| | Case 3:16-cv-04339 Documer | nt 1 Filed 08/02/16 Page 1 of 31 | | | |
|-----------------------|--|--|--|--|--|
| 1 2 3 4 5 | Kimberly D. Barone Baden (CA SBN 20773 Ann E. Rice Ervin Motley Rice LLP 28 Bridgeside Boulevard Mount Pleasant, SC 29464 (843) 216-9265 (Phone) (843) 216-9450 (Facsimile) kbarone@motleyrice.com ariceervin@motleyrice.com | 31) | | | |
| 6 | UNITED STATES DISTRICT COURT | | | | |
| 7 | NORTHERN DISTRICT OF CALIFORNIA | | | | |
| 8 | David R. Ankney, |) Case No.: | | | |
| 9 | Plaintiff, |)) COMPLAINT FOR DAMAGES | | | |
| 10 | vs. |) 1. Negligence) 2. Negligence Per Se | | | |
| 11 | vs. |) 3. Strict Products Liability (Failure to | | | |
| 12 | Pfizer Inc., Defendant |) Warn/Defective Design) | | | |
| | Derendant |) 4. Breach of Implied Warranty) 5. Breach of Express Warranty | | | |
| 13 | |) 6. Fraudulent Misrepresentation | | | |
| 14 | |) 7. Fraudulent Concealment) 8. Negligent Misrepresentation | | | |
| 15 | |) o. Regigent misrepresentation | | | |
| 16 | |)) DEMAND FOR JURY TRIAL | | | |
| 17 | | | | | |

Plaintiff, David R. Ankney, by and through his undersigned counsel, hereby submits this Complaint and Jury Demand against Defendant, Pfizer Inc. ("Pfizer" or "Defendant"), for compensatory damages, punitive damages, equitable relief and such other relief deemed just and proper arising from the injuries to David R. Ankney resulting from the ingestion of the prescription drug Viagra®. In support of this Complaint and Jury Demand, Plaintiff alleges the following:

18

19

20

21

22

23

24

25

26

27

28

This is an action for personal injuries and damages suffered by Plaintiff David R. Ankney ("Plaintiff") as a direct and proximate result of Pfizer Inc.'s ("Pfizer") negligent and wrongful conduct in connection with the design, development, manufacturing, testing, packaging, promoting, marking, distribution, labeling and/or sale of sildenafil citrate tablets sold under the brand name Viagra® ("Viagra®").

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 2 of 31

PARTIES

1.

Plaintiff, David R. Ankney, resides in the County of Pinal, State of Arizona.

2. Defendant, Pfizer Inc. ("Pfizer") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in the State of New York. Pfizer regularly conducts business in the States of Delaware, New York, California, Arizona and throughout the United States and derives substantial revenues from drugs it sells in the States of Delaware, New York, California, Arizona and throughout the United States. Pfizer is engaged in the business of designing, developing, manufacturing, labeling, promoting, marketing, distributing and selling pharmaceutical drugs, including the drug Viagra® in New York, California, Arizona and throughout the United States.

Pfizer may be served with process by registered mail with return receipt requested,
 upon CT Corporation System, 818 West Seventh Street, Suite 930, Los Angeles, CA, 90017. Pfizer's
 registered agent in New York is CT Corporation System, 111 Eighth Avenue, New York, New York,
 10011.

4. Pfizer, including its owners, employees, parent companies, subsidiaries, affiliates and agents, developed, designed, manufactured, assembled, tested, inspected, marketed, promoted, advertised, warranted, distributed, labeled, sold, packaged, and/or provided warnings and instructions for Viagra®.

5. Pfizer conducts substantial business within Delaware, New York, California, Arizona and throughout the United States through the marketing, distribution and sales of Viagra®.

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 3 of 31

JURISDICTION AND VENUE

Plaintiff is a citizen of the State of Arizona.

7. Pfizer maintains its principal place of business in New York.

8. The value of Plaintiff's claims exceeds the total of seventy-five thousand dollars (\$75,000.000), exclusive of recoverable interest and costs. None of the causes of action stated herein have been assigned or otherwise given to any other court or tribunal.

6.

9.

1

2

3

4

5

б

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

Therefore, this Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332.

10. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391 because Pfizer has engaged in continuous and substantial business within this Judicial District, and otherwise maintains the requisite minimum contacts within the State of California. Additionally, Pfizer markets, advertises, distributes, sells and receives substantial profits from the sales of Viagra® in this District, and has and continues to conceal and make material omissions in this District, so as to subject it to *in personam* jurisdiction in this Judicial District.

11. On December 11, 2015, a Petition was filed with the Judicial Panel on Multidistrict
Litigation ("JPML") seeking coordination of all such matters before the U.S. District Court for the
Northern District of California. *See In Re: Viagra Products Liability Litigation*, MDL No. 2691.
The Petition was fully briefed, unopposed by Pfizer and all other interested parties, and argued on
March 31, 2016.

12. On April 7, 2016, the JPML issued a Transfer Order and consolidation of related cases into *In Re: Viagra (Sildenafil Citrate) Products Liability Litigation*, MDL No. 2691 and transferred the consolidation to the United States District Court for the Northern District of California before The Honorable Richard Seeborg.

13. Therefore, venue is also proper in the Northern District of California pursuant to 28U.S.C. § 1407.

14. Related Viagra® actions are pending in this and other federal judicial districts
throughout the United States. In light of this pretrial coordination and cooperation, Plaintiff is filing
this Complaint in the Northern District of California. Plaintiff reserves the right to assert all other
legal claims under Arizona's substantive law. For purposes of remand and trial, venue is proper in
Plaintiff's home District, United States District Court for the District of Arizona, Phoenix Division.
15. Plaintiff is domiciled in Arizona, was prescribed and ingested Viagra® in California
and Arizona and sustained injuries in California.

FACTS

Background

16. On March 27, 1998, the U.S. Food and Drug Administration approved a new drug application ("NDA") for the manufacture and sale of sildenafil citrate.

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

18. Sildenafil citrate ("Sildenafil") is the active ingredient in Viagra®.

19. Erectile dysfunction is the medical diagnosis for a condition in which a man cannot achieve or maintain an erection sufficient for satisfactory sexual activity. Since achieving and/or 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.

б

20. 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, creating an erection.

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

Prevalence of Viagra® in the Market

22. In its 2013 Annual Report, Pfizer 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 Pfizer lost exclusivity of Viagra® throughout Europe in 2013, which in itself led to a
drop in profits from the previous calendar year.

