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1 2 3 4 5 6 7 8		LD & WADE, LLP DISTRICT COURT CT OF CALIFORNIA				
10	(SAN FRANCIS	SCO DIVISION)				
11	HARVEY ELLENTHAL	Case No.:				
12	Plaintiff,	COMPLAINT FOR DAMAGES 1. Unfair and Deceptive Trade Practices				
13 14	vs.	(Unfairness)				
15	PFIZER, INC.;	2. Unfair and Deceptive Trade Practices (Fraud)				
16	Defendant.	3. Unfair and Deceptive Trade Practices (Unlawfulness)				
17		4. Strict Liability – Defective Design5. Strict Liability – Failure to Warn				
18		6. Failure to Test7. Negligence				
19		8. Gross Negligence9. Negligence Per Se				
20		10. Breach of Express Warranty				
21		11. Breach of Implied Warranty12. Fraudulent Misrepresentation and				
22		Concealment 13. Negligent Misrepresentation and				
23		Concealment 14. Fraud and Deceit				
24		15. Willful, Wanton, and Malicious				
25		Conduct 16. Unjust Enrichment				
26		DEMAND FOR JURY TRIAL				
27	Plaintiff, HARVEY ELLENTHAL, individually alleges:					
28	<u>BACKGROUND</u>					
	1					

COMPLAINT

This is an action for personal injuries and damages suffered by Plaintiff Harvey Ellenthal ("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").

JURISDICTION AND VENUE

- 1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because Pfizer is a citizen of a state other than the state in which Plaintiff is a citizen.
- 2. The Parties conferred regarding jurisdiction and venue before filing in the Northern District of California.
- 3. On December 11, 2015, Plaintiff's counsel in this and in other similar cases pending in federal courts around the country filed a petition with the Judicial Panel on Multidistrict Litigation (JPML) seeking coordination of all such matters before this Honorable Court in the Northern District of California. *See In re Viagra Products Liability Litigation*, MDL No. 2691. The petition is fully briefed and unopposed by the Defendant and all other interested parties. The JPML heard oral arguments on March 31, 2016.
- 4. Related Viagra actions are pending in this and other federal judicial districts across the country. The parties have stipulated to stay all activity until the JPML issues an order ruling Plaintiffs' petition seeking coordination. In view of this pretrial cooperation, Plaintiff is filing this Complaint in the Northern District of California. Plaintiff reserves the right to assert all of his legal claims under California substantive law in that Plaintiff resides in the County of Broward County, State of Florida (hereinafter "Plaintiff's Home Forum"). For purposes of remand and trial, venue is proper in the Plaintiff's Home Forum, in Florida.
- 5. Plaintiff's Home Forum is the United States District Court for the Southern District of Florida. Plaintiff is domiciled in Florida. Plaintiff was prescribed Viagra in Florida, he was exposed to Viagra in Florida, and he sustained his injuries in Florida.

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- 6. Venue in this judicial district is proper under 28 U.S.C. § 1391(a) as Defendant is subject to this Court's personal jurisdiction.
- 7. At all times herein mentioned, Pfizer conducted, and continues to conduct, a substantial amount of business activity in this judicial district and the Plaintiff's Home Forum. Pfizer is registered to conduct business in this district, and engaged in interstate commerce when it advertised, promoted, supplied, and sold pharmaceutical products, including Viagra, to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the general public, deriving substantial revenue in California, Plaintiff's Home Forum, and throughout the United States.

PARTIES

- 8. Plaintiff, Harvey Ellenthal, is and was at all relevant times an adult resident citizen of the United States residing in the County of Broward, State of Florida. The named Plaintiff's Home Forum is proper for purposes of remand, transfer, and venue.
- 9. 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.
- 10. At all relevant times Pfizer, including its owners, employees, parent companies, subsidiaries, affiliates, and agents, were engaged in the business of designing, testing, manufacturing, packaging, marketing, distributing, promoting, selling, and providing warnings and/or instructions for Viagra in California, Plaintiff's Home Forum, and throughout the United States.

FACTS

A. <u>Background</u>

- 11. 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.
- 12. Sildenafil citrate, sold under the brand name Viagra, is an oral tablet prescribed to men with erectile dysfunction.

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- 13. 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.
- 14. Viagra treats erectile dysfunction by inhibiting the secretion 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.
- 15. The National Institutes of Health estimate that erectile dysfunction affects as many as thirty million men in the United States.¹

Prevalence of Viagra in Market В.

- 16. In its 2013 Annual Report, Pfizer states that it accumulated revenue exceeding \$1,800,000,000 from worldwide sales of Viagra. This statistic is particularly significant in light of the fact that Pfizer lost exclusivity of Viagra throughout Europe in 2013, which in itself led to a drop in profits from the previous calendar year.
- 17. Viagra holds approximately 45% of the Unites States market share for erectile dysfunction medications.²
- 18. Pfizer estimates that Viagra has been prescribed to more than 35 million men worldwide.3
- 19. In 2012 alone, physicians wrote approximately eight million prescriptions for Viagra.4

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

² Jacque Wilson, Viagra: The Little Blue Pill That Could, CNN, Mar. 27, 2013, available at: http://www.cnn.com/2013/03/27/health/viagra-anniversary-timeline/index.html.

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

http://query.nytimes.com/gst/fullpage.html?res=9B06E3DF173FF936A35755C0A9679D8B63. ⁴ Wilson, *supra* note 4.

C. <u>Pfizer's Knowledge of Defect</u>

20. In a 1997 FDA Carcinogenicity Assessment Committee Report, rats were given 60 mg/kg per day of sildenafil, a dose less than the maximum dose approved for human consumption, and an increased proliferation in thyroid follicular cells was observed.⁵ Evidence from a separate study suggested an alternative explanation of increased proliferation, however, this study was conducted with a different dosage and did not apply the 60 mg/kg dosage given to rats that experienced a proliferation of thyroid follicular cells.

