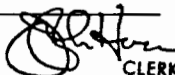


FILED

DEC 07 2015

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA


CLERK

DANIELLE SCHOENROCK,
individually and as Special Administrator
on behalf of the heirs and estate of
CURTIS STERN, deceased,

Plaintiff,

v.

PFIZER, INC., a Delaware corporation,

Defendants.

**COMPLAINT AND DEMAND FOR
JURY TRIAL**

Case no. 15 - CV - 4187

Judge _____

CIVIL ACTION COMPLAINT

1. This is an action for personal injuries, wrongful death, and damages suffered by Plaintiff and her father, Curtis Stern, as a direct and proximate result of Pfizer's (hereinafter "Defendant") negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of sildenafil citrate tablets sold under the brand name Viagra® ("Viagra").

II. PARTIES

2. Curtis Stern was a resident of Colman, South Dakota. Curtis Stern (“Plaintiff” or “Decedent”) was prescribed and used Viagra as directed from approximately 2009 to 2012. He was diagnosed with melanoma in 2012 and ultimately died from metastatic melanoma on December 12, 2012.

3. Danielle Schoenrock is and at all relevant times was an adult resident of Colman, South Dakota. She is Decedent’s adult daughter and has been appointed as the Special Administrator for purposes of maintaining an action on behalf of Decedent’s estate.

4. Defendant was at all times relevant hereto, a corporation organized and existing under the laws of the state of Delaware. Defendant maintains its principal place of business at 235 East 42nd Street, New York, New York 10017. Defendant is registered to do business in the state of Utah.

5. At all times mentioned herein, Defendant engaged in interstate commerce, including commerce within this judicial district, in the advertisement, promotion, distribution, and sale of Viagra.

III. JURISDICTION AND VENUE

6. This Court has jurisdiction over Defendant and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy between Plaintiff and Defendant exceeds \$75,000.00, exclusive of interest and cost.

7. This Court has personal jurisdiction over this Defendant because Defendant maintains significant contacts with this judicial district by virtue of conducting business within the district.

IV. FACTUAL BACKGROUND

A. Facts Regarding Pfizer and Viagra

8. On March 27, 1998, the U.S. Food and Drug Administration approved a new drug application (“NDA”) from Pfizer Pharmaceuticals Production Corporation Limited for the manufacture and sale of sildenafil citrate.

9. Sildenafil citrate, sold under the brand name Viagra, is an oral tablet prescribed to men with erectile dysfunction.

10. Erectile dysfunction is the medical designation for a condition in which a man cannot get or maintain an erection sufficient for satisfactory sexual activity. Since reaching and maintaining an erection involves the brain, nerves, hormones, and blood vessels, any condition that interferes with any of these functional areas of the body may be causally related to an individual’s erectile dysfunction. These problems become more common with age, but erectile dysfunction can affect a man at any age.

11. Viagra treats erectile dysfunction by inhibiting the secretion of phosphodiesterase type 5 (“PDE5”), an enzyme responsible for the degradation of cyclic guanosine monophosphate (“cGMP”). When the cGMP is not degraded by the PDE5, smooth muscles in the corpus cavernosum relax; this, in turn, permits an inflow of blood to the corpus cavernosum, creating an erection.

12. The National Institutes of Health estimate that erectile dysfunction affects as many as thirty million men in the United States.¹

13. Since Viagra’s FDA approval in 1998, Defendant has engaged in a continuous, expensive, and aggressive advertising campaign to market Viagra to men worldwide as a symbol of regaining and enhancing one’s virility.

¹ NIH Consensus Development Panel on Impotence (July 7, 1993).

14. Defendant has engaged in increasingly aggressive marketing techniques and strategies to promote the use of Viagra in the face of increasing pharmaceutical competition. By means of demonstration, a 2004 article in *The Chicago Tribune* cited industry reports stating that Viagra spent “tens of millions of dollars each month on direct-to-consumer advertising [].”²

15. Defendant has also been criticized by regulators, physicians and consumer groups for its attempts to target younger men in their advertising. Doctors and federal regulators have stated that “such ads sen[t] a confusing message to patients who might really benefit from the drug.”³

16. In its 2013 Annual Report, Defendant states that it accumulated revenue exceeding \$1,800,000,000 from worldwide sales of Viagra. This statistic is particularly significant in light of the fact that Defendant lost exclusivity of Viagra throughout Europe in 2013, which in itself led to a drop in profits from the previous calendar year.

17. Viagra holds approximately 45% of the U.S. market share for erectile dysfunction medications.⁴

18. Defendant estimates that Viagra has been prescribed to more than 35 million men worldwide.⁵ In 2012 alone, physicians wrote approximately eight million prescriptions for Viagra.⁶

² Bruce Japsen, *Viagra's 2 Rivals Grab Market Share In A Year*, CHICAGO TRIBUNE, Sept. 23, 2004, available at http://articles.chicagotribune.com/2004-09-23/business/0409230283_1_viagra-erectile-levitra.

³ Bruce Japsen, *Toned-Down Advertising Credited for Viagra Gains*, CHICAGO TRIBUNE, Feb. 8, 2007, available at http://articles.chicagotribune.com/2007-02-08/business/0702080063_1_viagra-erectile-pfizer-spokesman.