23. Viagra® holds approximately 45% of the U.S. market share for erectile dysfunction medications.²

24. Pfizer estimates that Viagra® has been prescribed to more than 35 million men worldwide.³

25. In 2012 alone, physicians wrote approximately eight million prescriptions for

¹ || Viagra \mathbb{R} .⁴

 ² 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.
 ³ Hilary Stout, *The Thrill That Was*, N.Y. TIMES, June 5, 2011, *available at*:

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

```
    http://query.nytimes.com/gst/fullpage.html?res=9B06E3DF173DF173FF936A35755C0A9679D8B63.
    <sup>4</sup> Wilson, supra note 4.
```

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 6 of 31

б

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

Pfizer's Knowledge

26. Unbeknownst to Viagra® users, studies have shown that the cellular activity providing the mechanism of action for Viagra® is associated with the development and/or exacerbation of melanoma.

27. The American Cancer Society states that melanoma is "the most serious type of skin cancer."⁵

28. 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.⁶

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

30. Upon information and belief, according to the Center for Drug Evaluation and Research "Joint Clinical Review" Internal Safety Review for Viagra (Sildenafil) NDA 20-895, Pfizer knew as early as approximately 1998 that there were people that dropped out of the clinical studies due to the development of carcinoma, including but not limited to melanoma, after taking Viagra® as part of a study.

31. A study published in 2011 found that treatment with Viagra® can promote melanoma cell invasion.⁷ 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.

25

⁵ American Cancer Society, *Skin Cancer Facts*, last revised March 19, 2014, *available at*: http://cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts.

⁶ National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 20111, *available at*: http://www.cancer.gov/cancertopics/wynthk/skin/page4.

²⁸ ⁷ I. Aozarena, et al., Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating The cGMP-Specific Phosphodiesterase PDE5A, 19 CANCER CELL 45 (2011).

1

2

3

4

5

б

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

32. A 2012 study published in the Journal of Cell Biochemistry also found that PDE5 inhibitors were shown to promote melanin synthesis,⁸ which may exacerbate melanoma development.⁹

33. 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.¹⁰ The JAMA study was published in the journal's June 2014 edition.

34. 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.¹¹

Consumer Expectations

35. Since Viagra®'s FDA approval in 1998, Pfizer 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.

36. Pfizer 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

⁸ X Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Though the PKG Pathway in B16 Melanoma Cells*, 113 J. CELL BIOCHEM. 2738 (2012).

CELL BIOCHEM. 2738 (2012).
 ⁹ F.P. Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation Requires Melanin Pigment*, 3
 NATURE COMMUNICATIONS 884 (2012).

 ¹⁰ 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).
 ¹¹ Id.

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 8 of 31

demonstration, a 2004 article in the Chicago Tribune cited industry reports stating that Pfizer spent "tens of millions of dollars each month on direct-to-consumer advertising."¹²

37. Pfizer has also been criticized by regulators, physicians and consumer groups for its attempt to target younger men in their advertising. Doctors and federal regulators stated that "such ads sen[t] a confusing message to patients who might really benefit from the drug."¹³

38. While designing and formulating Viagra®, Pfizer discovered or should have discovered that the drug's mechanism of action, the inhibition of PDE5, also presented a significant risk of the development and/or the exacerbation of melanoma.

39. Despite these significant findings, Pfizer has made no efforts in its ubiquitous Viagra® advertisements to warn users about the potential risk of developing and/or exacerbating melanoma that has been scientifically linked to its drug.

40. Members of the general public had no plausible means through which they could have discovered the significant risk of melanomagenesis associated with PDE5 inhibition.

41. Prescribing physicians would not have had the same level of access to the research and development conducted by Pfizer prior to its decision to manufacture Viagra® for general public use.

42. Pfizer failed to communicate to the general public that the inhibition of PDE5 inherently necessary to the efficacy of Viagra® would also present a significant risk of one's development and/or exacerbation of cancerous cells.

43. For example, no individual prescribed to use Viagra® would have believed or be expected to know that his use of Viagra® would expose him to an increased risk of developing melanoma or exacerbating the growth of melanocytes already present in the body.

^{7 &}lt;sup>12</sup> 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.

¹³ Bruce Japsen, *Toned-Down Advertising Credited for Viagra Gains*, CHICAGO TRIBUTED, Feb. 8, 2007, *available at* http://articles.chicagotribune.com/2007-02-08/business/0702080063_1_viagra-erectile-Pfizer-spokesman.

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 9 of 31

44. Pfizer expected or should have expected individuals who suffered from erectile 1 2 dysfunction to ingest Viagra® as a means to treat their condition. 3 45. Pfizer expected or should have expected physicians treating erectile dysfunction to 4 prescribe Viagra® as a means to treat this condition. 5 46. The risk presented by ingesting Viagra® would be present from the moment of б manufacture; that is, the user would not need to change or alter the drug itself or the means by which 7 8 it was ingested in order for the drug to carry the same risk of harm as described herein. 9 **Risks and Benefits of Viagra® Use** 10 47. Erectile dysfunction is not fatal, nor does it present any related symptoms or 11 characteristics harmful to one's physical health; however, those with erectile dysfunction are unable 12 to achieve and maintain an erection. 13 14 48. At all times relevant hereto, Viagra[®] was useful to some members of the population; 15 namely, men diagnosed with erectile dysfunction. 16 49. However, Viagra® also encourages the development of melanoma in the body of a 17 user, thereby placing them at a significant health risk. 18 50. Pfizer manufactured, marketed and sold Viagra® as a PDE5 inhibitor; however, the 19 mechanism of action that made the drug effective in treating erectile dysfunction simultaneously 20 21 increased the risk of the user developing melanoma. 22 51. At the time Viagra® was formulated and manufactured, Pfizer knew or should have 23 known that the drug posed a significantly heightened risk to users, specifically through the increased 24 likelihood that those users would develop melanoma because of the chemical reactions inherent to the 25 drug's functioning. 26 27 28