- 21. In the same FDA report, mice studies were not carried to completion due to increased mortality.⁶ Groups receiving a 30 mg/kg dose of sildenafil were near or below 20 percent survival and were terminated after 13-15 months of treatment. Groups receiving a 10 mg/kg dose of sildenafil were near 20 percent survival and were terminated after 19-22 months of treatment.
- 22. Unbeknownst to most Viagra users, recent studies have shown that the cellular activity providing the mechanism of action for Viagra may also be associated with the development and/or exacerbation of melanoma.
- 23. The American Cancer Society states that melanoma is "the most serious type of skin cancer."⁷
- 24. According to the National Cancer Institute, part of the National Institutes of Health, melanoma is more likely than other skin cancers to spread to other parts of the body, thereby causing further tissue damage and complicating the potential for effective treatment and eradication of the cancerous cells.⁸
- 25. Several studies have linked the mechanism of action for Viagra to cell mutation cultivating melanomagenesis, or the creation of melanocytes which develop into melanoma.

⁵ Carcinogenicity Assessment Report and FDA-CDER Rodent Carcinogenicity Database Factsheet, NDA #20-895 (1997), available at:

http://www.accessdata.fda.gov/drugsatfda_docs/nda/98/viagra/carcin_rep.pdf. ⁶ *Id*.

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

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

- 26. A study published in 2011 found that treatment with Viagra can promote melanoma cell invasion. Specifically, by inhibiting PDE5, Viagra mimics an effect of gene activation and therefore may potentially function as a trigger for the creation of melanoma cells.
- 27. A 2012 study published in the Journal of Cell Biochemistry also found that PDE5 inhibitors were shown to promote melanin synthesis, ¹⁰ which may exacerbate melanoma development. ¹¹
- 28. On April 7, 2014, an original study ("the JAMA study") was published on the website for the *Journal of the American Medical Association Internal Medicine* which, in light of the previous studies, sought to examine the direct relationship between sildenafil use and melanoma development in men in the United States.¹² The JAMA study was published in the journal's June 2014 edition.
- 29. Among 25,848 participants, the JAMA study reported that recent sildenafil users at baseline had a significantly elevated risk of invasive melanoma, with a "hazard ratio" of 1.84; in other words, the study participants who had recently used sildenafil exhibited an 84% increase in risk of developing or encouraging invasive melanoma.¹³

D. Consumer Expectations

- 30. 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.
- 31. 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

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

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

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

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

¹³ *Id*.

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that Viagra spent "tens of millions of dollars each month on direct-to-consumer advertising []."¹⁴

- 32. Pfizer has also been criticized by regulators, physicians and consumer groups for its attempts to target younger men in its advertising. Doctors and federal regulators stated that "such ads sen[t] a confusing message to patients who might really benefit from the drug." 15
- While designing and formulating Viagra, Pfizer discovered or should have 33. discovered that the drug's mechanism of action, the inhibition of PDE5, also presented a significant risk of exacerbating melanoma.
- 34. 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.
- 35. Members of the general public had no plausible means through which they could have discovered the significant risk of melanomagenesis associated with PDE5 inhibition.
- 36. 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.
- 37. 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.
- 38. 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.
- 39. Pfizer expected or should have expected individuals who suffered from erectile dysfunction to ingest Viagra as a means to treat their condition.

¹⁴ 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.

¹⁵ 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.

- 40. Pfizer expected or should have expected physicians treating erectile dysfunction to prescribe Viagra as a means to treat the condition.
- 41. 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

- 42. At all times relevant hereto, Viagra was useful to some members of the population; namely, men diagnosed with erectile dysfunction.
- 43. 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.
- 44. Viagra also encourages the development of melanoma in the body of a user, thereby placing them at a significant health risk.
- 45. 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.
- 46. 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.
- 47. 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.
- 48. 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.

49. 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

- 50. Plaintiff began pharmaceutical treatment for erectile dysfunction in November of 1999, when his physician, Dr. Gerald N. Halpern, prescribed Viagra.
- 51. Plaintiff continued to fill his Viagra prescriptions from Dr. Gerald N. Halpern and take the drug regularly until at least September 17, 2001.
- 52. On August 24, 2012, Dr. Pamela Rousseau of Skin Cancer and Associates conducted a biopsy of a skin lesion on Plaintiff's left chest. The biopsied skin was diagnosed as malignant melanoma in situ.
- 53. On September 20, 2012, Dr. Pamela Rousseau conducted a re-excision of Plaintiff's left chest melanoma.
- 54. Since first being diagnosed with melanoma, Plaintiff has had to remain vigilant in monitoring his skin for lesions.
- 55. As a direct, proximate, and legal result of Pfizer's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug Viagra, Plaintiff suffered severe and permanent physical and emotional injuries. His physical injuries have included melanoma as well as the multiple 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

56. 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 in California, Plaintiff's Home Forum, and throughout the United States.

- 57. For the duration of these efforts, Pfizer directed its advertising efforts to consumers located across the nation, including consumers in the State of California, Plaintiff's Home Forum, and throughout the United States. Such efforts were also aimed at prescribing physicians across the nation, including prescribing physicians in the State of California, Plaintiff's Home Forum, and throughout the United States.
- 58. 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.
- 59. 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 United States politicians, while downplaying known adverse and serious health effects.
- 60. Pfizer concealed material information related to melanoma development from potential Viagra users.
- 61. In particular, Pfizer fails to mention any potential risk for melanoma development and/or exacerbation associated with Viagra use in the drug label, package inserts, and the warnings the company includes in its commercials, online and print advertisements.
- 62. As a result of Pfizer's advertising and marketing, and representations about its product, men in the United States, including the Plaintiff, used Viagra. If Plaintiff in this action had known the risks and dangers associated with taking Viagra, Plaintiff would have elected not to take Viagra and, consequently, would not have been subject to the increased risk of melanoma.

