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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
(SAN FRANCISCO DIVISION)

EDMOND NICHOLAS

Plaintiff,

vs.

PFIZER, INC.;

Defendant.

Case No.: _____

**PLAINTIFF EDMOND NICHOLAS’
COMPLAINT; DEMAND FOR JURY
TRIAL**

Plaintiff, EDMOND NICHOLAS, individually alleges:

I. BACKGROUND

1. This is an action for personal injuries and damages suffered by Plaintiff Edmond Nicholas (“Plaintiff”) as a direct and proximate result of Pfizer, Inc.’s (“Pfizer”) 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. JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because Plaintiff is a citizen of the State of California, and Pfizer maintains its principal place of business and residence outside of California. The value of Plaintiff’s claims exceeds the total of seventy-five thousand dollars (\$75,000.00), exclusive of recoverable interest and costs. None of the causes of action stated herein has been assigned or otherwise given to any other court or tribunal.

1 3. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b)(2)
2 because a substantial part of the events and omissions concerning the claims of Plaintiff
3 occurred within this District. Furthermore, venue is proper in this District because Plaintiff
4 purchased Viagra in this District. The court has personal jurisdiction over the defendant because
5 Pfizer is a resident of a foreign state and does substantial business within the State of California
6 and in this Judicial District, and otherwise maintains the requisite minimum contacts within the
7 State of California. Additionally, Pfizer markets, advertises, distributes, sells, and receives
8 substantial profits from the sales of Viagra in this District, and has and continues to conceal and
9 make material omissions in this District, so as to subject it to *in personam* jurisdiction in this
10 Judicial District.

11 **III. PARTIES**

12 4. Plaintiff, EDMOND NICHOLAS, resides in the County of Contra Costa, State of
13 California.

14 5. Defendant Pfizer, Inc. is a Delaware corporation with its principal place of
15 business at 235 East 42nd Street, New York, New York, 10017. Defendant's registered agent is
16 C T Corporation System, 818 West Seventh Street, Suite 930, Los Angeles, California 90017.

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

21 7. Pfizer conducts substantial business within California through the marketing,
22 distribution, and sale of Viagra.

23 **IV. FACTS**

24 A. Background

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

28 9. Sildenafil citrate, sold under the brand name Viagra, is an oral tablet prescribed

1 to men with erectile dysfunction.

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

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

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

15 B. Prevalence of Viagra in Market

16 13. In its 2013 Annual Report, Pfizer states that it accumulated revenue exceeding
17 \$1,800,000,000 from worldwide sales of Viagra. This statistic is particularly significant in light
18 of the fact that Pfizer lost exclusivity of Viagra throughout Europe in 2013, which in itself led to
19 a drop in profits from the previous calendar year.

20 14. Viagra holds approximately 45% of the U.S. market share for erectile
21 dysfunction medications.²

22 15. Pfizer estimates that Viagra has been prescribed to more than 35 million men
23 worldwide.³

24 16. In 2012 alone, physicians wrote approximately eight million prescriptions for
25 Viagra.⁴

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

27 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>.

28 ³ Hilary Stout, *Viagra: The Thrill That Was*, N.Y. TIMES, June 5, 2011, available at:
<http://query.nytimes.com/gst/fullpage.html?res=9B06E3DF173FF936A35755C0A9679D8B63>.

1 B. Pfizer's Knowledge of Defect

2 17. Unbeknownst to most Viagra users, recent studies have shown that the cellular
3 activity providing the mechanism of action for Viagra may also be associated with the
4 development and/or exacerbation of melanoma.

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

7 19. According to the National Cancer Institute, part of the National Institutes of
8 Health, melanoma is more likely than other skin cancers to spread to other parts of the body,
9 thereby causing further tissue damage and complicating the potential for effective treatment and
10 eradication of the cancerous cells.⁶

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

13 21. A study published in 2011 found that treatment with Viagra can promote
14 melanoma cell invasion.⁷ Specifically, by inhibiting PDE5, Viagra mimics an effect of gene
15 activation and therefore may potentially function as a trigger for the creation of melanoma cells.

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

19 23. On April 7, 2014, an original study ("the JAMA study") was published on the
20 website for the *Journal of the American Medical Association Internal Medicine* which, in light
21 of the previous studies, sought to examine the direct relationship between sildenafil use and
22

23 ⁴ Wilson, *supra* note 4.