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 10 of 31

| 1 | 52. | Through the testing and formulating of Viagra®, and before the initiation of the drug's | | |
|----------|--|---|--|--|
| 2 | mass manufacturing, Pfizer knew or should have known in the exercise of ordinary care that the | | | |
| 3 | chemical reactions inherent to Viagra®'s mechanism of action would present a cancer-related health | | | |
| 4 | hazard to potential future users. | | | |
| 5 | 53. The risk presented by the use of Viagra® through PDE5 inhibition – a characteristic | | | |
| 6 | inherent to the drug's potential efficacy – was unquestionably far more significant than the benefit | | | |
| 7 8 | provided to its users. | | | |
| | | 5 45015. | | |
| 9 | 54. | Because the risk of using Viagra® so greatly outweighs the benefits of such use, the | | |
| 10 | drug presents | an unreasonably dangerous risk when used for its intended indication. | | |
| 11 | | Facts Regarding Plaintiff | | |
| 12 | | | | |
| 13 | 55. | Plaintiff, David R. Ankney, began pharmaceutical treatment for erectile dysfunction in | | |
| 14 | or about June 2003, when his physician prescribed Viagra®. | | | |
| 15 | 56. | Plaintiff continuously filled and regularly ingested Viagra® through 2013. | | |
| 16 | 57. | In March 2005, Plaintiff underwent a biopsy on his left upper back and the results of | | |
| 17 18 | the pathology report revealed malignant melanoma. | | | |
| 19 | 58. | On April 14, 2005, Plaintiff underwent a wide excision of the melanoma on his left | | |
| 20 | upper back ar | nd excisions of bilateral sentinel lymph nodes from each axilla. | | |
| 21 | 59. | Since first being diagnosed with melanoma, Plaintiff has had to remain vigilant in | | |
| 22 | monitoring his skin for lesions and must go for routine and regular check-ups. | | | |
| 23 | 60. | Had Pfizer properly disclosed the increased risk of melanoma associated with | | |
| 24 | | | | |
| 25 | Viagra®, Plai | intiff would have avoided the risk of developing melanoma from Viagra® use by not | | |
| 26 | taking Viagra | ® at all. | | |
| 27 | | | | |
| 28 | | | | |
| | | - 10 - | | |

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 11 of 31

28

1

61. As a direct, proximate and legal result of Pfizer's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug Viagra®, Plaintiff suffered severe and permanent physical and emotional injuries. His physical injuries have included melanoma as well as surgery necessitated by his skin cancer diagnosis. Plaintiff has endured not only physical pain and suffering but also an economic loss, including medical care and treatment. Because of the nature of his diagnosis, he will certainly continue to incur such medical expenses in the future. As a result of these damages, Plaintiff seeks actual and punitive damages from Pfizer.

<u>Summary</u>

62. At all times relevant to this lawsuit, Pfizer engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Viagra® for use among the general public.

63. For the duration of these efforts, Pfizer directed its advertising efforts to consumers located across the nation, including consumers in the States of California, Arizona and throughout the United States. Such efforts were also aimed at prescribing physicians across the nation, including prescribing physicians in the States of California, Arizona and throughout the United States.

64. At all times mentioned in this Complaint, Pfizer'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 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.

> - 11 -COMPLAINT FOR DAMAGES

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 12 of 31

65. Pfizer purposefully downplayed, understated and outright ignored the melanomarelated health hazards and increased risks associated with using Viagra®. Pfizer 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 consequences.

66. Pfizer concealed material information related to melanoma development from potential Viagra® users.

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

68. As a result of Pfizer's advertising and marketing, and representations about its product, men in the United States pervasively sought 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 developed melanoma. Similarly, if Plaintiff's physicians had been aware of the risks and dangers associated with taking Viagra®, they would not have prescribed Viagra® to Plaintiff.

CAUSES OF ACTION

FIRST CAUSE OF ACTION NEGLIGENCE

69. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

70. Pfizer had a duty to exercise reasonable care and comply with existing standards of care in the testing, designing, researching, developing, manufacturing, packaging, promoting, labeling, advertising, marketing, selling and/or distribution of Viagra® into the stream of commerce including a duty to ensure that the product would not cause users to suffer unreasonable and dangerous side effects.

71. Pfizer failed to exercise ordinary care and failed to comply with existing standards of care in the testing, designing, researching, developing, manufacturing, packaging, promoting,
labeling, advertising, marketing, selling and/or distribution of Viagra® into interstate commerce in that Pfizer knew or should have known that using Viagra® created an unreasonable risk of melanoma as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life as well as the need for lifelong medical treatment, monitoring, medications and/or death.

72. Pfizer, its agents, servants and/or employees failed to exercise ordinary care and failed to comply with existing standards of care in the following acts and/or omissions:

a. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety risks of Viagra® for treating men while promoting the use of Viagra® and providing kickbacks to healthcare professionals to convince healthcare professionals to prescribe Viagra® for erectile dysfunction;

b. Marketing Viagra® for the treatment of erectile dysfunction without testing it to determine whether Viagra® was safe for this use;

- c. Designing, manufacturing, producing, promoting, formulating, creating and/or developing Viagra® without adequately and thoroughly testing it;
- d. Selling Viagra® without conducting sufficient tests to identify the dangers posed by Viagra® to men;
- e. Failing to adequately and correctly warn Plaintiff, the public, the healthcare community, including Plaintiff, David R. Ankney's healthcare providers, as well as the FDA of the dangers of Viagra® in men;

| 1 | 1 | f. Failing to evaluate available data and safety information concerning Viagra® use | |
|-------------|--|---|--|
| 2 | | in men; | |
| 3 4 | 1 | g. Advertising and recommending the use of Viagra® without sufficient knowledge as to its dangerous propensities to cause and/or exacerbate melanoma; | |
| 5 | 1 | Representing that Viagra[®] was safe for treating men when in fact it was and is unsafe; | |
| 6 7 8 | i | Representing that Viagra® was safe and efficacious for treating erectile dysfunction when Defendant was aware that neither the safety nor efficacy for | |
| 9 | | such treatment has been established; | |
| 10 | J | Representing that Viagra® was not carcinogenic in the animal studies conducted in rats and rabbits; | |
| 11 | 1 | k. Failing to provide any warnings regarding melanoma; | |
| 12 13 | 1 | Failing to accompany Viagra® with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Viagra®; | |
| 14 | 1 | m. Failing to issue sufficiently strengthened warnings following additional evidence | |
| 15 | | associating Viagra® use with the increased risk of melanoma; | |
| 16 17 | 1 | n. Failing to advise Plaintiff, David R. Ankney's healthcare providers, the FDA and the healthcare community that neither the safety nor the efficacy of Viagra® for treating erectile dysfunction has been established and that the risks of using the drug for that condition outweigh any putative benefit; and | |
| 18 | | | |
| 19 20 | | b. Failing to advise Plaintiff, David R. Ankney's healthcare providers, the FDA and the healthcare community of clinically significant adverse events, specifically melanoma, associated with Viagra® use for erectile dysfunction. | |
| 21 | 73. | Despite the fact that Pfizer knew or should have known that Viagra® significantly | |
| 22 | increased the risk of melanoma, it continued and still continues to negligently market through false | | |
| 23 24 | and misleading promotion and communication, manufacture, distribute and/or sell Viagra® to | | |
| 25 | consumers including Plaintiff, David R. Ankney. | | |
| 26 | 74. Pfizer knew or should have known that consumers such as Plaintiff would foreseeably | | |
| 27 | suffer injury as | a result of its failure to exercise ordinary care as set forth above. | |
| 28 | | | |
| | | | |