CAUSES OF ACTION

FIRST CAUSE OF ACTION Unfair and Deceptive Trade Practices

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(Unfairness)

- 63. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- California Business & Professions Code Section 17200 ("Unfair Competition 64. Law" or "UCL") and applicable statutes and laws of Plaintiff's Home Forum preclude 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.
- 65. Pfizer has designed and continues to design, manufacture, market, sell, and place into the stream of commerce the Viagra purchased and used in California, Plaintiff's Home Forum, and throughout the United States. 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.
- Pfizer has been and remains obligated to disclose this material safety hazard 66. 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 to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers like Plaintiff and his physicians, Pfizer engaged in and continues to engage in unfair conduct under Cal. Bus. & Prof. Code §17200 and applicable statutes and laws of Plaintiff's Home Forum. Plaintiff incorporates herein paragraphs 1 and 25-57, supra, as particularized evidence of the pattern of omission and concealment perpetrated by Pfizer against Plaintiff.
- 67. As a result of Pfizer's violations of the UCL and applicable statutes and laws of Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable 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.
- 68. WHEREFORE, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages,

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27 28 exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SECOND CAUSE OF ACTION **Unfair and Deceptive Trade Practices** (Fraud)

- 69. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- California Business & Professions Code Section 17200 ("Unfair Competition 70. Law" or "UCL") and applicable statutes and laws of Plaintiff's Home Forum preclude 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.
- 71. Pfizer has designed and continues to design, manufacture, market, sell, and place into the stream of commerce the Viagra purchased and used in California, Plaintiff's Home Forum, and throughout the United States. 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.
- 72. 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 continues to engage in fraudulent conduct by omission under Cal. Bus. & Prof. Code §17200 and applicable statutes and laws in Plaintiff's Home Forum. Plaintiff incorporates herein paragraphs 1 and 25-57, supra, as particularized evidence of the pattern of omission and concealment perpetrated by Pfizer against Plaintiff.
- 73. As a result of Pfizer's violations of the UCL and applicable statutes and laws in Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable relief and monetary relief

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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.

74. WHEREFORE, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

THIRD CAUSE OF ACTION **Unfair and Deceptive Trade Practices** (Unlawfulness)

- 75. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 76. Pfizer's conduct is unlawful under the UCL because it violates Cal. Civ. Code § 1750, et seq. (hereinafter "Consumer Legal Remedies Act" or "CLRA") and applicable statutes and laws in Plaintiff's Home Forum. 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.
- 77. 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.
- 78. 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.
- 79. As a result of Pfizer's violations of the UCL and applicable statutes and laws in Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable 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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80. WHEREFORE, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FOURTH CAUSE OF ACTION (Strict Liability – Defective Design)

- Plaintiff adopts and incorporates all preceding paragraphs as if stated fully 81. herein.
- 82. Defendant has a duty to provide adequate warnings and instructions for Viagra, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately test its product.
- 83. At all times relevant to this action, Defendant researched, designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted, and sold Viagra, placing the drug into the stream of commerce.
- 84. At all times relevant to this action, Viagra was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendant in a condition that was defective and unreasonably dangerous to consumers, including the Plaintiff.
- 85. Viagra is defective in its design and/or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.
- 86. Viagra was expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.
- 87. Plaintiff used Viagra as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.
- 88. Viagra was unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including Plaintiff, when it was used as intended and in a reasonably foreseeable manner.

- 89. Viagra was unreasonably dangerous and defective in design or formulation for its intended use in that, when it left the hands of the manufacturers and/or supplier, it posed a risk of serious injury which could have been reduced or avoided by the adoption of a feasible reasonable alternative design. There were safer alternative methods and designs for the like product.
- 90. Viagra was insufficiently tested and caused harmful side effects that outweighed any potential utility.
- 91. Viagra, as manufactured and supplied, was defective due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study.
- 92. Viagra as manufactured and supplied by the Defendant was defective due to inadequate post-marketing warnings or instructions because, after Defendant knew or should have known of the risk of injuries from use and/or ingestion and acquired additional knowledge and information confirming the defective and dangerous nature of Viagra, Defendant failed to provide adequate warnings to the medical community and the consumers, to whom Defendant was directly marketing and advertising; and, further, Defendant continued to affirmatively promote Viagra as safe and effective.
- 93. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that Viagra should not have been marketed in that condition.
- 94. As a direct and proximate cause of the Defendant's defective design of Viagra, including the lack of appropriate warnings, Plaintiff was prescribed and used the drug rather than alternative erectile dysfunction therapies with better and/or similar efficacy. As a result, Plaintiff has suffered significant pain, injury, harm, suffering, and economic damages incurred through cancer treatment necessitated by Viagra use.
- 95. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages,

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exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTH CAUSE OF ACTION

(Strict Liability – Failure to Warn)

- Plaintiff adopts and incorporates all preceding paragraphs as if stated fully 96. herein.
- 97. 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.
- 98. Viagra was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to the development and/or exacerbation of melanoma.
- 99. Information given by Defendant to the medical community and to consumers concerning the safety and efficacy of Viagra, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects.
- 100. Had adequate warnings and instructions been provided, Plaintiff would not have been prescribed or taken Viagra, and would not have been at risk of the harmful side effects described herein.
- 101. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Viagra.
- 102. Defendant knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury and/or death associated with and/or caused by Viagra.
- 103. Plaintiff, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendant.

Defendant expected Plaintiff, individually and through his prescribing physician,

to rely upon the information contained in the subject product's package insert and other

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27 28 advertising and promotional materials. 105. Defendant had a continuing duty to warn Plaintiff and his prescribing physician of the risk of development and/or exacerbation of melanoma directly associated with Viagra

- 106. Safer alternatives were available that were just as effective and without the risks posed by Viagra.
- 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, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.
- 108. WHEREFORE, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTH CAUSE OF ACTION (Failure to Test)

- 109. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 110. 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.
 - 111. Defendant failed to adequately test the safety of Viagra.

- 112. Had Defendant adequately tested relative efficacy of Viagra compared with other readily available, alternative erectile dysfunction therapies and disclosed those results to the medical community and the public, Plaintiff would not have purchased and used Viagra.
- 113. As a direct and proximate result of Pfizer's failure to adequately test Viagra, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.
- 114. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SEVENTH CAUSE OF ACTION (Negligence)

- 115. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 116. Defendant owed Plaintiff a duty to exercise reasonable care when designing, testing, manufacturing, labeling, marketing, advertising, promoting, distributing, and/or selling Viagra.
- 117. At all relevant times to this action, Defendant owed a duty to properly warn Plaintiff, physicians, consumers, and the public of the risks, dangers and adverse side effects of Viagra, including the increased risk of serious injury and death, when the drug was used as intended or in a way that Defendant could reasonably have anticipated.
- 118. Defendant breached its duty by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of Viagra, as set forth below.
- 119. Defendant failed to exercise due care under the circumstances and therefore breached this duty in numerous ways, including the following:
 - failing to research and test Viagra properly and thoroughly before releasing the drug to the market;

