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11	Attorneys for Plaintiff							
12 13	UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA (SAN FRANCISCO DIVISION)							
14	DENNIS ANDREWS,	Case No.:						
15 16 17 18 19 20 21 22 23 24	Plaintiff, vs.  PFIZER, INC.;  Defendant.	<ol> <li>COMPLAINT FOR DAMAGES</li> <li>Violation of Bus. &amp; Prof. Code § 17200 et seq. (Unfairness)</li> <li>Violation of Bus. &amp; Prof. Code § 17200 et seq (Fraudulent)</li> <li>Violation of Bus. &amp; Prof. Code § 17200 et seq (Unlawfulness)</li> <li>Strict Liability – Defective Design</li> <li>Strict Liability – Failure to Warn</li> <li>Negligence</li> <li>Violation of Cal. Civil Code § 1790 et seq. (Breach of Express Warranty)</li> <li>Violation of Cal. Civil Code § 1790 et seq. (Breach of Implied Warranty)</li> <li>DEMAND FOR JURY TRIAL</li> </ol>						
25	Plaintiff, DENNIS ANDREWS, individ	ually alleges:						
26	BACKO	<u>GROUND</u>						
27   28		juries and damages suffered by Plaintiff Dennis e result of Pfizer, Inc.'s ("Pfizer") negligent and						
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Levin Simes, LLP

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").

### **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.
- 3. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1332(a)(2) because Pfizer is a resident of a foreign state and does substantial business within the State of California and in 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. A substantial part of the events and omissions concerning the claims of Plaintiff occurred within this District. Furthermore, venue is proper in this District because Plaintiff purchased Viagra in this District.

### **PARTIES**

- 4. Plaintiff, DENNIS ANDREWS, resides in the County of Humboldt, State of California.
- 5. Defendant Pfizer, Inc. is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York, 10017. Defendant's registered agent is C T Corporation System, 818 West Seventh Street, Suite 930, Los Angeles, California 90017.
- 6. Pfizer, including its owners, employees, parent companies, subsidiaries, affiliates, and agents, developed, designed, manufactured, assembled, tested, inspected, marketed, promoted, advertised, warranted, distributed, sold, packaged, and/or provided

warnings and instructions for Viagra.

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distribution, and sale of Viagra.

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<sup>1</sup> NIH Consensus Development Panel on Impotence (July 7, 1993).

7. Pfizer conducts substantial business within California through the marketing,

### **FACTS**

- A. Background
- 8. On March 27, 1998, the U.S. Food and Drug Administration approved a new drug application ("NDA") from Pfizer Pharmaceuticals Production Corporation Limited for the manufacture and sale of sildenafil citrate.
- 9. Sildenafil citrate, sold under the brand name Viagra, is an oral tablet prescribed to men with erectile dysfunction.
- 10. Erectile dysfunction is the medical designation for a condition in which a man cannot 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.
- 11. treats erectile dysfunction by inhibiting the secretion of phosphodiesterase type 5 ("PDE5"), an enzyme responsible for the degradation of cyclic guanosine monophosphate ("cGMP"). When the cGMP is not degraded by the PDE5, smooth muscles in the corpus cavernosum relax; this, in turn, permits an inflow of blood to the corpus cavernosum, creating an erection.
- 12. The National Institutes of Health estimate that erectile dysfunction affects as many as thirty million men in the United States.<sup>1</sup>
  - В. Prevalence of Viagra in Market
- 13. 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