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 15 of 31

75. Pfizer's negligence was the proximate cause of Plaintiff's injuries, harm and economic
 loss which Plaintiff suffered and/or will continue to suffer.

76. Had Plaintiff, David R. Ankney, not taken Viagra®, he would not have suffered those injuries and damages as described herein with particularity.

77. As a result of the foregoing acts and omissions, David R. Ankney was caused to suffer injuries from melanoma that are permanent and lasting in nature, physical pain and mental anguish including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medication.

78. Plaintiff, David R. Ankney, has also sustained severe emotional distress and suffering as a result of Pfizer's wrongful conduct.

79. As a result of the foregoing acts and omissions, David R. Ankney has required and will require future medical care for which he has incurred medical, health, incidental and related expenses. Plaintiff, David R. Ankney, believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention and services.

80. By reason of the foregoing, Plaintiff has been damaged by Pfizer's wrongful conduct. Pfizer's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross negligence so as to indicate a complete disregard of the rights and safety of Plaintiff and others justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

3

4

5

б

7

8

9

10

11

12

13

14

15

16

17

SECOND CAUSE OF ACTION

NEGLIGENCE *PER SE*

81. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

82. Pfizer had a duty to exercise reasonable care and comply with existing laws in the testing, designing, researching, developing, manufacturing, packaging, promoting, labeling, advertising, marketing, selling and/or distribution of Viagra® into the stream of commerce including a duty to ensure that the product would not cause users to suffer unreasonable and dangerous side effects.

83. Pfizer failed to exercise ordinary care and failed to comply with existing laws in the testing, designing, researching, developing, manufacturing, packaging, promoting, labeling, advertising, marketing, selling and/or distribution of Viagra® into interstate commerce in that Pfizer knew or should have known that using Viagra[®] created an unreasonable risk of melanoma as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life as well as the need for lifelong medical treatment, monitoring, medications and/or death.

84. Pfizer, its agents, servants and/or employees failed to exercise ordinary care and violated 21 U.S.C. § 331, 352; 42 U.S.C. § 1320a-7b; and 21 C.F.R. §§ 201.57, 201.128 in particular.

85. The laws violated by Pfizer were designed to protect Plaintiff and similarly situated persons against the risks and hazards that have occurred in this case. Therefore, Defendant's conduct constitutes negligence per se.

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 17 of 31

Ш

| 1 | 86. | Despite the fact that Pfizer knew or should have known that Viagra® significantly | | |
|----------|--|--|--|--|
| 2 | increased the risk of melanoma and/or the exacerbation of melanoma, it continues to negligently | | | |
| 3 | market through false and misleading promotion and communication, manufacture, distribute and/or | | | |
| 4 | sell Viagra® to consumers including Plaintiff, David R. Ankney. | | | |
| 5 | 87. Pfizer knew or should have known that consumers such as Plaintiff would foreseeably | | | |
| 7 | suffer injury as a result of its failure to exercise ordinary care as set forth above. | | | |
| 8 | 88. Pfizer's negligence was the proximate cause of Plaintiff injuries, harm and economic | | | |
| 9 | loss which Plaintiff suffered and/or will continue to suffer. | | | |
| 10 | 89. | Had Plaintiff, David R. Ankney, not taken Viagra®, he would not have suffered those | | |
| 11 12 | injuries and damages as described herein. | | | |
| 13 | 90. | As a result of the foregoing acts and omissions, David R. Ankney was caused to suffer | | |
| 14 | injuries from melanoma that are permanent and lasting in nature, physical pain and mental anguish | | | |
| 15 | including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring | | | |
| 16 | and/or medication. | | | |
| 17 | 91. | Plaintiff, David R. Ankney, has also sustained severe emotional distress and suffering | | |
| 18 19 | as a result of Pfizer's wrongful conduct and his injuries. | | | |
| 20 | 92. | As a result of the foregoing acts and omissions, David R. Ankney has required and | | |
| 21 | will require future medical care for which he has incurred medical, health, incidental and related | | | |
| 22 | expenses. Plaintiff, David R. Ankney, believes and further alleges that he will in the future be | | | |
| 23 | required to obtain further medical and/or hospital care, attention and services. | | | |
| 24 25 | | | | |
| 26 | | | | |
| 27 | | | | |
| 28 | | | | |
| | | - 17 - COMPLAINT FOR DAMAGES | | |

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 18 of 31

93. By reason of the foregoing, Plaintiff has been damaged by Pfizer's wrongful conduct. 1 2 Pfizer's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross 3 negligence so as to indicate a complete disregard of the rights and safety of Plaintiff and others 4 justifying an award of punitive damages. 5 WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for б compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such 7 8 other and further relief as this Court deems just and proper. Plaintiff also demands that the issues 9 herein contained be tried by a jury. 10 THIRD CAUSE OF ACTION 11 STRICT PRODUCTS LIABILITY (Failure to Warn/Design Defect) 12 94. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint 13 14 contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more 15 fully set forth herein. 16 95. Viagra® was tested, designed, researched, developed, manufactured, packaged, 17 promoted, labeled, advertised, marketed, sold, distributed and/or placed into the stream of commerce 18 by Pfizer and was defective at the time it left Pfizer's control in that, and not by way of limitation, the 19 drug labeling failed to include adequate warnings, instructions and directions relating to the 20 21 dangerous risks associated with the use of Viagra® to treat erectile dysfunction. Viagra® was also 22 defective in its design because the foreseeable risks of harm posed by the product could have been 23 reduced or avoided by the adoption of a reasonable alternative design. Safe and effective products 24 were available for the purpose for which Pfizer marketed Viagra® for use in men with erectile 25 dysfunction and neither the safety nor the efficacy of Viagra® for that purpose had been established. 26 27 28

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 19 of 31

96. Pfizer failed to provide adequate warnings to healthcare providers and consumers, including Plaintiff, David R. Ankney, and his treating healthcare providers of the increased risk and/or exacerbation of melanoma associated with Viagra® and aggressively promoted the product to healthcare providers, hospitals and directly to consumers.