- b. failing to analyze properly and thoroughly the data resulting from the premarketing tests of Viagra;
- c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of Viagra which indicated serious risks associated with its use;
- d. failing to conduct adequate post-market monitoring and surveillance of Viagra;
- e. failing to conduct adequate analysis of adverse event reports;
- f. designing, manufacturing, marketing, promoting, advertising, distributing, and selling Viagra to physicians and consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Viagra and without proper instructions to avoid the harm that could foreseeably occur as a result of using the drug;
- g. failing to exercise due care when advertising and promoting Viagra;
- h. negligently continuing to manufacture, market, advertise, and distribute
 Viagra after Defendant knew or should have known of the risks of serious
 injury and/or death associated with using the drug;
- failing to use due care in the preparation and development of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- failing to use due care in the design of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- failing to conduct adequate pre-clinical testing and research to determine the safety of Viagra;
- failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Viagra, while Defendant knew or should have known that post-marketing surveillance would be the only

means to determine the relative risk of Viagra for causing serious injury and/or death in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant of the need to change the drug's warnings or to withdraw it from the market altogether;

- m. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, Plaintiff's physicians, other consumers, the medical community, and the FDA;
- n. failing to accompany Viagra with adequate and proper warnings regarding all possible adverse side effects, including serious injury (e.g., development and/or exacerbation of melanoma) associated with the use of the same and instructions on ways to safely use Viagra to avoid injury;
- failing to use due care in the manufacture, inspection, and labeling of Viagra to prevent the aforementioned risk of injuries to individuals who used the drug;
- p. failing to use due care in the promotion of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- q. failing to use due care in the sale and marketing of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- r. failing to use due care in the selling of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- s. failing to provide adequate and accurate training and information to the sales representatives who sold the drug;
- t. failing to provide adequate and accurate training and information to

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healthcare providers for the appropriate use of Viagra;

- u. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing serious injury and death as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;
- v. failing to educate healthcare providers, patients, and the public about the safest use of the drug;
- w. failing to give patients and healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and
- x. being otherwise reckless, careless and/or negligent.
- 120. Despite the fact that Defendant knew or should have known that Viagra increased the risk of serious injury and/or death, Defendant continued to promote and market Viagra to doctors and to consumers, including Plaintiff, when safer and more effective methods of treatment were available.
- As a direct and proximate result of the negligence committed by Pfizer in testing and ultimately selling Viagra, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.
- 122. WHEREFORE, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

EIGHTH CAUSE OF ACTION (Gross Negligence)

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

- 124. Defendant had a duty to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Viagra, including a duty to ensure that Defendant's product, Viagra, did not cause users to suffer from unreasonable and dangerous side effects.
- 125. Defendant failed to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's product, Viagra, in that Defendant knew or should have known that taking Viagra caused unreasonable and life-threatening injuries, as alleged herein.
- 126. Defendant was grossly negligent under the circumstances and breached its duty of care in numerous ways, including the following:
 - failing to test Viagra properly and thoroughly before releasing the drug to the market;
 - b. failing to analyze properly and thoroughly the data resulting from the premarketing tests of Viagra;
 - c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of Viagra which indicated risks associated with its use;
 - failing to conduct adequate post-market monitoring and surveillance of Viagra;
 - e. failing to conduct adequate analysis of adverse event reports;
 - f. designing, manufacturing, marketing, advertising, distributing, and selling Viagra to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Viagra and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
 - g. failing to exercise due care when advertising and promoting Viagra;

- h. recklessly continuing to manufacture, market, advertise, and distribute
 Viagra after Defendant knew or should have known of the risks of serious
 injury and/or death associated with using the drug;
- failing to use due care in the preparation and development of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- j. failing to use due care in the design of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- failing to conduct adequate pre-clinical testing and research to determine the safety of Viagra;
- failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Viagra, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of Viagra for causing serious injury and death as alleged herein in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant to the need to change the drug's warnings or to withdraw it from the market altogether;
- m. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, her doctors, other consumers, the medical community, and the FDA;
- n. failing to accompany Viagra with proper warnings regarding all possible adverse side effects associated with the use of the same;
- failing to use due care in the manufacture, inspection, and labeling of Viagra to prevent the aforementioned risk of injuries to individuals who used the drug;

- p. failing to use due care in the promotion of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- q. failing to use due care in the sale and marketing of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- r. failing to provide adequate and accurate training and information to the sales representatives who sold the drug;
- s. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of Viagra;
- t. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing such serious injury and death, as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;
- failing to educate healthcare providers and the public about the safest use of the drug;
- v. failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and
- w. was otherwise grossly negligent.
- 127. Although Defendant knew, or recklessly disregarded, the fact that Defendant's product, Viagra, caused serious and potentially fatal side effects, Defendant continued to market Viagra to consumers, including Plaintiff, without disclosing these side effects including the risks of serious injury and/or death.
- 128. Defendant knew and/or consciously or recklessly disregarded the fact that consumers such as Plaintiff would suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

- 129. Defendant knew of, or recklessly disregarded the defective nature of Defendant's product, Viagra, as set forth herein, but continued to design, manufacture, market, and sell Viagra, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by Viagra.
- 130. As a direct and proximate result of Pfizer's gross negligence, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.
- 131. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

NINTH CAUSE OF ACTION (Negligence Per Se)

- 132. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 133. At all times herein mentioned, Defendant had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning, and post-sale warning and other communications of the risks and dangers of Viagra.
- 134. By reason of its conduct as alleged herein, Defendant violated provisions of statutes and regulations, including, but not limited to, the following:
 - a. Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331 and 352, by misbranding Viagra;
 - b. Defendant failed to follow the "[g]eneral requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.56;

- c. Defendant failed to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.57; and
- Defendant advertised and promoted Viagra in violation of 21 C.F.R. § 202.1;
 and
- e. Defendant violated 21 C.F.R. § 201.57(e) by failing to timely and adequately change the Viagra label to reflect the evidence of an association between Viagra and the development and/or exacerbation of melanoma suffered by Plaintiff.

These statutes and regulations impose a standard of conduct designed to protect consumers of drugs, including Plaintiff. Defendant's violations of these statutes and regulations constitute negligence per se.

