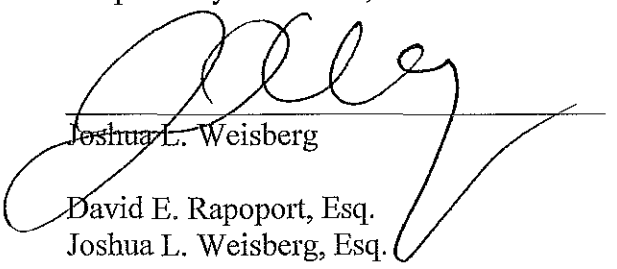
WHEREFORE, Wendy Dolin, as Independent Executor of the Estate of Stewart Dolin, deceased, prays for judgment against Defendants, MYLAN, GSK and H.D. SMITH, in such amount in excess of this Court's jurisdictional limit.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues triable as of right by a jury.

Dated: July 9, 2012

Respectfully Submitted,



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