⁴ Jacque Wilson, *Viagra: The Little Blue Pill That Could*, CNN, Mar. 27, 2013, available at: <http://www.cnn.com/2013/03/27/health/viagra-anniversary-timeline/index.html>.

⁵ Hilary Stout, *Viagra: The Thrill That Was*, N.Y. TIMES, June 5, 2011, available at: <http://query.nytimes.com/gst/fullpage.html?res=9B06E3DF173FF936A35755C0A9679D8B63>.

⁶ Wilson, *supra* note 4.

19. Upon information and belief, Defendant failed to conduct adequate pre-clinical and clinical testing and post-marketing monitoring to adequately determine the safety and health risks of Viagra.

20. Defendant Pfizer failed to use due care in designing, testing, and manufacturing Viagra so as to avoid these serious health risks.

21. Defendant knew of the significant risks of developing melanoma caused by ingesting Viagra, but Defendant did not adequately and sufficiently warn consumers, including the Plaintiff, or the medical community or such risks.

22. Despite this knowledge, Defendant continued to manufacture, sell, and promote Viagra without adequately warning of these serious health risks.

23. Despite this knowledge, Defendant failed to provide adequate training, information or education to physicians and consumers about these serious health risks and about the precautions necessary to avoid these health risks.

24. Despite this knowledge, Defendant represented to physicians, including Plaintiff's prescribing physician, and to consumers, including Plaintiff, that Viagra was safe and effective for use.

25. Defendant knowingly withheld and/or misrepresented information concerning these serious health risks of Viagra, which it was required to submit to the FDA.

26. Defendant even after it was informed through numerous medical reports of Viagra's serious health risks, intentionally failed and continues to fail to provide this information to and warn physicians and consumers, such as the Plaintiff.

27. Consumers, including the Plaintiff, who have used Viagra for treatment of ED/impotence, have several alternative safer products available to treat this condition.

28. Defendant knew, or should have known, that Viagra increased the risk of developing melanoma and increased the invasiveness of melanoma cells in those who ingested it.

B. Facts Regarding Viagra's Link to Melanoma

29. Unbeknownst to most Viagra users, and omitted from the slew of advertising proliferated by Defendant, recent studies have shown that the cellular activity providing the mechanism of action for Viagra may also be associated with the development and/or exacerbation of melanoma.

30. The American Cancer Society states that melanoma is “the most serious type of skin cancer.”⁷

31. According to the National Cancer Institute, part of the National Institutes of Health, melanoma is more likely than other skin cancers to spread to other parts of the body, thereby causing further tissue damage and complicating the potential for effective treatment and eradication of the cancerous cells.⁸

32. Several studies have linked the mechanism of action for Viagra to cell mutation cultivating melanomagenesis, or the creation of melanocytes which develop into melanoma.

33. A study published in 2011 found that treatment with Viagra can promote melanoma cell invasion.⁹ Specifically, by inhibiting PDE5, Viagra mimics an effect of gene activation and therefore may potentially function as a trigger for the creation of melanoma cells.

⁷ American Cancer Society, *Skin Cancer Facts*, last revised March 19, 2014, available at: <http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts>.

⁸ National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 2011, available at: <http://www.cancer.gov/cancertopics/wyntk/skin/page4>.

⁹ I. Aozarena, et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating The cGMP-Specific Phosphodiesterase PDE5A*, 19 *CANCER CELL* 45 (2011).

34. A 2012 study published in the *Journal of Cell Biochemistry* also found that PDE5 inhibitors were shown to promote melanin synthesis,¹⁰ which may exacerbate melanoma development.¹¹

35. On April 7, 2014, an original study (“the JAMA study”) was published on the website for the *Journal of the American Medical Association Internal Medicine* which, in light of the previous studies, sought to examine the direct relationship between sildenafil use and melanoma development in men in the United States.¹² The JAMA study was published in the journal’s June 2014 edition.

36. Among 25,848 participants, the JAMA study reported that recent sildenafil users at baseline had a significantly elevated risk of invasive melanoma, with a “hazard ratio” of 1.84; in other words, the study participants who had recently used sildenafil exhibited an 84% increase in risk of developing or encouraging invasive melanoma.¹³

37. Despite these significant findings, Defendant has made no efforts in its ubiquitous Viagra advertisements to warn users about the potential risk of developing melanoma that has been scientifically linked to its drug.

38. At all times relevant to this lawsuit, Defendant engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging

¹⁰ X Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Through the PKG Pathway in B16 Melanoma Cells*, 113 J. CELL BIOCHEM. 2738 (2012).

¹¹ F.P. Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation Requires Melanin Pigment*, 3 NATURE COMMUNICATIONS 884 (2012).

¹² Wen-Qing Li, Abrar A. Qureshi, Kathleen C. Robinson, & Jiali Han, *Sildenafil Use and Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*, 174 JAMA INTERNAL MEDICINE 964 (2014).

¹³ *Id.*

and/or advertising for sale or selling the prescription drug Viagra for use among the general public.

39. For the duration of these efforts, Defendant directed its advertising efforts to consumers located across the nation, including consumers in the state of Utah.

40. At all times mentioned in this Complaint, Defendant's officers and directors participated in, authorized, and directed the production and aggressive promotion of Viagra when they knew, or with the exercise of reasonable care should have known, of the risk of developing melanoma and exacerbating melanoma associated with Viagra use. In doing so, these officers and directors actively participated in the tortious conduct which resulted in the injuries suffered by many Viagra users, including Plaintiff.