- 135. As a direct and proximate result of Defendant's statutory and regulatory violations, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.
- 136. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

TENTH CAUSE OF ACTION (Breach of Express Warranty)

- 137. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 138. At all times relevant hereto, Pfizer expressly represented and warranted to Plaintiff and his healthcare providers, by and through statements made by Pfizer or its authorized agents or sales representatives, orally and in publications, package inserts and other

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27 28 written materials intended for physicians, medical patients and the general public, that Viagra is safe, effective, and proper for its intended use.

- Defendant breached expressed warranties with respect to Viagra in the following 139. particulars:
 - Defendant represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Viagra was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using Viagra;
 - b. Defendant represented that Viagra was as safe, and/or safer than other alternative medications and fraudulently concealed information that demonstrated that Viagra was not safer than alternatives available on the market; and
 - Defendant represented that Viagra was more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the drug.
- 140. Viagra does not conform to Defendant's express representations because its mechanism of action, the inhibition of the PDE5 enzyme, also increases the risk of the development and/or exacerbation of melanoma.
- At all relevant times, Viagra did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.
- 142. Plaintiff, Plaintiff's physicians, other consumers, and the medical community relied upon Defendant's express warranties, resulting in Plaintiff's ingestion of the drug.
- 143. As a direct and proximate result of the breach of warranty committed by Pfizer, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.
- 144. WHEREFORE, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages,

exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

ELEVENTH CAUSE OF ACTION

(Breach of Implied Warranty)

- 145. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 146. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold Viagra.
- 147. At all relevant times, Defendant intended that Viagra be used in the manner that Plaintiff in fact used it.
- 148. Defendant impliedly warranted Viagra to be of merchantable quality, safe and fit for the use for which Defendant intended it, and Plaintiff in fact used it.
- 149. Defendant was aware that consumers, including Plaintiff, would use Viagra to achieve and maintain an erection; which is to say that Plaintiff was a foreseeable user of Defendant's product Viagra.
- 150. Defendant knew, or had reason to know, that Plaintiff's physician would rely on Defendant's judgment and skill in providing Viagra for its intended use.
- 151. Plaintiff and his physician reasonably relied upon the skill and judgment of Defendant as to whether Viagra was of merchantable quality, safe and fit for its intended use.
- 152. The drug was expected to reach and did in fact did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.
- 153. Defendant breached various implied warranties with respect to Viagra including the following particulars:
 - a. Defendant represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Viagra was safe and fraudulently withheld and concealed information about the substantial risks of serious injury

and/or death associated with using Viagra;

- b. Defendant represented that Viagra was as safe, and/or safer than other alternative medications and fraudulently concealed information that demonstrated that Viagra was not safer than alternatives available on the market; and
- c. Defendant represented that Viagra was more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the drug.
- 154. In reliance upon Defendant's implied warranty, Plaintiff used Viagra as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.
- 155. 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 and/or exacerbating melanoma.
- 156. Defendant breached its implied warranty to Plaintiff in that Viagra is unreasonably dangerous, defective, and unfit for the ordinary purposes for which Viagra was used. It was not of merchantable quality, safe and fit for its intended use, or adequately tested.
- 157. As a direct and proximate result of the falsity of the warranties implicated by Pfizer's actions and omissions, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.
- 158. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

TWELFTH CAUSE OF ACTION (Fraudulent Misrepresentation and Concealment)

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- 159. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 160. Defendant intentionally and fraudulently misrepresented to consumers and physicians, including Plaintiff, Plaintiff's physicians and the public in general, that Viagra had been tested and found to be safe, well-tolerated and/or more efficacious than alternative medications and/or methods of erectile dysfunction therapy and that Viagra's benefits outweighed its risks when used as instructed, when, in fact, Defendant knew, or should have known, and fraudulently concealed that Viagra is dangerous to patients and that the benefits of its use are far outweighed by the risks for Plaintiff and many others.
- 161. At all relevant times, Defendant knew of the use for which Viagra was intended and expressly and/or impliedly warranted its drug was of merchantable quality and safe and fit for such use.
- 162. Defendant had sole access to material facts concerning the dangers and unreasonable risks of Viagra.
- 163. Defendant's superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and dangers of Viagra and its intentional dissemination of promotional and marketing information about Viagra for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the drug.
- 164. Defendant made false affirmative representations, omissions and/or fraudulently concealed material adverse information regarding the dangers, risks, safety, benefits, utility and effectiveness of Viagra in order to induce Plaintiff, Plaintiff's physicians, and the public in general to rely upon such representations and to use Viagra. By failing to disclose important safety and injury information and suppressing material facts about Viagra to Plaintiff, Plaintiff's physicians and the public in general, Defendant further led Plaintiff and Plaintiff's physicians to rely upon the safety of Viagra.

- 165. Defendant had a duty to disclose such information, arising from Defendant's actions of making, marketing, promoting, labeling, distributing and selling pharmaceutical products to Plaintiff and others.
- 166. Defendant's false representations and concealments were fraudulently made, in that Viagra in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.
- 167. Defendant committed acts of intentional misrepresentation and intentional concealment by suppressing material facts relating to the dangers and substantial risks of serious injuries and/or death associated with, and caused by, the use of Viagra.
- 168. Defendant made such false representations, omissions and concealments with the intent or purpose that Plaintiff and Plaintiff' physicians would rely upon such representations, leading to the use of Viagra by Plaintiff.
- 169. Defendant made fraudulent affirmative misrepresentations and omissions and fraudulent concealments of material facts regarding the safety and effectiveness of Viagra and of the dangers and risks of injuries associated with Viagra, including:
 - a. Defendant fraudulently represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Viagra had been adequately tested and found to be safe and effective for erectile dysfunction, and fraudulently concealed information about the substantial risks of serious injury and/or death associated with using Viagra; and
 - b. Defendant fraudulently represented that Viagra was as safe and/or safer and/or more efficacious than other alternative erectile dysfunction therapies, and fraudulently concealed information that demonstrated that Viagra was not safer and/or more efficacious than alternatives available on the market.
- 170. Defendant knew, had reason to know, or should have known that these representations and actively concealed adverse information were false, and that Viagra had

defects and was unreasonably dangerous. Yet, Defendant willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of Viagra to consumers, including Plaintiff, and to the medical community.