### Case 3:15-cv-04884 Document 1 Filed 10/23/15 Page 4 of 21

1	a drop in prof	its from the previous calendar year.								
2	14.	Viagra holds approximately 45% of the U.S. market share for erectile								
3	dysfunction medications. <sup>2</sup>									
4	15.	Pfizer estimates that Viagra has been prescribed to more than 35 million mer								
5	worldwide. <sup>3</sup>									
6	16.	In 2012 alone, physicians wrote approximately eight million prescriptions for								
7	Viagra. <sup>4</sup>									
8	C.	Pfizer's Knowledge of Defect								
9	17.	Unbeknownst to most Viagra users, recent studies have shown that the cellular								
10	activity prov	iding the mechanism of action for Viagra may also be associated with the								
11	development	and/or exacerbation of melanoma.								
12	18.	The American Cancer Society states that melanoma is "the most serious type of								
13	skin cancer."5									
14	19.	According to the National Cancer Institute, part of the National Institutes of								
15	Health, melar	noma is more likely than other skin cancers to spread to other parts of the body								
16	thereby causing further tissue damage and complicating the potential for effective treatment and									
17	eradication of	the cancerous cells. <sup>6</sup>								
18	20.	Several studies have linked the mechanism of action for Viagra to cell mutation								
19	cultivating me	elanomagenesis, or the creation of melanocytes which develop into melanoma.								
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24	1 *	on, Viagra: The Little Blue Pill That Could, CNN, Mar. 27, 2013, available at:								
25	<sup>3</sup> Hilary Stout	nn.com/2013/03/27/health/viagra-anniversary-timeline/index.html., <i>Viagra: The Thrill That Was</i> , N.Y. TIMES, June 5, 2011, <i>available at</i> :								
26	http://query.ng	ytimes.com/gst/fullpage.html?res=9B06E3DF173FF936A35755C0A9679D8B63. <i>ra</i> note 4.								
27	<sup>5</sup> American C	ancer Society, <i>Skin Cancer Facts</i> , last revised March 19, 2014, <i>available at</i> : ancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts.								
28	<sup>6</sup> National Car	ncer Institute, <i>Types of Skin Cancer</i> , last updated Jan. 11, 2011, <i>available at</i> : ancer.gov/cancertopics/wyntk/skin/page4.								

21.	A	study	published	in	2011	found	that	treatment	with	Viagra	can	promote
melanoma o	cell in	vasion	.7 Specific	call	y, by i	nhibitii	ng PI	DE5, Viagr	a min	nics an	effect	t of gene
activation a	nd the	refore	may potent	iall	y func	tion as	a trig	ger for the	creation	on of me	elano	ma cells.

- 22. A 2012 study published in the Journal of Cell Biochemistry also found that PDE5 inhibitors were shown to promote melanin synthesis,<sup>8</sup> which may exacerbate melanoma development.<sup>9</sup>
- 23. 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.<sup>10</sup> The JAMA study was published in the journal's June 2014 edition.
- 24. 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.<sup>11</sup>

### D. Consumer Expectations

- 25. 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.
- 26. Viagra has engaged in increasingly aggressive marketing techniques and strategies to promote the use of Viagra in the face of increasing pharmaceutical competition. By means of demonstration, a 2004 article in The Chicago Tribune cited industry reports stating

<sup>11</sup> *Id*.

<sup>&</sup>lt;sup>7</sup> I. Aozarena, et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating The cGMP-Specific Phosphodiesterase PDE5A*, 19 CANCER CELL 45 (2011).

<sup>&</sup>lt;sup>8</sup> X Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Through the PKG Pathway in B16 Melanoma Cells*, 113 J. CELL BIOCHEM. 2738 (2012).

<sup>&</sup>lt;sup>9</sup> F.P. Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation Requires Melanin Pigment*, 3 NATURE COMMUNICATIONS 884 (2012).

<sup>&</sup>lt;sup>10</sup> 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).

that Viagra spent "tens of millions of dollars each month on direct-to-consumer advertising [ ]." <sup>12</sup>

- 27. Pfizer has also been criticized by regulators, physicians and consumer groups for its attempts 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."
- 28. 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 exacerbating melanoma.
- 29. Despite these significant findings, Pfizer has made no efforts in its ubiquitous Viagra advertisements to warn users about the potential risk of developing melanoma that has been scientifically linked to its drug.
- 30. Members of the general public had no plausible means through which they could have discovered the significant risk of melanomagenesis associated with PDE5 inhibition.
- 31. 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.
- 32. 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 or exacerbation of cancerous cells.
- 33. For example, no individual prescribed to use Viagra would believe 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 his body.
- 34. Pfizer expected or should have expected individuals who suffered from erectile dysfunction to ingest Viagra as a means to treat their condition.

<sup>&</sup>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-

<sup>23/</sup>business/0409230283\_1\_viagra-erectile-levitra.

<sup>&</sup>lt;sup>13</sup> Bruce Japsen, *Toned-Down Advertising Credited for Viagra Gains*, CHICAGO TRIBUNE, Feb. 8, 2007, *available at* http://articles.chicagotribune.com/2007-02-08/business/0702080063\_1\_viagra-erectile-pfizer-spokesman.