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

25 ⁶ National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 2011, available at:
<http://www.cancer.gov/cancertopics/wyntk/skin/page4>.

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

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

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

1 melanoma development in men in the United States.¹⁰ The JAMA study was published in the
2 journal's June 2014 edition.

3 24. Among 25,848 participants, the JAMA study reported that recent sildenafil users
4 at baseline had a significantly elevated risk of invasive melanoma, with a "hazard ratio" of 1.84;
5 in other words, the study participants who had recently used sildenafil exhibited an 84%
6 increase in risk of developing or encouraging invasive melanoma.¹¹

7 C. Consumer Expectations

8 25. Since Viagra's FDA approval in 1998, Pfizer has engaged in a continuous,
9 expensive and aggressive advertising campaign to market Viagra to men worldwide as a symbol
10 of regaining and enhancing one's virility.

11 26. Viagra has engaged in increasingly aggressive marketing techniques and
12 strategies to promote the use of Viagra in the face of increasing pharmaceutical competition. By
13 means of demonstration, a 2004 article in The Chicago Tribune cited industry reports stating
14 that Viagra spent "tens of millions of dollars each month on direct-to-consumer advertising [
15]."¹²

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

19 28. While designing and formulating Viagra, Pfizer discovered or should have
20 discovered that the drug's mechanism of action, the inhibition of PDE5, also presented a
21 significant risk of exacerbating melanoma.

22
23
24 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).

25 ¹¹ *Id.*

26 ¹² 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](http://articles.chicagotribune.com/2004-09-23/business/0409230283_1_viagra-erectile-levitra).

27 ¹³ Bruce Japsen, *Toned-Down Advertising Credited for Viagra Gains*, CHICAGO TRIBUNE, Feb.
28 8, 2007, available at [http://articles.chicagotribune.com/2007-02-
08/business/0702080063_1_viagra-erectile-pfizer-spokesman](http://articles.chicagotribune.com/2007-02-08/business/0702080063_1_viagra-erectile-pfizer-spokesman).

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

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

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

9 32. Pfizer failed to communicate to the general public that the inhibition of PDE5
10 inherently necessary to the efficacy of Viagra would also present a significant risk of one's
11 development or exacerbation of cancerous cells.

12 33. For example, no individual prescribed to use Viagra would believe or be
13 expected to know that his use of Viagra would expose him to an increased risk of developing
14 melanoma or exacerbating the growth of melanocytes already present in his body.

15 34. Pfizer expected or should have expected individuals who suffered from erectile
16 dysfunction to ingest Viagra as a means to treat their condition.

17 35. Pfizer expected or should have expected physicians treating erectile dysfunction
18 to prescribe Viagra as a means to treat the condition.

19 36. The risk presented by ingesting Viagra would be present from the moment of
20 manufacture; that is, the user would not need to change or alter the drug itself or the means by
21 which it was ingested in order for the drug to carry the same risk of harm as described herein.

22 D. Risks and Benefits of Viagra Use

23 37. At all times relevant hereto, Viagra was useful to some members of the
24 population; namely, men diagnosed with erectile dysfunction.

25 38. Erectile dysfunction is not fatal, nor does it present any related symptoms or
26 characteristics harmful to one's physical health; however, it did provide the benefit of allowing
27 men with erectile dysfunction to achieve and maintain an erection.
28

1 39. Viagra also encourages the development of melanoma in the body of a user,
2 thereby placing them at a significant health risk.

3 40. Pfizer manufactured, marketed and sold Viagra as a PDE5 inhibitor; however,
4 the mechanism of action that made the drug effective in treating erectile dysfunction
5 simultaneously enhanced the risk of the user developing melanoma.

6 41. At the time Viagra was formulated and manufactured, Pfizer knew or should
7 have known that the drug posed a significantly heightened risk to users, specifically through the
8 increased likelihood that those users would develop melanoma because of the chemical
9 reactions inherent to the drug's functioning.

10 42. Through the testing and formulating of Viagra, and before the initiation of the
11 drug's mass manufacture, Pfizer knew or should have known in the exercise of ordinary care
12 that the chemical reactions inherent to Viagra's mechanism of action would present a cancer-
13 related health hazard to potential future users.

14 43. The risk presented by the use of Viagra through PDE5 inhibition – a
15 characteristic inherent to the drug's potential efficacy – was unquestionably far more significant
16 than the benefit provided to its users.