41. Defendant purposefully downplayed, understated and outright ignored the melanoma-related health hazards and risks associated with using Viagra. Defendant also deceived potential Viagra users by relaying positive information through the press, including testimonials from retired, popular U.S. politicians, while downplaying known adverse and serious health effects.

42. Defendant concealed material information related to melanoma development from potential Viagra users.

43. In particular, in the warnings the company includes in its commercials, online and print advertisements, Defendant fail to mention any potential risk for melanoma development and/or exacerbation associated with Viagra use.

44. As a result of Defendant's advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Viagra. If Plaintiff in this action had known the risks and dangers associated with taking Viagra, Plaintiff would have

elected not to take Viagra and, consequently, would not have been subject to its serious side effects.

C. Facts Regarding Plaintiff

45. Plaintiff began pharmaceutical treatment for erectile dysfunction in 2009, when his physician recommended that he begin taking Viagra.

46. Plaintiff filled his first prescription for Viagra on or about February 2009. He continued to fill his Viagra prescriptions and take the drug occasionally until at least 2012.

47. Plaintiff's use of Viagra over the course of several years put him at an increased risk of developing melanoma and for such melanoma to become more invasive than if he had not ingested Viagra.

48. On September 27, 2012, Plaintiff went to Avera Cancer Institute for evaluation of lesions involving the left and right frontal lobes. A CT scan of Plaintiff's head revealed multiple brain lesions consistent with metastatic melanoma. The melanoma had metastasized to his brain.

49. Plaintiff underwent whole brain radiation. On October 30, 2012, Plaintiff's physician recommended not proceeding with systemic treatment of the melanoma as Plaintiff's functioning was declining. Plaintiff enrolled in hospice care in early November 2012. Plaintiff passed away on December 12, 2012. Plaintiff's death certificate lists Mr. Stern's cause of death as metastatic melanoma.

50. Had Defendant properly disclosed the melanoma-related risks associated with Viagra, Plaintiff would have avoided the risk of developing melanoma by not using Viagra at all; severely limiting the dosage and length of its use; and/or more closely monitoring the degree to which the Viagra was adversely affecting his health.

51. As a result of Defendants actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence,

that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendants acts, omissions and representations.

52. The defective warnings, instructions, design and/or manufacturing of Viagra, as well as Defendants conduct as set forth above and below, were the direct and/or proximate causes of Plaintiff's injuries.

53. As a direct, proximate, and legal result of Defendant's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug Viagra, Plaintiff Curtis Stern suffered severe and permanent physical injuries, including metastatic melanoma, and ultimately died. Plaintiff Danielle Schoenrock suffered severe emotional injuries, including the loss of her father. His physical injuries have included melanoma as well as the numerous biopsies necessitated by his skin cancer diagnosis, extensive pain and suffering. Plaintiffs have endured not only physical pain and suffering but also economic loss, including significant expenses for medical care and treatment. As a result of these damages, Plaintiffs seek actual and punitive damages from Defendant.

V. CAUSES OF ACTION

COUNT I **Negligence**

54. Plaintiff adopts the preceding paragraphs of this Complaint as if fully set forth herein.

55. At all times relevant hereto, Defendant had a duty to individuals, including the Plaintiff, to exercise reasonable and ordinary care and properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers associated with the use of Viagra.

56. At all times relevant hereto, Defendant manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold Viagra while disregarding the fact that the foreseeable harm presented by the drug greatly outweighed the benefits it provided to users like Plaintiff.

57. At all times relevant hereto, Defendant failed to adequately test for and warn of the risks and dangers associated with the use of Viagra.

58. Defendant breached its duty of care and was negligent as described herein in the design, manufacture, labeling, warning, instruction, training, selling, marketing and distribution of Viagra in one or more of the following respects:

- a. Failing to design Viagra so as to avoid an unreasonable risk of harm to individuals who ingested Viagra, including Plaintiff;
- b. Failing to manufacture Viagra so as to avoid an unreasonable risk of harm to individuals who ingested Viagra, including Plaintiff;
- c. Failing to use reasonable care in the testing of Viagra so as to avoid an unreasonable risk of harm to individuals who ingested Viagra, including Plaintiff;
- d. Failing to use reasonable care in inspecting Viagra so as to avoid unreasonable risk of harm to individuals who ingested Viagra, including Plaintiff;
- e. Failing to use reasonable care in training its employees and health care providers related to the use of Viagra so as to avoid unreasonable risk of harm to individuals who ingested Viagra, including Plaintiff;
- f. Failing to use reasonable care in instructing and/or warning health care providers, the FDA, and the public as set forth herein of risks associated with Viagra, especially the risk of developing melanoma, so as to avoid unreasonable risks of harm to individuals who ingested Viagra, including Plaintiff;
- g. Failing to use reasonable care in marketing and promoting Viagra, so as to avoid unreasonable risk of harm to individuals who ingested Viagra, including Plaintiff; and
- h. Otherwise negligently or carelessly designing, manufacturing, marketing, distributing, warning, labeling studying, testing, or selling Viagra.