97. Prescribing physicians, healthcare providers and men neither knew nor had reason to know of the existence of the aforementioned melanoma at the time of prescribing and/or ingesting of Viagra®. Healthcare providers and/or consumers would not have recognized the potential risks or side effects for which Pfizer failed to include appropriate warnings and which it masked through the unbalanced promotion of Viagra® specifically for treatment in men with erectile dysfunction.

98. At all times herein mentioned, due to Pfizer's marketing of Viagra®, the drug was prescribed and used as intended by Plaintiff, David R. Ankney, and in a manner reasonably foreseeable to Pfizer.

99. Pfizer is liable to Plaintiff for the negligent and/or willful failure to provide adequate warnings and other clinically relevant information and data regarding the appropriate use of Viagra® to Plaintiff, David R. Ankney, and his healthcare providers.

100. Pfizer, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field. Further, Pfizer knew or should have known that the warnings and other clinically relevant information and data which they distributed, omitting the risks of developing and/or exacerbating melanoma, associated with the use of Viagra® were inadequate.

101. Pfizer had a continuing duty to provide consumers including Plaintiff, David R. Ankney, and his healthcare providers with warnings and other clinically relevant information and data regarding the risks and dangers associated with Viagra® as it became or could have become available to Pfizer.

28

1

2

3

4

5

б

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 20 of 31

| 1 | 102. Despite the fact that Pfizer knew or should have known that Viagra® caused and/or | | |
|----------|---|-----------|--|
| 2 | exacerbated melanoma, it continued to manufacture, package, promote, label, advertise, distribute | | |
| 3 | and sell Viagra® without stating that there existed safer and more equally effective alternative drug | | |
| 4 | products and | or prov | iding adequate clinically relevant information, warnings and data. |
| 5 | 103. | Pfizer | r knew or should have known that consumers and Plaintiff specifically would |
| 6 7 | foreseeably a | nd need | llessly suffer injury as a result of Pfizer's failures. |
| 8 | 104. | | r breached its duty to provide timely and adequate warnings, instructions and |
| 9 | | | blowing particulars: |
| 10 | | ii the io | nowing particulars. |
| 11 | | a. | failing to ensure Viagra® warnings to the healthcare community, physicians, David R. Ankney's healthcare providers and Plaintiff were accurate and |
| 12 | | | adequate despite having extensive knowledge of the risks associated with Viagra®; |
| 13 | | b. | failing in obligation to provide the healthcare community, physicians, David R. |
| 14 | | | Ankney's healthcare providers and Plaintiff with adequate clinically relevant information, data and warnings regarding the adverse health risks associated |
| 15 16 | | | with exposure to Viagra® and/or that there existed safer and more or equally effective alternative drug products; |
| 17 | | c. | failing to conduct post-market safety surveillance and report that information |
| 18 | | | to the healthcare community, David R. Ankney's healthcare providers and Plaintiff; |
| 19 | | d. | failing to include adequate warnings and/or providing adequate and clinically |
| 20 | | | relevant information and data that would alert the healthcare community, David R. Ankney's healthcare providers and Plaintiff to the dangerous risks of |
| 21 | | | Viagra® including among other things the increased risk of melanoma; |
| 22 | | e. | failing to continually monitor, test and analyze data regarding safety, efficacy |
| 23 | | | and prescribing practices of their marketed drugs including Viagra®; |
| 24 | | f. | failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of its warnings, |
| 25 26 | | | efficacy or safety including the risks and/or prevalence of side effects caused by Viagra® to the healthcare community, David R. Ankney's healthcare |
| 27 | | | providers and Plaintiff; |
| 28 | | | |
| | | | |
| | 1 | | - 20 - |

| | Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 21 of 31 | | |
|---|--|--|--|
| 1 2 3 4 5 6 7 8 9 | g. failing to provide adequate post-marketing warnings and instructions after Pfizer knew or should have known of the significant risks of, among other things, melanoma of Viagra®; h. failing to periodically review all medical literature regarding Viagra® and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy or safety of Viagra®; i. failing to disclose the results of the testing and other information in Pfizer's possession regarding Viagra® and the increased risk of melanoma and/or exacerbation of melanoma; and j. failing to warn adequately the healthcare community, the general public and Plaintiff of the dangers of using Viagra® for erectile dysfunction including the risk of melanoma and/or representing that Viagra® was safe for erectile | | |
| 10 11 | dysfunction when in fact Pfizer knew or should have known that Viagra® was unsafe for this use and that Viagra® increased the risk of melanoma and/or exacerbation of melanoma. | | |
| 12 13 | 105. As a direct and proximate result of the defective nature of Viagra®, David R. Ankney was caused to suffer injuries from melanoma that are permanent and lasting in nature, physical pain | | |
| 14 15 | and mental anguish including diminished enjoyment of life, as well as the need for lifelong medical | | |
| 16 | treatment, monitoring and/or medication. | | |
| 17 18 | 106. Plaintiff, David R. Ankney, has also sustained severe emotional distress and suffering as a result of Pfizer's wrongful conduct resulting in his injuries. | | |
| 19 20 | 107. As a result of the foregoing acts and omissions, David R. Ankney has required and will require future medical care for which he has incurred medical, health, incidental and related | | |
| 21 22 | expenses. Plaintiff, David R. Ankney, believes and further alleges that he will in the future be | | |
| 23 | required to obtain further medical and/or hospital care, attention and services. | | |
| 24 | 108. By reason of the foregoing, Plaintiff has been damaged by Pfizer's wrongful conduct. | | |
| 25 26 | Pfizer's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross | | |
| 27 | negligence so as to indicate a complete disregard of the rights and safety of Plaintiff and others | | |
| 28 | justifying an award of punitive damages. | | |
| | - 21 - | | |

COMPLAINT FOR DAMAGES

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

FOURTH CAUSE OF ACTION BREACH OF IMPLIED WARRANTY

109. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

110. Plaintiff used Viagra® in substantially the same condition it was in when it left the control of Pfizer.

111. Prior to the time that Plaintiff used Viagra®, Pfizer implicitly warrantied to Plaintiff and his physicians that Viagra® was of merchantable quality, safe to use and fit for the use for which it was intended.