17 44. Because the risk of using Viagra so greatly outweighs the benefits of such use,
18 the drug presents an unreasonably dangerous risk when used in its intended condition.

19 E. Facts Regarding Plaintiff

20 45. Plaintiff began pharmaceutical treatment for erectile dysfunction in May of 2007,
21 when his physician Dr. Clark Williams recommended that he begin taking Viagra.

22 46. Plaintiff continued to fill his Viagra prescriptions from Dr. Williams and take the
23 drug regularly until at least September 2013.

24 47. On March 10, 2010 Dr. Noel Chiu of Diablo Dermatology conducted a biopsy of
25 a spot on Plaintiff's back. On March 17, 2010 this biopsy returned a diagnosis of malignant
26 melanoma in Situ. On April 27, 2010 Plaintiff underwent an excision of the melanoma with
27 complex linear closure.

1 48. Over the course of several visits to Diablo Dermatology in January, February,
2 and March 2014, Plaintiff was diagnosed with Malignant Melanoma in Situ on his chest, left
3 arm, and right shoulder. These were all excised via surgery.

4 49. Since first being diagnosed with melanoma, Plaintiff has had to remain vigilant
5 in monitoring his skin for lesions.

6 50. Had Pfizer properly disclosed the melanoma-related risks associated with Viagra,
7 Plaintiff would have avoided the risk of developing melanoma from Viagra use by deciding not
8 to take Viagra at all; by severely limiting the dosage and/or length of time during which he used
9 it; and/or by more closely monitoring the degree to which his Viagra consumption was
10 adversely affecting his health.

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

19 F. Summary

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

25 53. For the duration of these efforts, Pfizer directed its advertising efforts to
26 consumers located across the nation, including consumers in the State of California. Such
27 efforts were also aimed at prescribing physicians across the nation, including prescribing
28 physicians in the State of California.

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

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

11 56. Pfizer concealed material information related to melanoma development from
12 potential Viagra users.

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

16 58. As a result of Pfizer's advertising and marketing, and representations about its
17 product, men in the United States pervasively seek out prescriptions for Viagra. If Plaintiff in
18 this action had known the risks and dangers associated with taking Viagra, Plaintiff would have
19 elected not to take Viagra and, consequently, would not have been subject to its serious side
20 effects. Similarly, if Plaintiff's physicians had been aware of the risks and dangers associated
21 with taking Viagra, they would have elected not to prescribe Viagra to Plaintiff or monitored his
22 condition more closely.

23 **VII. CAUSES OF ACTION**

24 **FIRST CAUSE OF ACTION**
25 **(Violation of Bus. & Prof. Code § 17200 *et seq.*)**
26 **(Unfairness)**

27 59. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully
28 herein.

1 60. California Business & Professions Code Section 17200 (“Unfair Competition
2 Law” or “UCL”) precludes unfair competition: *i.e.*, the employment of any unlawful, unfair or
3 fraudulent business acts or practices; and, any unfair, deceptive, untrue or misleading
4 advertising (Cal. Bus. & Prof. Code Section 17500). This prohibition extends to any act,
5 omission, or conduct affecting the rights of consumers within the State of California.

6 61. Pfizer has designed and continues to design, manufacture, market, sell, and place
7 into the stream of commerce the Viagra purchased and used across California. Pfizer has failed
8 and continues to fail to disclose and conceal the serious safety hazard posed by the design of
9 Viagra—it does not warn Plaintiff or his physicians of the increased risk of developing
10 melanoma as a result of using Viagra, and should not be purchased or used for that purpose.

11 62. Pfizer has been and remains obligated to disclose this material safety hazard
12 because reasonable consumers expect Viagra to perform its only intended and reasonably
13 expected function and purpose of allowing a user to achieve and maintain an erection. In failing
14 to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers like
15 Plaintiff and his physicians, Pfizer engaged in and continue to engage in unfair conduct under
16 Cal. Bus. & Prof. Code §17200. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as
17 particularized evidence of the pattern of omission and concealment perpetrated by Pfizer against
18 Plaintiff.

19 63. As a result of Pfizer’s violations of the UCL, Plaintiff is entitled to appropriate
20 equitable relief, including injunctive relief, and monetary relief in the form of restitution and
21 interest. Plaintiff is also entitled to recover penalties, as well as an award of attorneys’ fees,
22 costs, and expenses for prosecuting this action.