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- 35. Pfizer expected or should have expected physicians treating erectile dysfunction to prescribe Viagra as a means to treat the condition.
- 36. The risk presented by ingesting Viagra would be present from the moment of manufacture; that is, the user would not need to change or alter the drug itself or the means by which it was ingested in order for the drug to carry the same risk of harm as described herein.
  - E. Risks and Benefits of Viagra Use
- 37. At all times relevant hereto, Viagra was useful to some members of the population; namely, men diagnosed with erectile dysfunction.
- 38. Erectile dysfunction is not fatal, nor does it present any related symptoms or characteristics harmful to one's physical health; however, it did provide the benefit of allowing men with erectile dysfunction to achieve and maintain an erection.
- 39. Viagra also encourages the development of melanoma in the body of a user, thereby placing them at a significant health risk.
- 40. Pfizer manufactured, marketed and sold Viagra as a PDE5 inhibitor; however, the mechanism of action that made the drug effective in treating erectile dysfunction simultaneously enhanced the risk of the user developing melanoma.
- 41. At the time Viagra was formulated and manufactured, Pfizer knew or should have known that the drug posed a significantly heightened risk to users, specifically through the increased likelihood that those users would develop melanoma because of the chemical reactions inherent to the drug's functioning.
- 42. Through the testing and formulating of Viagra, and before the initiation of the drug's mass manufacture, Pfizer knew or should have known in the exercise of ordinary care that the chemical reactions inherent to Viagra's mechanism of action would present a cancer-related health hazard to potential future users.
- 43. The risk presented by the use of Viagra through PDE5 inhibition a characteristic inherent to the drug's potential efficacy was unquestionably far more significant than the benefit provided to its users.

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

#### F. Facts Regarding Plaintiff

- 45. Plaintiff began pharmaceutical treatment for erectile dysfunction in January of 2009, when his physician Dr. Holst at Eureka Family Practice recommended that he begin taking Viagra.
- 46. Plaintiff continued to fill his Viagra prescriptions from Dr. Holst and take the drug regularly until at least May of 2013.
- 47. On July 10, 2013, Dr. Elliott Gagnon of Humboldt Medical Specialists conducted a biopsy of a changing skin lesion on Plaintiff's left lateral leg. On July 11, 2013, the biopsied skin was diagnosed as malignant melanoma, both invasive and superficial spreading. As the melanoma filled and focally expanded into the papillary dermis, Plaintiff's melanoma was categorized as Clark's level III melanoma.
- 48. On July 29, 2013, Plaintiff was scheduled to undergo a wide local excision of his left lateral leg melanoma at Harrison Plastic Reconstructive Surgery, part of the St. Joseph Health System. On August 2, 2013, Dr. Gagnon performed a full-thickness skin graft reconstruction to the large wound on Plaintiff's left leg that remained after his melanoma had been removed.
- 49. Since first being diagnosed with melanoma, Plaintiff has had to remain vigilant in monitoring his skin for lesions.
- 50. Had Pfizer properly disclosed the melanoma-related risks associated with Viagra, Plaintiff would have avoided the risk of developing melanoma from Viagra use by deciding not to take Viagra at all; by severely limiting the dosage and/or length of time during which he used it; and/or by more closely monitoring the degree to which his Viagra consumption was adversely affecting his health.
- As a direct, proximate, and legal result of Pfizer's negligence and wrongful 51. conduct, and the unreasonably dangerous and defective characteristics of the drug Viagra, Plaintiff suffered severe and permanent physical and emotional injuries. His physical injuries

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have included melanoma as well as the numerous surgeries necessitated by his skin cancer diagnosis. Plaintiff has endured not only physical pain and suffering but also economic loss, including significant expenses for 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.

### G. Summary

- 52. 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.
- 53. For the duration of these efforts, Pfizer directed its advertising efforts to consumers located across the nation, including consumers in the State of California. Such efforts were also aimed at prescribing physicians across the nation, including prescribing physicians in the State of California.
- 54. 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.
- 55. Pfizer purposefully downplayed, understated and outright ignored the melanomarelated health hazards and 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 effects.
- 56. Pfizer concealed material information related to melanoma development from potential Viagra users.

In particular, in the warnings the company includes in its commercials, online

and print advertisements, Pfizer fail to mention any potential risk for melanoma development and/or exacerbation associated with Viagra use.

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

effects. Similarly, if Plaintiff's physicians had been aware of the risks and dangers associated with taking Viagra, they would have elected not to prescribe Viagra to Plaintiff or monitored his

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

condition more closely.