112. Pfizer implicitly warrantied the safety of Viagra® through a multimedia advertising campaign conducted over a span of several years, as Viagra® had been on the market for many years prior to the time when Plaintiff was first prescribed Viagra®.

113. Pfizer implicitly warrantied the merchantable quality of Viagra® by opting to massproduce and promote the prescription and sale of Viagra®.

114. Pfizer implicitly warrantied that Viagra® was fit for the use for which it was intended by offering assertions through multimedia advertisements that the drug was used for the treatment of erectile dysfunction.

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 23 of 31

115. 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 Pfizer in deciding to use Viagra®.

116. Plaintiff's physicians would not have had the same level of access to the research and development conducted by Pfizer prior to its decision to manufacture Viagra® for general use.

117. Viagra® was neither safe for its intended use nor of merchantable quality, as had been implicitly warranted by Pfizer, in that Viagra®'s mechanism of action – the inhibition of PDE5 – inherently presented a significant increased risk of developing and/or exacerbating melanoma.

118. As a direct and proximate result of the falsity of the warranties implicated by Pfizer's actions and omissions, Plaintiff suffered significant pain, suffering, invasive procedures and economic damages incurred for the treatment of melanoma caused by Viagra® use.

119. By reason of the foregoing, Plaintiff has been damaged by Pfizer's wrongful conduct.Pfizer's conduct was willful, wanton, reckless and, at the very least, arose to the level of grossnegligence so as to indicate a complete disregard of the rights and safety of Plaintiff and othersjustifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

FIFTH CAUSE OF ACTION BREACH OF EXPRESS WARRANTY

120. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

121. At all times relevant hereto, Pfizer expressly represented and warranted to Plaintiff and his healthcare providers, by and through statements made by Pfizer 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® was safe, effective and proper for its intended use.

122. These representations include, but are not limited to, the information disseminated in Pfizer's patient information and prescribing information publications, Pfizer's website and on the FDA's website, since the drug entered the market.

123. The warranties expressly made by Pfizer through its marketing and labeling were false as Viagra® is unsafe.

124. Specifically, Viagra® is unsafe in that its mechanism of action, the inhibition of the PDE5 enzyme, also increases the risk of the development and proliferation of melancyotic cells in the user's body.

125. Plaintiff's physicians acted as reasonable physicians in relying on what they believed to be the superior knowledge, judgment and access to research information possessed by Pfizer in choosing to prescribe Viagra® to Plaintiff.

126. Plaintiff acted as a reasonable consumer, relied on what he believed to be the superior skill, judgment, representations and express warranties of Pfizer in deciding to purchase and use Viagra®.

127. In direct reliance upon the warranties made by Pfizer that Viagra® was safe to use in treating erectile dysfunction, Plaintiff's physicians prescribed and Plaintiff ingested Viagra® and ultimately developed melanoma as a result.

б

Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 25 of 31

128. As a direct and proximate result of the breach of warranty committed by Pfizer,Plaintiff suffered significant pain, suffering, invasive procedures and economic damages incurred for the treatment of melanoma caused by Viagra® use.

129. By reason of the foregoing, Plaintiff has been damaged by Pfizer's wrongful conduct.
Pfizer's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross
negligence so as to indicate a complete disregard of the rights and safety of Plaintiff and others
justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SIXTH CAUSE OF ACTION FRAUDULENT MISREPRESENTATION

130. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

131. Pfizer falsely and fraudulently represented to men suffering with erectile dysfunction and the healthcare community, including Plaintiff, David R. Ankney's healthcare providers that:

a. Viagra® was safe and effective for treating erectile dysfunction;
b. Viagra® had been adequately tested and studied in men with erectile dysfunction;
c. Viagra® use was safe by omitting knowledge of an increased risk of melanoma; and
d. Viagra®'s designation established the safety and efficacy of Viagra® for treating erectile dysfunction.

132. These representations made by Pfizer were material, false and misleading.

133. When Pfizer made these representations, it knew they were false.

134. Pfizer made these representations with the intent of defrauding and deceiving the public in general, and the healthcare community in particular, and were made with the intent of inducing the public in general, and the healthcare community in particular, including Plaintiff, David R. Ankney's healthcare providers, to recommend, prescribe, dispense and/or purchase Viagra® to treat erectile dysfunction, all of which evidenced a callous, reckless willful, depraved indifference to the health, safety and welfare of Plaintiff herein.

135. At the time the aforesaid representations were made by Pfizer and at the time Plaintiff, David R. Ankney, was prescribed and ingested Viagra® to treat erectile dysfunction, he was unaware of the falsity of said representations and reasonably believed them to be true.

136. In reliance upon said representations, David R. Ankney's prescriber was induced to prescribe Viagra® to Plaintiff and Plaintiff, David R. Ankney, was induced to and did ingest Viagra® to treat erectile dysfunction.

137. Pfizer knew that Viagra® had not been sufficiently tested for erectile dysfunction and that it lacked adequate warnings.

138. Pfizer knew or should have known that Viagra® increases the risk of melanoma and/or the exacerbation of melanoma.

139. As a result of the foregoing acts and omissions, David R. Ankney was caused to suffer injuries from melanoma that are permanent and lasting in nature, physical pain and mental anguish including diminished enjoyment of life, invasive procedures, as well as the need for lifelong medical treatment, monitoring and/or medication.

б

140. Plaintiff, David R. Ankney, has also sustained severe emotional distress and suffering as a result of Pfizer's wrongful conduct and the injuries from melanoma.

141. As a result of the foregoing acts and omissions, David R. Ankney has required and will require future medical care for which he has incurred medical, health, incidental and related expenses. Plaintiff, David R. Ankney, believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention and services.