23 **SECOND CAUSE OF ACTION**
24 **(Violation of Bus. & Prof. Code § 17200 *et seq.*)**
 (Fraudulent)

25 64. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully
26 herein.

27 65. California Business & Professions Code Section 17200 (“Unfair Competition
28 Law” or “UCL”) precludes unfair competition: *i.e.*, the employment of any unlawful, unfair or

1 fraudulent business acts or practices; and, any unfair, deceptive, untrue or misleading
2 advertising (Cal. Bus. & Prof. Code Section 17500). This prohibition extends to any act,
3 omission, or conduct affecting the rights of consumers within the State of California.

4 66. Pfizer has designed and continues to design, manufacture, market, sell, and place
5 into the stream of commerce the Viagra purchased and used across California. Pfizer has failed
6 and continues to fail to disclose and conceal the serious safety hazard posed by the design of
7 Viagra—it does not warn Plaintiff or his physicians of the increased risk of developing
8 melanoma as a result of using Viagra, and should not be purchased or used for that purpose.

9 67. Pfizer has been and remains obligated to disclose this material safety hazard
10 because reasonable consumers like Plaintiff expect Viagra to perform its only intended and
11 reasonably expected function and purpose of allowing them to achieve and maintain an erection.
12 In failing to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers
13 like Plaintiff or his physicians, Pfizer engaged in and continue to engage in fraudulent conduct
14 by omission under Cal. Bus. & Prof. Code §17200. Plaintiff incorporates herein paragraphs 1
15 and 25-57, *supra*, as particularized evidence of the pattern of omission and concealment
16 perpetrated by Pfizer against Plaintiff.

17 68. As a result of Pfizer’s violations of the UCL, Plaintiff is entitled to appropriate
18 equitable relief, including injunctive relief, and monetary relief in the form of restitution and
19 interest. Plaintiff is also entitled to recover penalties, as well as an award of attorneys’ fees,
20 costs, and expenses for prosecuting this action.

21 **THIRD CAUSE OF ACTION**
22 **(Violation of Bus. & Prof. Code § 17200 *et seq.*)**
23 **(Unlawfulness)**

24 69. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully
25 herein.

26 70. Pfizer’s conduct is unlawful under the UCL because it violates Cal. Civ. Code §
27 1750, *et seq.* (hereinafter “Consumer Legal Remedies Act” or “CLRA”). Through omission and
28 concealment, Pfizer has misrepresented and continues to misrepresent that Viagra: (a) has
characteristics, uses or benefits that it does not have (Section 1770(a)(5)); and, (b) is of a

1 particular standard, quality, or grade when they are of another (Section 1770(a)(7)). Plaintiff
2 incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of
3 misrepresentation by omission perpetrated by Pfizer against Plaintiff.

4 71. Were it not for Pfizer's unlawful conduct, Plaintiff would not have purchased
5 Viagra. Instead, he would have purchased safe and reliable erectile dysfunction medication fit
6 and safe for its intended purpose.

7 72. Plaintiff has and will continue to suffer injury in fact and lose money as a direct
8 result of Pfizer's unfair competition in that he has had to undergo multiple surgeries and will
9 continue to be required to undergo periodic skin checks to ensure against recurrence.

10 73. As a result of Pfizer's violations of the UCL, Plaintiff is entitled to appropriate
11 equitable relief, including injunctive relief, and monetary relief in the form of restitution and
12 interest. Plaintiff is also entitled to recover penalties, as well as an award of attorneys' fees,
13 costs, and expenses for prosecuting this action.

14 **FOURTH CAUSE OF ACTION**
15 **(Strict Liability – Defective Design)**

16 74. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully
17 herein.

18 75. Pfizer formulated, manufactured, marketed, and sold Viagra with the intent that
19 its users take the drug as a means of treating erectile dysfunction.

20 76. Plaintiff's physician prescribed Viagra to Plaintiff with the intent that Plaintiff
21 purchase and ingest the drug to treat his erectile dysfunction.

22 77. Plaintiff's physician prescribed Viagra to Plaintiff with the belief and expectation
23 that the drug's mechanism of action – the inhibition of the PDE5 enzyme – would effectuate
24 Plaintiff's treatment goals in a foreseeable manner; i.e., Plaintiff would no longer suffer from
25 the symptoms of erectile dysfunction.