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### **CAUSES OF ACTION**

# FIRST CAUSE OF ACTION (Violation of Bus. & Prof. Code § 17200 et seq.) (Unfairness)

- 59. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 60. California Business & Professions Code Section 17200 ("Unfair Competition Law" or "UCL") precludes unfair competition: *i.e.*, the employment of any unlawful, unfair or fraudulent business acts or practices; and, any unfair, deceptive, untrue or misleading advertising (Cal. Bus. & Prof. Code Section 17500). This prohibition extends to any act, omission, or conduct affecting the rights of consumers within the State of California.
- 61. Pfizer has designed and continues to design, manufacture, market, sell, and place into the stream of commerce the Viagra purchased and used across California. Pfizer has failed and continues to fail to disclose and conceal the serious safety hazard posed by the design of Viagra—it does not warn Plaintiff or his physicians of the increased risk of developing melanoma as a result of using Viagra, and should not be purchased or used for that purpose.
- 62. Pfizer has been and remains obligated to disclose this material safety hazard because reasonable consumers expect Viagra to perform its only intended and reasonably expected function and purpose of allowing a user to achieve and maintain an erection. In failing

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to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers like Plaintiff and his physicians, Pfizer engaged in and continue to engage in unfair conduct under Cal. Bus. & Prof. Code §17200. Plaintiff incorporates herein paragraphs 1 and 25-57, supra, as particularized evidence of the pattern of omission and concealment perpetrated by Pfizer against Plaintiff.

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

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

- Plaintiff adopts and incorporates all preceding paragraphs as if stated fully 64. herein.
- California Business & Professions Code Section 17200 ("Unfair Competition 65. Law" or "UCL") precludes unfair competition: i.e., the employment of any unlawful, unfair or fraudulent business acts or practices; and, any unfair, deceptive, untrue or misleading advertising (Cal. Bus. & Prof. Code Section 17500). This prohibition extends to any act, omission, or conduct affecting the rights of consumers within the State of California.
- 66. Pfizer has designed and continues to design, manufacture, market, sell, and place into the stream of commerce the Viagra purchased and used across California. Pfizer has failed and continues to fail to disclose and conceal the serious safety hazard posed by the design of Viagra—it does not warn Plaintiff or his physicians of the increased risk of developing melanoma as a result of using Viagra, and should not be purchased or used for that purpose.
- 67. Pfizer has been and remains obligated to disclose this material safety hazard because reasonable consumers like Plaintiff expect Viagra to perform its only intended and reasonably expected function and purpose of allowing them to achieve and maintain an erection. In failing to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers like Plaintiff or his physicians, Pfizer engaged in and continue to engage in fraudulent conduct

by omission under Cal. Bus. & Prof. Code §17200. Plaintiff incorporates herein paragraphs 1

and 25-57, *supra*, as particularized evidence of the pattern of omission and concealment perpetrated by Pfizer against Plaintiff.

68. As a result of Pfizer's violations of the UCL, Plaintiff is entitled to appropriate equitable relief, including injunctive relief, and monetary relief in the form of restitution and

interest. Plaintiff is also entitled to recover penalties, as well as an award of attorneys' fees,

costs, and expenses for prosecuting this action.

# THIRD CAUSE OF ACTION (Violation of Bus. & Prof. Code § 17200 et seq.) (Unlawfulness)

- 69. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 70. Pfizer's conduct is unlawful under the UCL because it violates Cal. Civ. Code § 1750, *et seq*. (hereinafter "Consumer Legal Remedies Act" or "CLRA"). Through omission and 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 particular standard, quality, or grade when they are of another (Section 1770(a)(7)). Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of misrepresentation by omission perpetrated by Pfizer against Plaintiff.
- 71. Were it not for Pfizer's unlawful conduct, Plaintiff would not have purchased Viagra. Instead, he would have purchased safe and reliable erectile dysfunction medication fit and safe for its intended purpose.
- 72. Plaintiff has and will continue to suffer injury in fact and lose money as a direct result of Pfizer's unfair competition in that he has had to undergo multiple surgeries and will continue to be required to undergo periodic skin checks to ensure against recurrence.
- 73. As a result of Pfizer's violations of the UCL, Plaintiff is entitled to appropriate equitable relief, including injunctive relief, and monetary relief in the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well as an award of attorneys' fees, costs, and expenses for prosecuting this action.