142. By reason of the foregoing, Plaintiff has been damaged by Pfizer's wrongful conduct.
Pfizer's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross
negligence so as to indicate a complete disregard of the rights and safety of Plaintiff and others
justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SEVENTH CAUSE OF ACTION FRAUDULENT CONCEALMENT

143. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

144. In representations to Plaintiff, David R. Ankney's healthcare providers, men with erectile dysfunction (including Plaintiff, David R. Ankney) and the FDA, Pfizer fraudulently concealed and intentionally omitted the following material facts:

a. Pfizer was illegally paying and offering to pay doctors remuneration to promote and prescribe Viagra®;

| | Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 28 of 31 | | | |
|----------|--|--|--|--|
| 1 2 | b. Viagra® use increases the risk of developing melanoma and/or exacerbates melanoma; c. the risks of melanoma associated with the consumption of Viagra® by men with | | | |
| 3 4 | erectile dysfunction were not adequately tested prior to Pfizer's marketing of Viagra®; | | | |
| 5 6 | d. the safety and efficacy of Viagra® for treating erectile dysfunction had not been established; | | | |
| 7 | e. Viagra® is not safe and effective for treating erectile dysfunction; and | | | |
| 8 | f. Pfizer's internal data and information associated Viagra® with melanoma. | | | |
| 9 | 145. Pfizer's concealment and omissions of material facts concerning, among other things, | | | |
| 10 11 | the safety and efficacy of Viagra® for erectile dysfunction was made purposefully, willfully, | | | |
| 12 | wantonly and/or recklessly to mislead physicians, hospital, healthcare providers and men with | | | |
| 13 | erectile dysfunction including Plaintiff, David R. Ankney, into reliance, continued use of Viagra® | | | |
| 14 | and to cause them to promote, purchase, prescribe and/or dispense Viagra®. | | | |
| 15 | 146. Pfizer knew that physicians, hospitals, healthcare providers and men with erectile | | | |
| 16 | dysfunction such as Plaintiff, David R. Ankney, had no way to determine the truth behind Pfizer's | | | |
| 17 18 | concealment and material omissions of facts surrounding Viagra® as set forth herein. | | | |
| 19 | 147. Plaintiff, David R. Ankney, and his healthcare providers reasonably relied on Pfizer's | | | |
| 20 | promotional statements concerning the asserted safety and efficacy of Viagra ® for men with erectile | | | |
| 21 | dysfunction from which Pfizer negligently, fraudulently and/or purposefully omitted material facts. | | | |
| 22 | 148. As a result of the foregoing acts and omissions, David R. Ankney was caused to suffer | | | |
| 23 | injuries from melanoma that are permanent and lasting in nature, physical pain and mental anguish | | | |
| 24 | including diminished enjoyment of life, invasive procedures, as well as the need for lifelong medical | | | |
| 25 26 | treatment, monitoring and/or medication. | | | |
| 20 | | | | |
| 28 | | | | |

149. Plaintiff, David R. Ankney, has also sustained severe emotional distress and suffering as a result of Pfizer's wrongful conduct and the injuries from melanoma.

150. As a result of the foregoing acts and omissions, David R. Ankney has required and will require future medical care for which he has incurred medical, health, incidental and related expenses. Plaintiff, David R. Ankney, believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention and services.

151. By reason of the foregoing, Plaintiff has been damaged by Pfizer's wrongful conduct.
Pfizer's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross
negligence so as to indicate a complete disregard of the rights and safety of Plaintiff and others
justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

EIGHTH CAUSE OF ACTION NEGLIGENT MISREPRESENTATION

152. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

153. Pfizer falsely and negligently represented to the healthcare community and men with erectile dysfunction, including Plaintiff, David R. Ankney, and his healthcare providers that:

a.

- Viagra® was safe and effective for treating erectile dysfunction;
- b. Viagra® had been adequately tested and studied in men with erectile dysfunction;

c. Viagra® use pursuant to Pfizer's labeling was safe; and

- d. Viagra®'s designation established the safety and efficacy of Viagra® for treating erectile dysfunction.
- 154. These representations made by Pfizer were, in fact, false and misleading.

155. As a result of the foregoing acts and omissions, David R. Ankney was caused to suffer injuries from melanoma that are permanent and lasting in nature, physical pain and mental anguish including diminished enjoyment of life, invasive procedures, as well as the need for lifelong medical treatment, monitoring and/or medication.

156. Plaintiff, David R. Ankney, has also sustained severe emotional distress and suffering as a result of Pfizer's wrongful conduct and his injuries.

157. As a result of the foregoing acts and omissions, David R. Ankney has required and will require future medical care for which he has incurred medical, health, incidental and related expenses. Plaintiff, David R. Ankney, believes and further alleges that he will in the future be required to obtain further medical and/or hospital care, attention and services.

158. By reason of the foregoing, Plaintiff has been damaged by Pfizer's wrongful conduct. Pfizer's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross negligence so as to indicate a complete disregard of the rights and safety of Plaintiff and others justifying an award of punitive damages.

WHEREFORE, Plaintiff respectfully request that this Court enter judgment in his favor for
compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such
other and further relief as this Court deems just and proper. Plaintiff also demands that the issues
herein contained be tried by a jury.

| | Case 3:16-cv-04339 Document 1 Filed 08/02/16 Page 31 of 31 |
|----|---|
| 1 | DEMAND FOR JURY TRIAL |
| 2 | Plaintiff demands a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure |
| 3 | and the Seventh Amendment of the United States Constitution. |
| 4 | PRAYER FOR RELIEF |
| 5 | |
| 6 | WHEREFORE, Plaintiff demands judgment against Defendant on each of the above- |
| 7 | referenced claims and causes of action and as follows: |
| 8 | a. For general damages in a sum in excess of the jurisdictional minimum of this Court; |
| 9 | b. For medical, incidental and hospital expenses according to proof; |
| 10 | c. For pre-judgment and post-judgment interest as provided by law; d. For full refund of all purchase costs of Viagra®; |
| 11 | e. For consequential damages in excess of the jurisdictional minimum of this |
| 12 | Court;f. For compensatory damages in excess of the jurisdictional minimum of this |
| 13 | Court; |
| 14 | g. For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and |
| 15 | punish the Defendant for the conduct described herein; |
| 16 | h. For attorneys' fees and costs of this action; andi. For equitable relief and such other and further relief as this Court deems |
| 17 | necessary, just and proper. |
| 18 | |
| 10 | Dated: August 2, 2016 /s/ Kimberly D. Barone Baden |
| 20 | Kimberly D. Barone Baden (CA SBN 207731) Ann E. Rice Ervin |
| 21 | Motley Rice LLP |
| | 28 Bridgeside Boulevard Mount Pleasant, SC 29464 |
| 22 | (843) 216-9265 (Phone) (843) 216-9450 (Facsimile) |
| 23 | Email: <u>kbarone@motleyrice.com</u> |
| 24 | Email: <u>ariceervin@motleyrice.com</u> |
| 25 | Attorneys for Plaintiff |
| 26 | |
| 27 | |
| 28 | |
| | - 31 - |
| | COMPLAINT FOR DAMAGES |