26 78. Plaintiff, following the advice of his physician, purchased and ingested Viagra
27 with the expectation that the drug would safely treat his erectile dysfunction.
28

1 79. However, the Viagra ingested by Plaintiff failed to treat his erectile dysfunction
2 in a safe manner, even though he used the drug as it was intended to be used, as the drug's
3 inhibition of PDE5 encouraged the development of melanoma throughout Plaintiff's internal
4 systems and organs.

5 80. Viagra, as a drug, presented no open and obvious danger, but instead appeared to
6 be a benign, harmless pill.

7 81. At all times relevant hereto, Viagra was useful to some members of the
8 population; namely, men diagnosed with erectile dysfunction.

9 82. Erectile dysfunction is not fatal, nor does it present any related symptoms or
10 characteristics harmful to one's physical health; however, it did provide the benefit of allowing
11 men with erectile dysfunction to achieve and maintain an erection.

12 83. Viagra also encourages the development of melanoma in the body of a user,
13 thereby placing them at a significant health risk.

14 84. The risk presented by the use of Viagra through PDE5 inhibition – a
15 characteristic inherent to the drug's potential efficacy – was far more significant than the benefit
16 provided to its users. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as
17 particularized evidence of the defective design used by Pfizer in manufacturing and selling
18 Viagra to Plaintiff.

19 85. Because the risk of using Viagra so greatly outweighs the benefits of such use,
20 the drug presents an unreasonably dangerous risk when used in its intended condition.

21 86. Plaintiff did not change or alter the condition of the Viagra pills he ingested in
22 any way, shape or form before ingesting them; instead, at the time he consumed the pills, they
23 were in the same condition they were when those pills were manufactured and sold by Pfizer.

24 87. Because of the disproportionate risk presented by the use of Viagra, and/or
25 because the drug did not perform as expected by a reasonable consumer, Viagra was
26 unreasonably dangerous when it left the control of Pfizer.

27

28

1 88. As a direct and proximate result of Viagra's unreasonably dangerous design,
2 Plaintiff has suffered significant pain, suffering, and economic damages incurred through cancer
3 treatment necessitated by Viagra use.

4 **FIFTH CAUSE OF ACTION**
5 **(Strict Liability – Failure to Warn)**

6 89. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully
7 herein.

8 90. While designing and formulating Viagra, Pfizer discovered or should have
9 discovered that the drug's mechanism of action, the inhibition of PDE5, also presented a
10 significant risk of exacerbating melanoma.

11 91. As a member of the general public, Plaintiff had no plausible means through
12 which he could have discovered the significant risk of melanomagenesis associated with PDE5
13 inhibition.

14 92. Plaintiff's physician would not have had the same level of access to the research
15 and development conducted by Pfizer prior to its decision to manufacture Viagra for general
16 use.

17 93. Pfizer failed to communicate to Plaintiff or his physician that the inhibition of
18 PDE5 inherently necessary to the efficacy of Viagra would also present a significant risk of
19 one's development or exacerbation of cancerous cells.

20 94. If Pfizer had communicated the risk of developing or exacerbating
21 melanomagenesis directly associated with Viagra use to Plaintiff's physician, he would not have
22 prescribed Viagra to Plaintiff; severely limited the dosage he prescribed to Plaintiff; and/or
23 closely monitored the length to which the Viagra was adversely affecting Plaintiff's health.

24 95. If Pfizer had communicated the risk of developing or exacerbating
25 melanomagenesis directly associated with Viagra use to Plaintiff, Plaintiff would not have taken
26 Viagra; severely limited the dosage he ingested; and/or closely monitored the length to which
27 the Viagra was adversely affecting his personal health. Plaintiff incorporates herein paragraphs
28 1 and 25-57, *supra*, as particularized evidence of the failures to warn perpetrated by Pfizer
against Plaintiff.

1 96. Plaintiff did not change or alter the condition of the Viagra pills he ingested in
 2 any way, shape or form before ingesting them; instead, at the time he consumed the pills, they
 3 were in the same condition they were when those pills were manufactured and sold by Pfizer.

4 97. As a direct and proximate result of Pfizer's failure to warn Plaintiff or his
 5 physician of the significant melanoma-related risks associated with Viagra's mechanism of
 6 action, Plaintiff suffered significant pain, suffering, and economic damages incurred through
 7 cancer treatment from melanoma caused by Viagra use.

8 **SIXTH CAUSE OF ACTION**
 9 **(Negligence)**

10 98. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully
 11 herein.

12 99. At all times relevant hereto, as the manufacturer of a product, Pfizer had a duty
 13 to design reasonably safe products.