59. Defendant further breached its duty of care and was negligent by failing to conduct post-market vigilance or surveillance and by:

- a. Failing to monitor or act on findings in the scientific and medical literature regarding individuals who developed melanoma after ingesting or while ingesting Viagra; and
- b. Failing to monitor or investigate and evaluate reports in the FDA adverse event databases for their potential significance for use of Viagra, including the incidence and development of melanoma during or after ingestion of Viagra.

60. Despite the fact that Pfizer knew or should have known that Viagra caused unreasonably dangerous side effects, Defendant continued to aggressively market Viagra to consumers, including Plaintiff, when there were safer alternative methods of treating erectile dysfunction than taking Viagra.

61. Defendant knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of the company's failure to exercise ordinary care while developing, marketing, and/or selling Viagra.

62. Defendant's negligence proximately caused the injuries, harm and economic loss which Plaintiff has and will continue to suffer.

COUNT II **Gross Negligence**

63. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint as if fully set forth herein.

64. The wrongful acts committed by Defendant were aggravated by malice, fraud, and grossly negligent disregard for the rights of the general public.

65. Defendant's conduct involved an extreme degree of risk, considering the probability and magnitude of potential harm to the general public.

66. Despite Defendant's awareness of the severity of the risk associated with its actions, it nevertheless chose to proceed with the manufacture, promotion, distribution and sale of Viagra with conscious indifference to the rights, safety, or welfare of the general public.

67. Plaintiff relied on the representations made by Defendant and suffered serious injury as a proximate result of such reliance; and the Plaintiff, as an individual, suffered damages including both economic and non-economic losses, including but not limited to obligations to pay for medical services, other expenses, other damages, and loss of consortium.

COUNT III
Breach of Implied Warranty

68. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint as if fully set forth herein.

69. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted and sold Viagra.

70. Prior to the time that Plaintiff used Viagra, Defendant implicitly warranted to Plaintiff and Plaintiff's healthcare providers that Viagra was of merchantable quality, safe to use, and fit for the use for which it was intended.

71. At all relevant times, Defendant intended that Viagra be used for the purposes and in the manner that Plaintiff or Plaintiff's physicians in fact used and Defendant impliedly warranted each product to be of merchantable quality, safe and fit for such use, even though it was not adequately tested.

72. Defendant was aware that consumers, including Plaintiff or Plaintiff's physicians, would prescribe Viagra in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of Viagra.

73. Viagra was expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which it was manufactured and sold by Defendant.

74. Defendant breached various implied warranties with respect to Viagra, including, but not limited to, the following particulars:

- a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Viagra was safe and fraudulently withheld and concealed information about the substantial risks of melanoma and potential death associated with using Viagra;
- b. Defendant represented that Viagra was safe, and/or safer than other alternative treatment and that complications were rare, and fraudulently concealed information, which demonstrated that Viagra was not as safe, or safer than, alternatives available on the market.

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

76. Plaintiff was and is unskilled in the research, design and manufacture of erectile dysfunction medications, and therefore reasonably relied entirely on the skill, judgment and implied warranty of Defendant in deciding to use Viagra.

77. Viagra was neither safe for its intended use nor of merchantable quality, as had been implicitly warranted by Defendant, in that Viagra has dangerous propensities when used as intended and will cause severe injuries to users.

78. Defendant breached its implied warranty to Plaintiff in that Viagra was not of merchantable quality, safe and fit for their intended use, or adequately tested, in violation of Common Law principles and the statutory provisions of Utah.

79. As a direct and proximate result of the breach of warranty committed by Defendant, Plaintiff suffered serious injury, harm, damages, and economic and non-economic loss. He will continue to suffer such harm, damages and losses in the future.

COUNT IV
Breach of Express Warranty

80. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint as if fully set forth herein.

81. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted and sold Viagra.

82. At all relevant times, Defendant intended that Viagra be used in the manner that Plaintiff in fact used it, and Defendant expressly warranted that Viagra was safe and fit for use by consumers, that Viagra was of merchantable quality, that its side effects were minimal and comparable to other erectile dysfunction treatments, and that it was adequately tested and fit for their intended use.

83. At all relevant times, Defendant expressly represented and warranted to Plaintiff and Plaintiff's healthcare providers, by and through statements made by Defendant or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Viagra is safe, effective, and proper for its intended use.

84. At all relevant times, Defendant was aware that consumers, including Plaintiff, would use Viagra; which is to say that Plaintiff was a foreseeable user of Viagra.

85. Viagra was expected to reach and did in fact reach consumers, including Plaintiff and his physicians, without substantial change in the condition in which it was manufactured and sold by Defendant.

86. Defendant breached various express warranties with respect to Viagra including the following particulars:

- a. Defendant represented to Plaintiff and his physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Viagra was safe and fraudulently withheld and concealed information about the substantial risks of melanoma and/or death associated with using Viagra; and,
- b. Defendant represented to Plaintiff and his physicians and healthcare providers that Viagra was as safe and fraudulently concealed information, which demonstrated that Viagra was not safer than alternatives available on the market.

87. The warranties expressly made by Defendant through its marketing and labeling were false in that Viagra is unsafe and unfit for its intended use

88. Plaintiff relied on the skill, judgment, representations, and express warranties of Defendant in deciding to purchase and use Viagra.