JS-CAND 44 (Rev. 07/16) Case 3:16-cv-04339 Counter replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM)

| Court to initiate the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF | · · · · · · · · · · · · · · · · · · · | | | |
|--|--|--|--|--|
| I. (a) PLAINTIFFS | DEFENDANTS | | | |
| DAVID R. ANKNEY | PFIZER INC. | | | |
| (b) County of Residence of First Listed Plaintiff PINAL COUNTY (EXCEPT IN U.S. PLAINTIFF CASES) (c) Attorneys (Firm Name, Address, and Telephone Number) Motley Rice LLP 28 Bridgeside Boulevard Mount Pleasant, SC 29464 (843) 216-9265 | County of Residence of First Listed Defendant NY (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED. Attorneys (If Known) | | | |
| II. BASIS OF JURISDICTION (Place an "X" in One Box Only) | III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff | | | |
| 1 U.S. Government 3 Federal Question Plaintiff (U.S. Government Not a Party) | (For Diversity Cases Only) PTF DEF DEF DEF Citizen of This State 1 Incorporated or Principal Place 4 4 4 | | | |
| 2 U.S. Government Defendant Image: A Diversity (Indicate Citizenship of Parties in Item III) | Citizen of Another State 2 Incorporated and Principal Place 5 5 5 | | | |
| | Citizen or Subject of a 3 3 3 Foreign Nation 6 6 6 | | | |
| IV. NATURE OF SUIT (Place an "X" in One Box Only) | | | | |
| CONTRACT TORTS | FORFEITURE/PENALTY BANKRUPTCY OTHER STATUTES HUDY 625 Drug Poloted Solution 1422 Append 28 USC & 158 275 Folge Claims Act | | | |
| 110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment Of Veteran's Benefits 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment of Veteran's Benefits 150 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise 210 Land Condemnation 220 Foreclosure 230 All Other Real Property 440 Other Civil Rights 443 Housing/ Accommodations 250 General 251 Medicare Act 255 Prison Condit 260 Civil Rights 275 Other Real Property 245 Tort Product Liability 290 All Other Real Property 448 Education | ary - of Property 21 USC § 881 423 Withdrawal 376 Qui Tam (31 USC sal 28 USC § 157 400 State Reapportionment y 820 Copyrights 830 Patent 820 Copyrights 830 Patent 430 Banks and Banking sonal 840 Trademark 450 Commerce tet LABOR SOCIAL SECURITY PERTY 710 Fair Labor Standards 861 HIA (1395ff) Act 863 DIVC/DIWW (405(g)) 863 DIVC/DIWW (405(g)) 844 Stalt Leave Act 770 Other Labor Act 865 RSI (405(g)) 751 Family and Medical 865 RSI (405(g)) 890 Other Statutory Actions 790 Other Labor Litigation FEDERAL TAX SUITS 896 Arbitration 791 Employee Retirement Income Security Act 871 IRS-Third Party 26 USC § 7609 y 4462 Naturalization Application 871 IRS-Third Party 26 USC § 7609 950 Constitutionality of y 465 Other Immigration Actions 950 Constitutionality of State Statutes | | | |
| V. ORIGIN (Place an "X" in One Bax Only) I Original Proceeding 2 Removed from State Court I Original Proceeding 3 Remanded from Appellate Court I Original Proceeding 2 Removed from State Court I Original Proceeding 3 Remanded from Appellate Court I Original Proceeding 3 Remanded | | | | |
| VI. CAUSE OF ACTION 28 U.S.C. 1332 Brief description of cause: Product Liability | | | | |
| VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, Fed. R. Civ. P. DEMAND \$ Exceeds \$75,000.00 CHECK YES only if demanded in complaint: JURY DEMAND: Yes No | | | | |
| VIII. RELATED CASE(S), IF ANY (See instructions): JUDGE The Honorable Richard Seeborg DOCKET NUMBER 3:16-md-02691 | | | | |
| IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2) | | | | |
| (Place an "X" in One Box Only) | | | | |
| DATE: 08/02/2016 SIGNATURE | E OF ATTORNEY OF RECORD: /s/Kimberly D. Barone Baden | | | |

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS-CAND 44

Authority For Civil Cover Sheet. The JS-CAND 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- **I.** a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)."
- **II. Jurisdiction.** The basis of jurisdiction is set forth under Federal Rule of Civil Procedure 8(a), which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 - (1) United States plaintiff. Jurisdiction based on 28 USC §§ 1345 and 1348. Suits by agencies and officers of the United States are included here.
 - (2) <u>United States defendant</u>. When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 - (3) <u>Federal question</u>. This refers to suits under 28 USC § 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 - (4) <u>Diversity of citizenship</u>. This refers to suits under 28 USC § 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity cases.)
- **III. Residence (citizenship) of Principal Parties.** This section of the JS-CAND 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- **IV.** Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.
- V. Origin. Place an "X" in one of the six boxes.
 - (1) Original Proceedings. Cases originating in the United States district courts.
 - (2) <u>Removed from State Court</u>. Proceedings initiated in state courts may be removed to the district courts under Title 28 USC § 1441. When the petition for removal is granted, check this box.
 - (3) <u>Remanded from Appellate Court</u>. Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 - (4) <u>Reinstated or Reopened</u>. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 - (5) <u>Transferred from Another District</u>. For cases transferred under Title 28 USC § 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 - (6) <u>Multidistrict Litigation Transfer</u>. Check this box when a multidistrict case is transferred into the district under authority of Title 28 USC § 1407. When this box is checked, do not check (5) above.
 - (8) <u>Multidistrict Litigation Direct File</u>. Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket.

<u>Please note that there is no Origin Code 7</u>. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity. Example: U.S. Civil Statute: 47 USC § 553. <u>Brief Description</u>: Unauthorized reception of cable service.
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Federal Rule of Civil Procedure 23.

Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

- VIII. Related Cases. This section of the JS-CAND 44 is used to identify related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.
- IX. Divisional Assignment. If the Nature of Suit is under Property Rights or Prisoner Petitions or the matter is a Securities Class Action, leave this section blank. For all other cases, identify the divisional venue according to Civil Local Rule 3-2: "the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated."

Date and Attorney Signature. Date and sign the civil cover sheet.