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# FOURTH CAUSE OF ACTION (Strict Liability – Defective Design)

- 74. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 75. Pfizer formulated, manufactured, marketed, and sold Viagra with the intent that its users take the drug as a means of treating erectile dysfunction.
- 76. Plaintiff's physician prescribed Viagra to Plaintiff with the intent that Plaintiff purchase and ingest the drug to treat his erectile dysfunction.
- 77. Plaintiff's physician prescribed Viagra to Plaintiff with the belief and expectation that the drug's mechanism of action the inhibition of the PDE5 enzyme would effectuate Plaintiff's treatment goals in a foreseeable manner; i.e., Plaintiff would no longer suffer from the symptoms of erectile dysfunction.
- 78. Plaintiff, following the advice of his physician, purchased and ingested Viagra with the expectation that the drug would safely treat his erectile dysfunction.
- 79. However, the Viagra ingested by Plaintiff failed to treat his erectile dysfunction in a safe manner, even though he used the drug as it was intended to be used, as the drug's inhibition of PDE5 encouraged the development of melanoma throughout Plaintiff's internal systems and organs.
- 80. Viagra, as a drug, presented no open and obvious danger, but instead appeared to be a benign, harmless pill.
- 81. At all times relevant hereto, Viagra was useful to some members of the population; namely, men diagnosed with erectile dysfunction.
- 82. Erectile dysfunction is not fatal, nor does it present any related symptoms or characteristics harmful to one's physical health; however, it did provide the benefit of allowing men with erectile dysfunction to achieve and maintain an erection.
- 83. Viagra also encourages the development of melanoma in the body of a user, thereby placing them at a significant health risk.

84	4.	The	risk	presented	by	the	use	of	Viagra	throug	gh	PDE5	inhi	bition	– a
character	ristic	inhere	ent to	the drug's	pote	ntial	effica	acy -	- was far	more	sig	nificar	nt than	the be	enefi
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Viagra to	) Plai	ntiff.													

- 85. Because the risk of using Viagra so greatly outweighs the benefits of such use, the drug presents an unreasonably dangerous risk when used in its intended condition.
- 86. Plaintiff did not change or alter the condition of the Viagra pills he ingested in any way, shape or form before ingesting them; instead, at the time he consumed the pills, they were in the same condition they were when those pills were manufactured and sold by Pfizer.
- 87. Because of the disproportionate risk presented by the use of Viagra, and/or because the drug did not perform as expected by a reasonable consumer, Viagra was unreasonably dangerous when it left the control of Pfizer.
- 88. As a direct and proximate result of Viagra's unreasonably dangerous design, Plaintiff has suffered significant pain, suffering, and economic damages incurred through cancer treatment necessitated by Viagra use.

### <u>FIFTH CAUSE OF ACTION</u> (Strict Liability – Failure to Warn)

- 89. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 90. 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 exacerbating melanoma.
- 91. As a member of the general public, Plaintiff had no plausible means through which he could have discovered the significant risk of melanomagenesis associated with PDE5 inhibition.

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- 92. Plaintiff's physician 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.
- 93. Pfizer failed to communicate to Plaintiff or his physician that the inhibition of PDE5 inherently necessary to the efficacy of Viagra would also present a significant risk of one's development or exacerbation of cancerous cells.
- 94. If Pfizer had communicated the risk of developing or exacerbating melanomagenesis directly associated with Viagra use to Plaintiff's physician, he would not have prescribed Viagra to Plaintiff; severely limited the dosage he prescribed to Plaintiff; and/or closely monitored the length to which the Viagra was adversely affecting Plaintiff's health.
- 95. If Pfizer had communicated the risk of developing or exacerbating melanomagenesis directly associated with Viagra use to Plaintiff, Plaintiff would not have taken Viagra; severely limited the dosage he ingested; and/or closely monitored the length to which the Viagra was adversely affecting his personal health. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the failures to warn perpetrated by Pfizer against Plaintiff.
- 96. Plaintiff did not change or alter the condition of the Viagra pills he ingested in any way, shape or form before ingesting them; instead, at the time he consumed the pills, they were in the same condition they were when those pills were manufactured and sold by Pfizer.
- 97. As a direct and proximate result of Pfizer's failure to warn Plaintiff or his physician of the significant melanoma-related risks associated with Viagra's mechanism of action, Plaintiff suffered significant pain, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

## SIXTH CAUSE OF ACTION (Negligence)

- 98. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
  - 99. At all times relevant hereto, as the manufacturer of a product, Pfizer had a duty

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to design reasonably safe products.