14 100. At the time Viagra was formulated and manufactured, Pfizer knew or should
 15 have known that the drug posed a significantly heightened risk to users, specifically through the
 16 increased likelihood that those users would develop melanoma because of the chemical
 17 reactions inherent to the drug's functioning.

18 101. Through the testing and formulating of Viagra, and before the initiation of the
 19 drug's mass manufacture, Pfizer knew or should have known in the exercise of ordinary care
 20 that the chemical reactions inherent to Viagra's mechanism of action would present a cancer-
 21 related health hazard to potential future users like Plaintiff.

22 102. In proceeding to manufacture, market, and sell Viagra, Pfizer carelessly
 23 disregarded the hazard inherently presented by the drug.

24 103. Pfizer expected or should have expected individuals who suffered from erectile
 25 dysfunction, like Plaintiff, to purchase and ingest Viagra.

26 104. Pfizer expected or should have expected physicians treating erectile dysfunction,
 27 like Plaintiff's physician, to prescribe Viagra as a means to treat the condition.
 28

1 105. Pfizer manufactured, marketed and sold Viagra as a PDE5 inhibitor; however,
2 the mechanism of action that made the drug effective in treating erectile dysfunction
3 simultaneously enhanced the risk of the user developing melanoma.

4 106. Through its design, Viagra's design makes it dangerous to its users. Plaintiff
5 incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of
6 negligent behaviors perpetrated by Pfizer against Plaintiff.

7 107. As a direct and proximate result of the negligence committed by Pfizer in testing
8 and ultimately selling Viagra, Plaintiff suffered significant pain, suffering, and economic
9 damages incurred through cancer treatment from melanoma caused by Viagra use.

10 **SEVENTH CAUSE OF ACTION**
11 **(Violation of Cal. Civil Code § 1790 *et seq.*)**
12 **(Breach of Express Warranty)**

13 108. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully
14 herein.

15 109. At all times relevant hereto, Pfizer expressly represented and warranted to
16 Plaintiff and his healthcare providers, by and through statements made by Pfizer or their
17 authorized agents or sales representatives, orally and in publications, package inserts and other
18 written materials intended for physicians, medical patients and the general public, that Viagra is
19 safe, effective, and proper for its intended use.

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

23 111. The warranties expressly made by Pfizer through its marketing and labeling were
24 false in that Viagra is unsafe.

25 112. Specifically, Viagra is unsafe in that its mechanism of action, the inhibition of
26 the PDE5 enzyme, also increases the risk of the development and proliferation of melanocytic
27 cells in the user's body.
28

1 113. Plaintiff's physician acted as a reasonable physician in relying on what he
2 believed to be the superior knowledge, judgment, and access to research information possessed
3 by Pfizer in choosing to prescribe Viagra to Plaintiff.

4 114. Plaintiff, acting as a reasonable consumer, relied on what he believed to be the
5 superior skill, judgment, representations, and express warranties of Pfizer in deciding to
6 purchase and use Viagra.

7 115. In direct reliance upon the warranties made by Pfizer that Viagra was safe to use
8 in treating erectile dysfunction, Plaintiff's physician prescribed and Plaintiff used Viagra and
9 ultimately developed melanoma from the mechanism of action rendering the drug effective.
10 Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the
11 pattern of omission and concealment perpetrated by Pfizer against Plaintiff.

12 116. As a direct and proximate result of the breach of warranty committed by Pfizer,
13 Plaintiff suffered significant pain, suffering, and economic damages incurred through cancer
14 treatment from melanoma caused by Viagra use.

15 **EIGHTH CAUSE OF ACTION**
16 **(Violation of Cal. Civil Code § 1790 *et seq.*)**
17 **(Breach of Implied Warranty)**

18 117. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully
19 herein.

20 118. Plaintiff used Viagra in substantially the same condition it was in when it left the
21 control of Pfizer.

22 119. Prior to the time that Plaintiff used Viagra, Pfizer implicitly warrantied to
23 Plaintiff and his physician that Viagra was of merchantable quality, safe to use, and fit for the
24 use for which it was intended.

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

28 121. Pfizer implicitly warrantied the merchantable quality of Viagra by opting to
mass-produce and promote the prescription and sale of Viagra.

1 122. Pfizer implicitly warranted that Viagra was fit for the use for which it was
2 intended by offering assertions through multimedia advertisements that the drug was used for
3 the treatment of erectile dysfunction.