89. In reliance upon Defendant's express warranties, Plaintiff used Viagra as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

90. At the time of making such express warranties, Defendant knew or should have known that Viagra does not conform to these express representations because Viagra was not safe and had numerous serious side effects that Defendant did not accurately warn about, thus making Viagra unreasonably unsafe for its intended purpose.

91. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the Public relied upon the representations and warranties of Defendant in connection with the use recommendation, description, and/or dispensing of Viagra.

92. Defendant breached its express warranties to Plaintiff in that Viagra was not of merchantable quality, safe and fit for its intended uses, nor was it adequately tested.

93. Defendant's breaches constitute violations of common law principles and the statutory provisions of Utah.

94. As a direct and proximate result of the breach of express warranty by Defendant, Plaintiff suffered serious injury, harm, damages, and economic and non-economic loss. He will continue to suffer such harm, damages and losses in the future.

COUNT V
Fraud

95. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint as if fully set forth herein.

96. At all times relevant hereto, Defendant conducted a sales and marketing campaign to promote the sale of Viagra and willfully deceive Plaintiff, Plaintiff's healthcare providers, and the general public as to the benefits, health risks, and consequences of using Viagra.

97. At all times relevant hereto, Defendant falsely and fraudulently represented and continues to represent to the medical and healthcare community and the public that Viagra has been tested and was found to be safe and effective.

98. The representations made by Defendant were in fact, false. When Defendant made its representations, Defendant knew and/or had reason to know that those representations were false, and Defendant willfully, wantonly and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of Viagra, including, but not limited to the increased risk of developing melanoma and potentially, death.

99. While conducting its sales and marketing campaign, Defendant knew that Viagra is neither safe nor fit for human consumption; that using Viagra is hazardous to health; and that Viagra has a propensity to cause serious injuries, such as those suffered by Plaintiff.

100. From the time the company first marketed and distributed Viagra until the present, Defendant willfully deceived Plaintiff by concealing from him, his healthcare providers, and the general public the risks and dangers concerning the use of Viagra.

101. The representations were made by Defendant with the intent of defrauding and deceiving the medical community, the Plaintiff, and the public, and were also made to induce the medical community, the Plaintiff and the public to recommend, prescribe, dispense and purchase Viagra as a means of treatment for erectile dysfunction, all of which evinced a callous, willful, and depraved indifference to the health, safety and welfare of the Plaintiff.

102. Defendant intentionally concealed and suppressed the facts concerning Viagra's melanoma-related risks with the intent to defraud potential consumers, as Defendant knew that healthcare providers would not prescribe Viagra, and consumers like Plaintiff would not use Viagra, if they were aware of the dangers posed by using Viagra.

103. In representations to the Plaintiff and his healthcare providers, Defendant fraudulently concealed and intentionally or recklessly omitted the following material information:

- a. That Viagra was not as safe as other treatment for Erectile Dysfunction;
- b. That Viagra was not adequately tested;
- c. That Defendant deliberately failed to follow-up on the adverse results from clinical studies and formal/informal reports from physicians and other healthcare providers and buried and/or misrepresented those findings;
- d. That Defendant deliberately chose to forego studies that might reveal the true rate of adverse events or otherwise necessitate the need to reveal information as to adverse events to Plaintiff, the medical community, or the regulatory authorities;

- e. That Viagra was defective and that it caused dangerous and adverse side effects, including, but not limited to, higher incidence of melanoma, at a much higher rate than other treatment available to treat erectile dysfunction;
- f. That Viagra was manufactured negligently;
- g. That Viagra was designed negligently, and designed defectively; and
- h. That ingestion of Viagra could not cause melanoma and potentially, death.

104. Defendant was under a duty to disclose to the Plaintiff and his physicians the defective nature of Viagra, including, but not limited to, the heightened risks of melanoma and potentially, death.

105. Defendant had sole access to material facts concerning the defective nature of Viagra and its propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used Viagra.

106. Defendant's concealment and omissions of material facts concerning the safety of Viagra was made purposefully, wantonly, willfully and/or recklessly to mislead, to cause Plaintiff's physicians and health care providers to purchase, prescribe and/or dispense Viagra; and/or to mislead Plaintiff into reliance and cause Plaintiff to use Viagra.

107. At the time these representations were made by Defendant, and at the time the Plaintiff used Viagra, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

108. Defendant knew and/or had reason to know that Viagra could and would cause severe and grievous personal injury to the users of Viagra, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate or downplayed warnings.

109. In reliance upon these false representations, Plaintiff was induced to and did use Viagra, thereby sustaining severe and permanent personal injuries and damages. Defendant

knew or had reason to know that Plaintiff and his physicians and other healthcare providers had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding the use of Viagra, as described in detail herein.

110. Plaintiff reasonably relied on revealed facts which foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of Viagra.

111. Having knowledge based upon Defendant's research and testing, Defendant blatantly and intentionally distributed false information, including, but not limited to, assuring the Plaintiff, the public, and Plaintiff's healthcare providers and physicians that Viagra was safe for use as a means of providing relief from erectile dysfunction and was safe or safer than other treatment available and on the market. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, the Plaintiff, and the public at large.

112. Defendant had a duty when disseminating information to the public to disseminate truthful information, and had a parallel duty not to deceive the public, the Plaintiff, the Plaintiff's health care providers and the United States Food and Drug Administration ("FDA").