- 171. Defendant did not have adequate proof upon which to base such representations, and in fact, given Defendant's knowledge about Viagra's pharmacology and reported adverse events, Defendant knew or should have known that these representations, omissions and/or concealments were false and fraudulent. Specifically, Defendant knew of, possessed evidence and/or had reason to know that Viagra had defects and was unreasonably dangerous, causing the development and/or exacerbation of melanoma, as detailed herein.
- 172. Defendant's misrepresentations were made with the intent that physicians and patients, including Plaintiff, would rely upon them and were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Viagra.
- 173. Plaintiff's physicians, and others, did rely upon and/or were induced by the misrepresentations, omissions and/or active concealment of the dangers of Viagra to the detriment of the Plaintiff.
- 174. Defendant's fraudulent representations and concealments evince its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.
- 175. In selecting treatment, Plaintiff's physicians and Plaintiff relied on and were induced by Defendant's misrepresentations concerning the dangers of Viagra.
- 176. As detailed herein, Defendant made these fraudulent misrepresentations, omissions and concealments through statements and comments to the press, labeling, advertising, marketing and promotion materials, seminar presentations, publications, Dear Doctor letters and regulatory submissions.
- 177. Plaintiff and the treating medical community did not know that the representations, omissions, and/or concealments made by Defendant were false and were justified in reasonably relying upon Defendant's representations.

- 178. Had Defendant not fraudulently misrepresented and concealed such information, Plaintiff would not have ingested Viagra and suffered resulting harm.
- 179. Defendant made the aforesaid representations and concealments intentionally and in the course of Defendant's business as designers, manufacturers, and distributors of Viagra despite having no reasonable basis for the assertion that these representations were true, without having accurate or sufficient information concerning the aforesaid representations and/or knowing these representations were false. Defendant was aware that without such information it could not accurately make the aforesaid representations.
- 180. At the time Defendant made the aforesaid representations and at the time Plaintiff received Viagra, Plaintiff, Plaintiff's physicians, and the public in general reasonably believed them to be true. At the time that Plaintiff received Viagra, Defendant failed to adequately inform Plaintiff and/or his prescribing doctors that Viagra use increased the risk of the development and/or exacerbation of melanoma, despite Defendant being in possession of such evidence. Plaintiff received no adequate warnings, either written or verbal, that Viagra caused these side effects, and relied on these omissions and concealments.
- 181. As a direct and proximate consequence of Defendant's fraudulent misrepresentations, omissions and intentional concealment of material facts, upon which Plaintiff reasonably relied, Plaintiff sustained significant pain, injury, harm, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.
- 182. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

<u>THIRTEENTH CAUSE OF ACTION</u> (Negligent Misrepresentation and Concealment)

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

and expressly and/or impliedly warranted that the drug was of merchantable quality and safe

confidence with doctors and the public, its specific knowledge regarding the risks and dangers

of Viagra and its intentional dissemination of promotional and marketing information about

Viagra for the purpose of maximizing its sales, each gave rise to the affirmative duty to disclose

physicians, and other persons and professionals whom Defendant knew would rely, that Viagra

and provide all material information about the risks and harms associated with the drug.

At all relevant times, Defendant designed, tested, manufactured, packaged,

At all relevant times, Defendant knew of the use for which Viagra was intended

Defendant's superior knowledge and expertise, its relationship of trust and

Defendant recklessly, and/or negligently represented to Plaintiff, Plaintiff's

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and fit for such use.

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marketed, distributed, promoted, and sold Viagra.

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important safety and efficacy information, thereby suppressing material facts about the drug, while having a duty to disclose such information, which duty arose from its actions of making, marketing, promoting, distributing and selling pharmaceutical products to Plaintiff and others.

- 189. Defendant led Plaintiff to rely upon the safety of the product in its use.
- 190. The false representations of the Defendant were recklessly and/or negligently made in that Viagra in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.
- 191. Defendant committed acts of reckless and/or negligent misrepresentation and reckless and/or negligent concealment by suppressing material facts relating to the dangers and injuries associated with, and caused by, the use of Viagra.
- 192. Defendant knew or should have known that its representations and/or omissions were false. Defendant made such false, negligent and/or reckless representations with the intent

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or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations, leading to the use of Viagra by Plaintiff.

- 193. Defendant recklessly and/or negligently misrepresented, and/or omitted information with respect to Viagra in the following particulars:
 - a. Defendant represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, regulatory submissions that Viagra was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using Viagra;
 - b. Defendant represented that Viagra was as safe and/or safer than other alternative erectile dysfunction therapies and fraudulently concealed information, which demonstrated that Viagra was not safer than alternatives available on the market; and
 - Defendant represented that Viagra was more efficacious than other alternative erectile dysfunction therapies and fraudulently concealed information, regarding the true efficacy of the drug.
- 194. Defendant made affirmative misrepresentations and recklessly and/or negligently omitted material adverse information regarding the safety and effectiveness of Viagra.
- 195. Defendant made these misrepresentations and/or omissions at a time when Defendant knew or had reason to know that Viagra had defects and was unreasonably dangerous and was not what Defendant had represented to the medical community, the FDA and the consuming public, including Plaintiff.
- 196. Defendant omitted, suppressed, and/or concealed material facts concerning the dangers and risk of injuries associated with the use of Viagra including, serious injury and death. Furthermore, Defendant was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Viagra in order to increase sales.

with an intent that doctors and patients, including Plaintiff, rely upon them.

Defendant's misrepresentations and/or omissions were undertaken by Defendant

Defendant's misrepresentations and/or omissions were undertaken with the intent

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consumers, including Plaintiff.

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and encourage the sale of Viagra.