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

7 124. Plaintiff's physician would not have had the same level of access to the research
8 and development conducted by Pfizer prior to its decision to manufacture Viagra for general
9 use.

10 125. Viagra was neither safe for its intended use nor of merchantable quality, as had
11 been implicitly warranted by Pfizer, in that Viagra's mechanism of action – the inhibition of
12 PDE5 – inherently presented a significant increase in the user's risk of developing melanoma.

13 126. As a direct and proximate result of the falsity of the warranties implicated by
14 Pfizer's actions and omissions, Plaintiff suffered significant pain, suffering, and economic
15 damages incurred through cancer treatment from melanoma caused by Viagra use.

16 **VIII. PUNITIVE DAMAGES**

17 127. Prior to the manufacturing, sale, and distribution of Viagra, Pfizer knew that said
18 medication was in a defective condition as previously described herein, and knew that those
19 who were prescribed the medication would experience and had already experienced severe
20 physical, mental, and emotional injuries.

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

25 129. Pfizer and its agents, officers, and directors intentionally proceeded with the
26 manufacturing, sale, and distribution and marketing of Viagra knowing these actions would
27 expose persons to serious danger in order to advance the company's market share and profits.
28

- 1 4. Interest; and
- 2 5. Such other and further relief as the Court deems proper.

3 **ON THE FIFTH CAUSE OF ACTION:**

- 4 1. Equitable and/or injunctive relief as appropriate;
- 5 2. Monetary relief including restitution and fluid recovery;
- 6 3. Attorneys' fees, expenses, and costs of suit;
- 7 4. Interest; and
- 8 5. Such other and further relief as the Court deems proper.

9 **ON THE SIXTH CAUSE OF ACTION:**

- 10 1. Equitable and/or injunctive relief as appropriate;
- 11 2. Monetary relief including restitution and fluid recovery;
- 12 3. Attorneys' fees, expenses, and costs of suit;
- 13 4. Interest; and
- 14 5. Such other and further relief as the Court deems proper.

15 **ON THE SEVENTH CAUSE OF ACTION:**

- 16 1. Equitable and/or injunctive relief as appropriate;
- 17 2. Monetary relief including restitution and fluid recovery;
- 18 3. Attorneys' fees, expenses, and costs of suit;
- 19 4. Interest; and
- 20 5. Such other and further relief as the Court deems proper.

21 **ON THE EIGHTH CAUSE OF ACTION:**

- 22 1. Equitable and/or injunctive relief as appropriate;
- 23 2. Monetary relief including restitution and fluid recovery;
- 24 3. Attorneys' fees, expenses, and costs of suit;
- 25 4. Interest; and
- 26 5. Such other and further relief as the Court deems proper.

27 **DEMAND FOR JURY**

28 Plaintiff Edmond Nicholas demands a trial by jury.

1 Dated: November 17, 2015.
2

3 DAVIS & CRUMP, P.C.
4

5 /s/ Trevor B. Rockstad
6 Trevor B. Rockstad
7 CA Bar No. 277274
8 DAVIS & CRUMP, P.C.
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10 Gulfport, MS 39501
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JS 44 (Rev. 12/12) cand rev (1/15/13)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither 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 by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

EDMOND NICHOLAS

(b) County of Residence of First Listed Plaintiff CONRA COSTA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
Trevor B. Rockstad, Davis & Crump, P.C., 2601 14th Street, Gulfport,
MS 39501; (228) 863-6000

DEFENDANTS

PFIZER, INC.

County of Residence of First Listed Defendant New York
(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)

- 1 U.S. Government Plaintiff
- 2 U.S. Government Defendant
- 3 Federal Question (U.S. Government Not a Party)
- 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | | | | | |
|---|---------------------------------------|---------------------------------------|---|----------------------------|---------------------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input checked="" type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS			
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Remanded from Appellate Court
- 4 Reinstated or Reopened
- 5 Transferred from Another District (specify)
- 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. Section 1332

Brief description of cause:
Product liability claim involving prescription drug Viagra.

VII. REQUESTED IN COMPLAINT:

- CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F R C v P
- DEMAND \$ _____
- CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE: 11/17/2015 SIGNATURE OF ATTORNEY OF RECORD: _____

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

- (Place an "X" in One Box Only)
- SAN FRANCISCO/OAKLAND
 - SAN JOSE
 - EUREKA