113. The information distributed to the public, the medical community, the FDA and the Plaintiff by Defendant included, but was not limited to, websites, information presented at professional and medical meetings, information disseminated by sales representatives to physicians and other medical care providers, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, and other commercial media containing material misrepresentations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of Viagra.

114. Defendant intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of Viagra, specifically, that it did not have dangerous and/or serious adverse health safety concerns, and that Viagra was as safe or safer than other means of treating erectile dysfunction.

115. Defendant intentionally failed to inform the public, including the Plaintiff, of the high risk of developing melanoma, and the risk of permanent injury.

116. Defendant chose to over-promote the purported safety, efficacy and benefits of Viagra instead.

117. Defendant's intent and purpose in making these misrepresentations was to deceive and defraud the public, the medical community and the Plaintiff to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of Viagra; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use Viagra.

118. Defendant made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that Viagra had innovative beneficial properties and did not present serious health risks.

119. These representations, and others made by Defendant, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

120. These representations, and others made by Defendant, were made with the intention of deceiving and defrauding Plaintiff, Plaintiff's healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiff, and their respective healthcare professionals, to rely on misrepresentations, and caused Plaintiff to

purchase, rely, use, and request Viagra and their healthcare professionals to dispense, recommend, or prescribe Viagra.

121. Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving and lulling Plaintiff, as well as his healthcare professionals, into a false sense of security, so that Plaintiff and his healthcare providers would rely on Defendant's representations, and Plaintiff would request and purchase Viagra, and that his healthcare providers would dispense, prescribe, and recommend Viagra.

122. Defendant utilized substantial direct-to-consumer advertising to market, promote, and advertise Viagra.

123. At the time the representations were made, Plaintiff and his healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of Viagra. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendant, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

124. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Viagra, Plaintiff would not have purchased, used, or relied on Viagra.

125. Defendant's wrongful conduct constitutes fraud and deceit, and was committed and perpetrated willfully, wantonly, and/or purposefully on Plaintiff.

126. As a result of Defendant's fraudulent and deceitful conduct, Plaintiff suffered serious injury, harm, damages, and economic and non-economic loss. He will continue to suffer such harm, damages and losses in the future.

COUNT VI
Fraudulent Misrepresentation

127. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint as if fully set forth herein.

128. From the time the company first marketed and distributed Viagra until the present, Defendant willfully deceived Plaintiff by concealing from him, his healthcare providers, and the general public the facts concerning Viagra's risks and dangers.

129. At all times relevant hereto, Defendant conducted a sales and marketing campaign to promote the sale of Viagra and, in doing so, willfully deceived Plaintiff, Plaintiff's healthcare providers and the general public as to the benefits, health risks and consequences of using Viagra.

130. At all points during its sales and marketing campaign, Defendant knew that Viagra was and is not safe for human consumption; was and is hazardous to a user's health; and showed and shows a propensity to cause serious injury to a user.

131. Defendant had the duty to disclose the facts concerning the melanoma-related risks and dangers posed by ingestion of Viagra.

132. Defendant intentionally concealed and suppressed the facts evidencing Viagra's melanoma-related risks with the intent to defraud potential consumers, as Defendant knew that healthcare providers would not prescribe Viagra, and consumers like Plaintiff would not use Viagra, if they were aware of the dangers posed by using Viagra.

133. As a result of the foregoing fraudulent misrepresentations made by Defendant, Plaintiff suffered serious injury, harm, damages, and economic and non-economic loss; further, he will continue to suffer such harm, damages and losses in the future.

COUNT VII
Fraudulent Concealment

134. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint as if fully set forth herein.

135. Throughout the relevant time period, Defendant knew that Viagra was defective and unreasonably unsafe for its intended purpose.

136. Defendant fraudulently withheld and concealed information about the substantial risks of using Viagra by representing through Viagra's labeling, advertising, marketing materials, detail persons, sales representatives, seminar presentations, publications, notice letters, and regulatory submissions that Viagra was safe.

137. Defendant fraudulently concealed from and/or failed to disclose to or warn the Plaintiff, his physicians and the medical community that Viagra was defective, unsafe, and unfit for the purposes intended, and that it was not of merchantable quality.

138. Defendant fraudulently concealed information which demonstrated that Viagra was not safer than other erectile dysfunction treatments available on the market, and instead represented that Viagra was safer than other alternative medications.

139. Defendant was under a duty to the Plaintiff to disclose and warn of the defective nature of Viagra because:

- a. Defendant was in a superior position to know the true quality, safety, and efficacy of Viagra;
- b. Defendant knowingly made false claims about the safety and quality of Viagra in the documents and marketing materials Defendant provided to the FDA, physicians and general public and;
- c. Defendant fraudulently and affirmatively concealed the defective nature of Viagra from Plaintiff and his physicians, specifically, the increased risk of melanoma and potential death.

140. Defendant had access to material facts and information concerning the unreasonable risk of developing and/or exacerbating the spread of cancerous cells posed by using Viagra.

141. The concealment of information by Defendant about the risks posed by Viagra use was intentional and conducted with awareness that the company's actual representations were false.

142. Defendant's concealment of the risks associated with using Viagra and dissemination of untrue information to the contrary was conducted with the intent that healthcare providers would prescribe, and patients would subsequently purchase and use, Viagra.

143. The facts concealed and/or not disclosed by Defendant to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Viagra.