199. Defendant's misrepresentations and/or omissions evinced the Defendant's callous, reckless, willful, and depraved indifference to the health, safety, and welfare of

of defrauding and/or deceiving Plaintiff, other consumers, and the medical community to induce

- 200. Plaintiff's physician and Plaintiff relied on and were induced by Defendant's misrepresentations, omissions, and/or active concealment of the dangers of Viagra in selecting treatment.
- 201. Plaintiff and Plaintiff's physicians did not know that the representations made by Defendant were false and were justified in relying upon Defendant's representations.
- 202. Had Plaintiff been aware of the increased risk of side effects associated with Viagra and the relative efficacy of Viagra compared with other readily available alternative erectile dysfunction therapies, Plaintiff would not have taken Viagra.
- 203. As a direct and proximate consequence of Defendant's misrepresentations, Plaintiff sustained injuries and damages alleged herein including specifically those alleged herein.
- 204. Plaintiff relied on the misrepresentations made by Pfizer in purchasing and using Viagra.
- 205. Plaintiff's reliance on Pfizer's misrepresentations was justified because such misrepresentations were made by entities that were in a position to know of and disclose any potentially harmful information concerning the use of Viagra.
- 206. If Plaintiff had known of the information concealed by Pfizer regarding the melanoma-related risks posed by Viagra, Plaintiff would not have purchased and subsequently used Viagra.
 - 207. As a direct and proximate result of the negligent misrepresentations by

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Defendant, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

208. WHEREFORE, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FOURTEENTH CAUSE OF ACTION (Fraud and Deceit)

- 209. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 210. At all times relevant hereto, Pfizer conducted a sales and marketing campaign to promote the sale of Viagra and willfully deceive Plaintiff, Plaintiff's healthcare providers, and the general public as to the benefits, health risks, and consequences of using Viagra.
- 211. While conducting its sales and marketing campaign, Pfizer knew that Viagra is neither safe nor fit for human consumption; that using Viagra is hazardous to health; and that Viagra has a propensity to cause serious injuries, such as those suffered by Plaintiff.
- 212. From the time the company first marketed and distributed Viagra until the present, Pfizer willfully deceived Plaintiff by concealing from him, his healthcare providers, and the general public the risks and dangers concerning the use of Viagra.
- 213. Pfizer intentionally concealed and suppressed the facts concerning Viagra's melanoma-related risks with the intent to defraud potential consumers, as Pfizer knew that healthcare providers would not prescribe Viagra, and consumers like Plaintiff would not use Viagra, if they were aware of the dangers posed by using Viagra.
- 214. As a direct and proximate result of Pfizer's fraudulent and deceitful conduct, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.
- 215. WHEREFORE, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages,

exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

FIFTEENTH CAUSE OF ACTION

(Willful, Wanton, and Malicious Conduct)

- 216. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.
- 217. Pfizer directly or indirectly, maliciously and wantonly made, created, manufactured, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold Viagra.
- 218. Pfizer breached its duty and was wanton and malicious in its actions, misrepresentations, and omissions in that it:
 - a. failed to test Viagra properly and thoroughly before releasing the drug to the market;
 - failed to analyze properly and thoroughly the data resulting from the premarketing tests of Viagra;
 - c. failed to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of Viagra which indicated risks associated with its use;
 - d. failed to conduct adequate post-market monitoring and surveillance of Viagra;
 - e. failed to conduct adequate analysis of adverse event reports;
 - f. designed, manufactured, marketed, advertised, distributed, and sold Viagra to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Viagra and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
 - g. failed to exercise due care when advertising and promoting Viagra;

- willfully and wantonly continued to manufacture, market, advertise, and distribute Viagra after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;
- willfully and wantonly failed to use due care in the preparation and development of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- j. willfully and wantonly failed to use due care in the design of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- k. failed to conduct adequate pre-clinical testing and research to determine the safety of Viagra;
- failed to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Viagra, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of Viagra for causing such serious injury and death as alleged herein in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant to the need to change the drug's warnings or to withdraw it from the market altogether;
- m. failed to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, Plaintiff's physicians, other consumers, the medical community, and the FDA;
- failed to accompany Viagra with proper warnings regarding all possible adverse side effects associated with the use of the same;
- willfully and wantonly failed to use due care in the manufacture, inspection, and labeling of Viagra to prevent the aforementioned risk of injuries to individuals who used the drug;

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- p. willfully and wantonly failed to use due care in the promotion of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- q. willfully and wantonly failed to use due care in the sale and marketing of Viagra to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- r. willfully and wantonly failed to use due care in the selling of Viagra to
 prevent the aforementioned risk of injuries to individuals when the drug
 was ingested;
- s. failed to provide adequate and accurate training and information to the sales representatives who sold the drug;
- t. failed to provide adequate and accurate training and information to healthcare providers for the appropriate use of Viagra;
- u. failed to conduct or fund research into the development of medications of this type which would pose the least risk of causing serious injury and death as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;
- v. failed to educate healthcare providers and the public about the safest use of the drug;
- w. failed to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and
- x. otherwise behaved willfully, wantonly, and maliciously.
- 219. Pfizer knew or should have known that Viagra was unreasonably dangerous and could cause serious injuries, including death.
- 220. As a direct and proximate result of the wanton and malicious acts and omissions of Pfizer, the Plaintiff sustained injuries and damages alleged herein.

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221. As a direct and proximate result of Pfizer's willful, wanton and malicious conduct, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra use.

222. WHEREFORE, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SIXTEENTH CAUSE OF ACTION (Unjust Enrichment)

- Plaintiff adopts and incorporates all preceding paragraphs as if stated fully 223. herein.
- At all times relevant to this action, Defendant designed, advertised, marketed, 224. promoted, manufactured, distributed, supplied, and/or sold Viagra.
- 225. Plaintiff purchased Viagra for the purpose of achieving and maintaining an erection.
 - 226. Defendant has accepted payment from Plaintiff for the purchase of Viagra.
- 227. Plaintiff did not receive the safe and effective pharmaceutical product for which Plaintiff intended to purchase.
- 228. It is inequitable and unjust for Defendant to retain this money because the Plaintiff did not in fact receive the product Defendant represented Viagra to be.
- 229. Based on the foregoing, Plaintiff is entitled to equitable relief against Defendant on account of its unjust enrichment.
- WHEREFORE, Plaintiff demands judgment against Defendant and seeks 230. damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

PUNITIVE DAMAGES

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

- 232. Pfizer, through its officers, directors, managers, and agents, knew that Viagra presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and, as such, Pfizer unreasonably subjected consumers of said drugs to risk of injury or death from using Viagra.
- 233. Pfizer and its agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Viagra knowing these actions would expose persons to serious danger in order to advance the company's market share and profits.
- 234. The acts, conduct, and omissions of Pfizer, as alleged throughout this Complaint, were willful and malicious.
- 235. Pfizer's unconscionable conduct warrants an award of exemplary and punitive damages against the company.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays judgment against Pfizer as follows:

- A. Declare, adjudge and decree the conduct of Defendant as alleged herein to be unlawful:
- B. Actual, compensatory, punitive and/or exemplary damages in such amount to be determined at trial and as provided by applicable law;
- C. Costs of suit, including reasonable attorneys' fees, and expenses as provided by law; and
- D. Other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

DEMAND FOR JURY TRIAL

Plaintiff Harvey Ellenthal demands a trial by jury.