- 100. At the time Viagra was formulated and manufactured, Pfizer knew or should have known that the drug posed a significantly heightened risk to users, specifically through the increased likelihood that those users would develop melanoma because of the chemical reactions inherent to the drug's functioning.
- 101. Through the testing and formulating of Viagra, and before the initiation of the drug's mass manufacture, Pfizer knew or should have known in the exercise of ordinary care that the chemical reactions inherent to Viagra's mechanism of action would present a cancerrelated health hazard to potential future users like Plaintiff.
- 102. In proceeding to manufacture, market, and sell Viagra, Pfizer carelessly disregarded the hazard inherently presented by the drug.
- 103. Pfizer expected or should have expected individuals who suffered from erectile dysfunction, like Plaintiff, to purchase and ingest Viagra.
- 104. Pfizer expected or should have expected physicians treating erectile dysfunction, like Plaintiff's physician, to prescribe Viagra as a means to treat the condition.
- 105. Pfizer manufactured, marketed and sold Viagra as a PDE5 inhibitor; however, the mechanism of action that made the drug effective in treating erectile dysfunction simultaneously enhanced the risk of the user developing melanoma.
- 106. Through its design, Viagra's design makes it dangerous to its users. Plaintiff incorporates herein paragraphs 1 and 25-57, supra, as particularized evidence of the pattern of negligent behaviors perpetrated by Pfizer against Plaintiff.
- 107. As a direct and proximate result of the negligence committed by Pfizer in testing and ultimately selling Viagra, Plaintiff suffered significant pain, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

### SEVENTH CAUSE OF ACTION (Violation of Cal. Civil Code § 1790 et seq.) (Breach of Express Warranty)

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

- 109. 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 is safe, effective, and proper for its intended use.
- 110. These representations include, but are not limited to, the information disseminated in Pfizer's patient information and prescribing information publications, available on its website and on the FDA's website, since the drug entered the market.
- 111. The warranties expressly made by Pfizer through its marketing and labeling were false in that Viagra is unsafe.
- 112. 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 melanocytic cells in the user's body.
- 113. Plaintiff's physician acted as a reasonable physician in relying on what he believed to be the superior knowledge, judgment, and access to research information possessed by Pfizer in choosing to prescribe Viagra to Plaintiff.
- 114. Plaintiff, acting 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.
- 115. In direct reliance upon the warranties made by Pfizer that Viagra was safe to use in treating erectile dysfunction, Plaintiff's physician prescribed and Plaintiff used Viagra and ultimately developed melanoma from the mechanism of action rendering the drug effective. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the pattern of omission and concealment perpetrated by Pfizer against Plaintiff.
- 116. As a direct and proximate result of the breach of warranty committed by Pfizer, Plaintiff suffered significant pain, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

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#### **EIGHTH CAUSE OF ACTION**

### (Violation of Cal. Civil Code § 1790 et seq.) (Breach of Implied Warranty)

- 117. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 118. Plaintiff used Viagra in substantially the same condition it was in when it left the control of Pfizer.
- 119. Prior to the time that Plaintiff used Viagra, Pfizer implicitly warrantied to Plaintiff and his physician that Viagra was of merchantable quality, safe to use, and fit for the use for which it was intended.
- 120. 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 several years prior to the time when Plaintiff was first prescribed Viagra.
- 121. Pfizer implicitly warrantied the merchantable quality of Viagra by opting to mass-produce and promote the prescription and sale of Viagra.
- 122. Pfizer implicitly warranted 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.
- 123. 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.
- 124. Plaintiff's physician 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.
- 125. 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 increase in the user's risk of developing melanoma.
- 126. As a direct and proximate result of the falsity of the warranties implicated by Pfizer's actions and omissions, Plaintiff suffered significant pain, suffering, and economic