144. Plaintiff and his healthcare providers justifiably relied upon Defendant's misrepresentations to their detriment and were unaware of the substantial risk of Viagra which Defendant concealed from the public.

145. In relying on Defendant's misrepresentations, and unaware of Defendant's concealment of information regarding the risk posed by Viagra, Plaintiff purchased and used Viagra.

146. Plaintiff would not have purchased or used Viagra if he had been aware of the fact of Defendant's concealment of harmful information and/or dissemination of misrepresentations that Viagra was safe and fit for human consumption.

147. Defendant, by concealment or other action, intentionally prevented Plaintiff and his physicians and other healthcare providers from acquiring material information regarding the lack of safety and effectiveness of Viagra, and is subject to the same liability to Plaintiff for his

pecuniary losses, as though Defendant had stated the non-existence of such material information regarding Viagra's lack of safety and effectiveness and dangers and defects, and as though Defendant had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from discovering the truth. Defendant therefore has liability for fraudulent concealment under all applicable laws, including, *inter alia*, *Restatement (Second) of Torts* §550 (1977).

148. As a result of the foregoing fraudulent concealment by Defendant, Plaintiff suffered serious injury, harm, damages, and economic and non-economic loss, and will continue to suffer such harm, damages and losses in the future.

COUNT VIII
Negligent Misrepresentation

149. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint as if fully set forth herein.

150. From the time the company first marketed and distributed Viagra until the present, Defendant made representations to Plaintiff, Plaintiff's healthcare providers, and the general public that Viagra was safe and fit for human consumption.

151. Defendant made representations regarding the safety of consuming Viagra without any reasonable ground for believing such representations to be true.

152. Representations concerning Viagra's safety and fitness for human consumption were made directly by Defendant or its sales representatives and other authorized agents, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of promotion of prescribing, purchasing and using of Viagra.

153. The representations by Defendant were false, in that Viagra is not safe or fit for human consumption; using Viagra is hazardous to health; and Viagra has a propensity to cause serious injuries, including those suffered by Plaintiff, to its users.

154. Plaintiff relied on the misrepresentations made by Defendant in purchasing and using Viagra.

155. Plaintiff's reliance on Defendant's misrepresentations was justified because such misrepresentations were made by entities that were in a position to know of and disclose any potentially harmful information concerning the use of Viagra.

156. If Plaintiff had known of the information concealed by Defendant regarding the melanoma-related risks posed by Viagra, Plaintiff would not have purchased and subsequently used Viagra.

157. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered serious injury, harm, damages, and economic and non-economic loss; further, he will continue to suffer such harm, damages and losses in the future.

COUNT IX
Strict Liability

158. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint as if fully set forth herein.

159. Viagra was designed, manufactured, marketed, promoted, sold and introduced into the stream of interstate commerce by Defendant, including in the State of Utah.

160. Viagra and its warnings and instructions were defective and unreasonably dangerous to the user or consumer.

161. The nature and magnitude of the risk of harm associated with the design of Viagra, particularly the risk of developing and/or exacerbating the spread of cancerous cells in the product's user, is significant in light of the drug's intended and reasonably foreseeable use.

162. Specifically, the ingestion of Viagra significantly increases the user's risk of developing melanoma and/or exacerbating cancer-related conditions already present in the user's cellular composition.

163. In developing, marketing, and selling Viagra, it was both technically and economically feasible for Defendant to develop an alternative design which would either eliminate or substantially reduce the significant risk of developing melanoma presented by the drug's current design.

164. It was both technologically and economically feasible for Defendant to develop an alternative product which was safer in light of its intended or reasonably foreseeable use.

165. It is highly unlikely that Viagra users like Plaintiff would be aware of the risks associated with Viagra through warnings, general knowledge or other sources of information provided to them by Defendant, but Defendant knew or should have known of the melanoma-related risks associated with Viagra which were present even when the drug was used as instructed.

166. Viagra and its warnings, instructions and packaging, were expected to and did reach the Plaintiff and his physician without substantial change in the condition in which Viagra was sold.

167. Plaintiff used Viagra in substantially the same condition it was in when it left the control of Defendant. If any changes or modifications were made to the product after it left the custody and control of Defendant, such changes or modifications were foreseeable by Defendant.

168. Neither Plaintiff nor his healthcare providers misused or materially altered the Viagra prior to Plaintiff's use of the product.

169. The defective condition of Viagra includes, but is not limited to, defects as follows:

- a. Improper instructions and warnings regarding the use of Viagra and its risks and benefits;
- b. Failure to adequately and properly warn of the increased risk of developing melanoma with recent Viagra use;
- c. Failure to adequately and properly warn of the increased risk of developing melanoma with ever Viagra use;
- d. Failure to provide any information regarding the link between Viagra use and increased risk of melanoma anywhere in the product literature or information provided to Plaintiff or his healthcare providers;
- e. Failure to adequately and properly warn of the increased risk of permanent injury associated with melanoma with Viagra use;
- f. Failure to adequately and properly warn of the increased risk of death due to melanoma with Viagra use;
- g. Failure to provide any information regarding the lack of testing regarding the link between Viagra use and increased risk of melanoma;
- h. Failure to provide information regarding the risks and benefits of using or prescribing Viagra for erectile dysfunction given the increased risk of melanoma, permanent injury and death;
- i. Design and/or manufacture of Viagra by using improper ingredients;
- j. Design and/or manufacture of Viagra by using incompatible ingredients;
- k. Failure to recall Viagra upon learning that its design features, warnings and/or instructions rendered Viagra unsafe to users;
- l. Failure to take reasonable and necessary steps to design, test, and/or manufacture Viagra;
- m. Selection and/or use of ingredients and/or other components not it for their intended use;

- n. Failure to adequately and properly test Viagra and/or all of its ingredients; and
- o. Other defects as may be learned through discovery.