Dated: August 11, 2016.

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	THE MICHAEL BRADY LYNCH FIRM
1	
2	/s/ Michael B. Lynch
3 4	Michael B. Lynch THE MICHAEL BRADY LYNCH FIRM 127 West Fairbanks Avenue., Suite 528 Winter Park, Florida 32789 Telephone: (877) 513-9517 Facsimile: (321) 972-3568
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COMPLAINT

JS 44 (Rev. 12/12) Cand rev (1/15/13)

8/11/2016

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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.

purpose of initiating the civil do	ocket sheet. (SEE INSTRUCT	TIONS ON NEXT PAG	E OF THIS	S FORM.)	, 1					
I. (a) PLAINTIFFS			DEFENDANTS							
HARVEY ELLENTH	AL		PFIZER, INC.;	PFIZER, INC.;						
(b) County of Residence	of First Listed Plaintiff Bro	oward County, FL		County of Residence	of First Listed Defendant	New York County, NY				
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(c) Attorneys (Firm Name, A The Michael Brady Ly	Address, and Telephone Number Inch Firm	-)		Attorneys (If Known)						
127 West Fairbanks Á	venue., Suite 528									
Winter Park, Florida 32789 (877) 513-9517										
II. BASIS OF JURISDICTION (Place an "X" in One Box Only) III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff										
☐ 1 U.S. Government	3 Federal Question			(For Diversity Cases Only) PT	T DEF	and One Box for Defendant) PTF DEF				
Plaintiff	(U.S. Government Not a Party)		(Citizen of This State \Box 1 \Box 1 Incorporated or Principal Place \Box 4 \Box 4						
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120 Marine	☐ 310 Airplane	☐ 365 Personal Inju		of Property 21 USC 881	☐ 422 Appeal 28 USC 138	400 State Reapportionment				
130 Miller Act	315 Airplane Product	Product Liab		☐ 690 Other	28 USC 157	410 Antitrust				
140 Negotiable Instrument	Liability	■ 367 Health Care/			DD ODEDWY DIGHTS	430 Banks and Banking				
☐ 150 Recovery of Overpayment & Enforcement of Judgment	320 Assault, Libel & Slander	Pharmaceutical Personal Injury			PROPERTY RIGHTS 820 Copyrights	☐ 450 Commerce☐ 460 Deportation				
☐ 151 Medicare Act	☐ 330 Federal Employers'	Product Liabi	lity		☐ 830 Patent	470 Racketeer Influenced and				
☐ 152 Recovery of Defaulted Student Loans	Liability 340 Marine	368 Asbestos Pers Injury Produc			840 Trademark	Corrupt Organizations 480 Consumer Credit				
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☐ 153 Recovery of Overpayment	Liability	PERSONAL PRO	PERTY [☐ 710 Fair Labor Standards	861 HIA (1395ff)	850 Securities/Commodities/				
of Veteran's Benefits ☐ 160 Stockholders' Suits	☐ 350 Motor Vehicle ☐ 355 Motor Vehicle	☐ 370 Other Fraud ☐ 371 Truth in Lend	lino [Act ☐ 720 Labor/Management	☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g))	Exchange 890 Other Statutory Actions				
☐ 190 Other Contract	Product Liability	380 Other Person	al	Relations	864 SSID Title XVI	891 Agricultural Acts				
195 Contract Product Liability	360 Other Personal	Property Dam		740 Railway Labor Act	☐ 865 RSI (405(g))	893 Environmental Matters				
☐ 196 Franchise	Injury 362 Personal Injury -	385 Property Dan Product Liabi		☐ 751 Family and Medical Leave Act		895 Freedom of Information Act				
	Medical Malpractice			790 Other Labor Litigation		☐ 896 Arbitration				
REAL PROPERTY 210 Land Condemnation	CIVIL RIGHTS 440 Other Civil Rights	PRISONER PETIT	CIONS	791 Employee Retirement	FEDERAL TAX SUITS 870 Taxes (U.S. Plaintiff	899 Administrative Procedure				
220 Foreclosure	440 Other Civil Rights 441 Voting	Habeas Corpus: ☐ 463 Alien Detains	ee	Income Security Act	or Defendant)	Act/Review or Appeal of Agency Decision				
230 Rent Lease & Ejectment	442 Employment	☐ 510 Motions to V			☐ 871 IRS—Third Party	☐ 950 Constitutionality of				
240 Torts to Land	443 Housing/	Sentence			26 USC 7609	State Statutes				
☐ 245 Tort Product Liability ☐ 290 All Other Real Property	Accommodations 445 Amer. w/Disabilities	530 General 535 Death Penalty	,	IMMIGRATION						
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VI. CAUSE OF	28 U.S.C. 1332	ite under which you	are filing	g (Do not cite jurisdictional statu	tes unless diversity):					
ACTION	Brief description of caus	se.								
ACTION Direct description of cause.										
VII. REQUESTED IN CHECK IF THIS IS A CLASS ACTION DEMAND \$ CHECK YES only if demanded in complaint:										
COMPLAINT: UNDER RULE 23, F.R.Cv.P. JURY DEMAND: SYes No										
VIII. RELATED CASI	(See instructions):									
IF ANY		JUDGE Richa	rd Seebo	rg	DOCKET NUMBER _M	DL 2961				
IX. DIVISIONAL ASS	IGNMENT (Civil L.I	R. 3-2)								
(Place an "X" in One Box Only) (X) SAN FRANCISCO/OAKLAND () SAN JOSE () EUREKA										
DATE	··	SIGNATURE OF A								

/s/ Michael B. Lynch

Case 3:16-cv-04577 Document 1-1 Filed 08/11/16 Page 2 of 2

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. 1343 and 1348. Suits by agencies and officers of the United States are included new 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 date

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.