damages incurred through cancer treatment from melanoma caused by Viagra use. 1 **PUNITIVE DAMAGES** 2 Prior to the manufacturing, sale, and distribution of Viagra, Pfizer knew that said 3 127. medication was in a defective condition as previously described herein, and knew that those 4 5 who were prescribed the medication would experience and had already experienced severe physical, mental, and emotional injuries. 6 7 128. Pfizer, through their officers, directors, managers, and agents, knew that Viagra 8 presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and, as 9 such, Pfizer unreasonably subjected consumers of said drugs to risk of injury or death from 10 using Viagra. 129. 11 Pfizer and its agents, officers, and directors intentionally proceeded with the 12 manufacturing, sale, and distribution and marketing of Viagra knowing these actions would 13 expose persons to serious danger in order to advance the company's market share and profits. 130. The acts, conduct, and omissions of Pfizer, as alleged throughout this Complaint, 14 15 were willful and malicious. 131. Pfizer's unconscionable conduct warrants an award of exemplary and punitive 16 17 damages against the company. 18 RELIEF REQUESTED 19 WHEREFORE, Plaintiff prays judgment against Pfizer as follows: 20 ON THE FIRST CAUSE OF ACTION: 21 1. Equitable and/or injunctive relief as appropriate; 2. 22 Monetary relief including restitution and fluid recovery; 23 3. Attorneys' fees, expenses, and costs of suit; 24 4. Interest; and 25 5. Such other and further relief as the Court deems proper. ON THE SECOND CAUSE OF ACTION: 26 27 1. Equitable and/or injunctive relief as appropriate; 28 2. Monetary relief including restitution and fluid recovery;

1	3.	Attorneys' fees, expenses, and costs of suit;
2	4.	Interest; and
3	5.	Such other and further relief as the Court deems proper.
4		ON THE THIRD CAUSE OF ACTION:
5	1.	Equitable and/or injunctive relief as appropriate;
6	2.	Monetary relief including restitution and fluid recovery;
7	3.	Attorneys' fees, expenses, and costs of suit;
8	4.	Interest; and
9	5.	Such other and further relief as the Court deems proper.
10		ON THE FOURTH CAUSE OF ACTION:
11	1.	Injunctive relief;
12	2.	Damages including punitive damages;
13	3.	Attorneys' fees, expenses, and costs of suit;
14	4.	Interest; and
15	5.	Such other and further relief as the Court deems proper.
16		ON THE FIFTH CAUSE OF ACTION:
17	1.	Equitable and/or injunctive relief as appropriate;
18	2.	Monetary relief including restitution and fluid recovery;
19	3.	Attorneys' fees, expenses, and costs of suit;
20	4.	Interest; and
21	5.	Such other and further relief as the Court deems proper.
22		ON THE SIXTH CAUSE OF ACTION:
23	1.	Equitable and/or injunctive relief as appropriate;
24	2.	Monetary relief including restitution and fluid recovery;
25	3.	Attorneys' fees, expenses, and costs of suit;
26	4.	Interest; and
27	5.	Such other and further relief as the Court deems proper.
28	///	

1		ON THE SEVEN	TH CAUSE OF ACTION:					
2	1.	Equitable and/or injunctive r	elief as appropriate;					
3	2.	Monetary relief including res	stitution and fluid recovery;					
4	3. Attorneys' fees, expenses, and costs of suit;							
5	4.	Interest; and						
6	5.	Such other and further relief	as the Court deems proper.					
7		ON THE EIGHT	TH CAUSE OF ACTION:					
8	1.	Equitable and/or injunctive r	elief as appropriate;					
9	2.	Monetary relief including res	stitution and fluid recovery;					
10	3.	Attorneys' fees, expenses, ar	nd costs of suit;					
11	4.	Interest; and						
12	5.	Such other and further relief	as the Court deems proper.					
13		<b>DEMAND</b>	FOR JURY TRIAL					
14	Plaint	iff Dennis Andrews demands a	a trial by jury.					
15								
16	D . 1 0 . 1	22 2015	I EVIDA CIDATE CALLID					
17	Dated: Octobe	er 23, 2015.	LEVIN SIMES, LLP					
18			/s/ Rachel Abrams					
19			Rachel Abrams LEVIN SIMES, LLP					
20			44 Montgomery Street, 32 <sup>nd</sup> Floor San Francisco, CA, 94104					
21			Telephone: (415) 426-3000 Facsimile: (415) 426-3001					
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Levin Simes, LLP

## $_{\text{JS 44}} \text{ (Rev. 12/12) cand rev (1/15/13)} \textbf{ Case 3:15-cv-04884} \quad \textbf{Document 1-1} \textbf{ Fixed 10/23/15} \textbf{ Page 1 of 2}$

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.)