170. Due to the defects described herein, Viagra is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and does not meet or perform to the expectations of patients and their health care providers.

171. The melanoma-related risks associated with Viagra rendered Viagra unreasonably dangerous or far more dangerous than a reasonably prudent consumer or healthcare provider would expect when such a product was used in an intended and/or foreseeable manner.

172. As Defendant chose to distribute Viagra without adequate warnings as to the product's dangers and defects, Defendant's conduct shows a reckless disregard for the safety of individuals ingesting Viagra, such as Plaintiff.

173. Viagra creates risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of Viagra.

174. Defendant has intentionally and recklessly manufactured Viagra with wanton and willful disregard for the rights and health of the Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

175. One or more of Viagra's defective conditions played a substantial role in causing Plaintiff's injuries.

176. As a direct and proximate result of one or more of Defendant's wrongful acts or omissions, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss.

COUNT X
Wrongful Death

177. Plaintiffs incorporate the preceding paragraphs of this Complaint as if fully set forth herein.

178. Decedent used Viagra as prescribed by his physician and developed metastatic melanoma, from which he died on December 12, 2012.

179. Decedent's death was caused by the Defendant's wrongful acts, neglect, carelessness, and unskillfulness as set forth above.

180. Plaintiff Danielle Schoenrock is a surviving heir of Decedent and brings this claim on her own behalf and on behalf of Decedent's children. Ms. Schoenrock and her siblings have lost the loss of the love, companionship, comfort, affection, society, solace, and moral support of their father.

COUNT XII
Survival Claim

181. Plaintiffs incorporate the preceding paragraphs by reference as if fully set forth herein.

182. As a result of taking Viagra, Decedent suffered extensive injuries, pain, suffering, death, and economic harm as described above.

183. Pursuant to S.D. CODIFIED LAWS § 21-5-2 (2011). Plaintiff, as representative of the heirs and estate of Decedent, is entitled to special and general damages resulting from the injuries caused by Defendant that Decedent suffered prior to his death.

COUNT XIII
Discovery Rule and Equitable Tolling/Estoppel

184. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint as if fully set forth herein.

185. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

186. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

187. Despite diligent investigation by Plaintiff into the cause of the injuries, including consultations with the relevant medical providers regarding the nature of the Plaintiff's injuries and damages, its relationship to Viagra was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs suit was filed well within the applicable statutory limitations period.

188. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendant is estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from the Plaintiff and his physicians, of the true risks associated with Viagra. As a result of Defendant's fraudulent concealment, the Plaintiff and his physicians were unaware, and could not have known or have learned through reasonable diligence, that he had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant.

Plea for Punitive Damages

189. Prior to the manufacture, sale, and distribution of Viagra, Defendant knew that said medication was in a defective condition as previously described herein, and knew that those

who were prescribed the medication would experience and had already experienced severe physical, mental, and emotional injuries.

190. Defendant, through their officers, directors, managers, and agents, knew that Viagra presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and, as such, Defendant unreasonably subjected consumers of said drugs to risk of injury or death from using Viagra.

191. Defendant and its agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Viagra knowing these actions would expose persons to serious danger in order to advance the company's market share and profits.

192. Defendant's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of Viagra.

193. At all times material hereto, Defendant knew and intentionally and/or recklessly disregarded the fact that Viagra causes debilitating and potentially lethal side effects with greater frequency than alternative treatment and recklessly failed to advise healthcare providers, the public and the FDA of same.

194. Notwithstanding the foregoing, Defendant continues to aggressively market Viagra to consumers, without disclosing the true risk of side effects and complications.

195. Defendant knew or should have known of Viagra's defective and unreasonably dangerous nature, but continues to manufacture, produce, assemble, market, distribute, and sell Viagra so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by Viagra.

196. Defendant continues to intentionally conceal and/or recklessly and/or grossly

negligently fail to disclose to the public, including Plaintiff, the serious side effects of Viagra in order to ensure continued and increased sales.

197. Defendant' intentionally, reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable him to weigh the true risks of using Viagra against their benefits.

198. The acts, conduct, and omissions of Defendant, as alleged throughout this Complaint, were willful and malicious.

199. Defendant's unconscionable conduct warrants an award of exemplary and punitive damages against the company.

PRAYER FOR RELIEF

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

(a) Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all her injuries and damages, both past and present;

(b) Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering;

(c) Special and general damages for the injuries Decedent suffered prior to his death;

(d) Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendant who demonstrated a complete disregard and reckless indifference for the

safety and welfare of the general public and to Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct;

- (e) Attorneys' fees, expenses, and costs of this action;
- (f) Pre-judgment and post-judgment interest in the maximum amount allowed by law; and
- (g) Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

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

Dated: December 7, 2015

Respectfully submitted,



James Even

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