purpose of initiating the civil d	ocket sheet. (SEE INSTRUC	TIONS ON NEXT PAGE OF TI	HIS FORM.)					
I. (a) PLAINTIFFS DENNIS ANDREWS			<b>DEFENDANTS</b> PFIZER, INC.					
(b) County of Residence o  (E.  (c) Attorneys (Firm Name, Rachel Abrams Levin Simes, LLP: 44 Mo	XCEPT IN U.S. PLAINTIFF CA Address, and Telephone Numbe	r)	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)					
94104; (415) 426-3000  II. BASIS OF JURISDI	ICTION (Place an "X" in G	One Box Only)	L CITIZENSHIP OF P	RINCIPAL PARTIES	(Place an "X" in One Box for Plaintif			
ii. Drisis of vertisbi	TC 11011 (Trace an X in O	me Box Only)	(For Diversity Cases Only)	MINCH THE THREE	and One Box for Defendant)			
☐ 1 U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government)	Not a Party)		TF DEF  (1 □ 1 Incorporated or Pr of Business In T				
☐ 2 U.S. Government Defendant	■ 4 Diversity (Indicate Citizensh.)	ip of Parties in Item III)	Citizen of Another State	2				
			Citizen or Subject of a Foreign Country	3 G 3 Foreign Nation	□ 6 □ 6			
IV. NATURE OF SUIT			EODEELTHDE/DENALTW	DANKDURTCV	OTHED STATUTES			
CONTRACT  ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment	PERSONAL INJURY  310 Airplane  315 Airplane Product Liability  320 Assault, Libel &	PERSONAL INJURY  365 Personal Injury - Product Liability  367 Health Care/ Pharmaceutical Personal Injury - Product Liability  368 Asbestos Personal Injury Product Liability  368 Asbestos Personal Injury Product Liability  PERSONAL PROPERTY  370 Other Fraud  371 Truth in Lending  380 Other Personal Property Damage  Property Damage  70 385 Property Damage  463 Alien Detainee  510 Motions to Vacate Sentence  530 General  535 Death Penalty  Other:  540 Mandamus & Other  550 Civil Rights  555 Prison Condition  560 Civil Detainee - Conditions of Confinement	FORFEITURE/PENALTY    625 Drug Related Seizure of Property 21 USC 881     690 Other      710 Fair Labor Standards Act     720 Labor/Management Relations     740 Railway Labor Act     751 Family and Medical Leave Act     790 Other Labor Litigation     791 Employee Retirement Income Security Act      IMMIGRATION     462 Naturalization Application     465 Other Immigration Actions	BANKRUPTCY  □ 422 Appeal 28 USC 158 □ 423 Withdrawal 28 USC 157  PROPERTY RIGHTS □ 820 Copyrights □ 830 Patent □ 840 Trademark  SOCIAL SECURITY □ 861 HIA (1395ff) □ 862 Black Lung (923) □ 863 DIWC/DIWW (405(g)) □ 864 SSID Title XVI □ 865 RSI (405(g))  FEDERAL TAX SUITS □ 870 Taxes (U.S. Plaintiff or Defendant) □ 871 IRS—Third Party 26 USC 7609	□ 400 State Reapportionment □ 410 Antitrust □ 430 Banks and Banking □ 450 Commerce □ 460 Deportation □ 470 Racketeer Influenced and Corrupt Organizations □ 480 Consumer Credit □ 490 Cable/Sat TV □ 850 Securities/Commodities/Exchange (g)) □ 890 Other Statutory Actions □ 891 Agricultural Acts □ 893 Environmental Matters □ 895 Freedom of Information Act □ 896 Arbitration □ 899 Administrative Procedure			
VI. CAUSE OF ACTION VII. REQUESTED IN	moved from 3 the Court  Cite the U.S. Civil State  Brief description of car  Product Liability	Appellate Court atute under which you are fi ause:  IS A CLASS ACTION	(specify lling (Do not cite jurisdictional state DEMAND \$	cr District Litigation  tutes unless diversity):  CHECK YES only	if demanded in complaint:			
COMPLAINT: VIII. RELATED CASI IF ANY		JUDGE	More than \$75,00	O JURY DEMAND: DOCKET NUMBER	: X Yes □ No			
DATE 10/23/2015 IX. DIVISIONAL ASSIGNMEN	T (Civil L.R. 3-2)	signature of attor /s/ Rachel Abrams						
(Place an "X" in One Box Only)	_	SAN FRANCISCO/OAKLA	AND SAN JOSE E	EUREKA				

#### INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 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 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. 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 Rule 8(a), F.R.Cv.P., 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.

  United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 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.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 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 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.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

- 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 Brief Description: 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 Rule 23, F.R.Cv.P.

  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 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

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