

Rachel B. Abrams (SBN 209316)  
Meghan McCormick (SBN 283853)  
LEVIN SIMES LLP  
44 Montgomery Street, 32<sup>nd</sup> Floor  
San Francisco, California, 94104  
Telephone: (415) 426-3000  
Facsimile: (415) 426-3001  
Email: rabrams@levinsimes.com  
Email: mmccormick@levinsimes.com

Ernest Cory (Will Seek Admission *Pro Hac Vice*)  
Kristian W. Rasmussen (Will Seek Admission *Pro Hac Vice*)  
Lauren S. Miller (Will Seek Admission *Pro Hac Vice*)  
CORY WATSON, P.C.  
2131 Magnolia Avenue  
Birmingham, AL 35205  
Telephone: (205) 328-2200; Facsimile: (205) 324-7896  
Email: ecory@corywatson.com; krasmussen@corywatson.com;  
lmiller@corywatson.com

*Attorneys for Plaintiff*

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

TERRENCE HAYES,

Plaintiff,

vs.

PFIZER, INC.;

Defendant.

Case No.: 3:16-cv-1093

**COMPLAINT FOR DAMAGES**

- 1. Unfair and Deceptive Trade Practices (Unfairness)**
  - 2. Unfair and Deceptive Trade Practices (Fraud)**
  - 3. Unfair and Deceptive Trade Practices (Unlawfulness)**
  - 4. Strict Liability – Defective Design**
  - 5. Strict Liability – Failure to Warn**
  - 6. Failure to Test**
  - 7. Negligence**
  - 8. Gross Negligence**
  - 9. Negligence Per Se**
  - 10. Breach of Express Warranty**
  - 11. Breach of Implied Warranty**
  - 12. Fraudulent Misrepresentation and Concealment**
  - 13. Negligent Misrepresentation and Concealment**
  - 14. Fraud and Deceit**
  - 15. Willful, Wanton, and Malicious Conduct**
  - 16. Unjust Enrichment**
- DEMAND FOR JURY TRIAL**

1 Plaintiff, TERRENCE HAYES, individually alleges:

2 **BACKGROUND**

3 This is an action for personal injuries and damages suffered by Plaintiff Terrence Hayes  
4 (“Plaintiff”) as a direct and proximate result of Pfizer, Inc.’s (“Pfizer”) negligent and wrongful  
5 conduct in connection with the design, development, manufacture, testing, packaging,  
6 promoting, marketing, distribution, labeling, and/or sale of sildenafil citrate tablets sold under  
7 the brand name Viagra® (“Viagra”).

8 **JURISDICTION AND VENUE**

9 1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332,  
10 because the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and  
11 because Pfizer is a citizen of a state other than the state in which Plaintiff is a citizen.

12 2. The Parties conferred regarding jurisdiction and venue before filing in the  
13 Northern District of California.

14 3. On December 11, 2015, Plaintiff’s counsel in this and in other similar cases  
15 pending in federal courts around the country filed a petition with the Judicial Panel on  
16 Multidistrict Litigation (JPML) seeking coordination of all such matters before this Honorable  
17 Court in the Northern District of California. *See In re Viagra Products Liability Litigation*,  
18 MDL No. 2691. The petition is fully briefed and unopposed by the Defendant and all other  
19 interested parties. The JPML will hear oral arguments on March 31, 2016.

20 4. Related Viagra actions are pending in this and other federal judicial districts  
21 across the country. The parties have stipulated to stay all activity until the JPML issues an order  
22 ruling Plaintiffs’ petition seeking coordination. In view of this pretrial cooperation, Plaintiff is  
23 filing this Complaint in the Northern District of California. Plaintiff reserves the right to assert  
24 all of his legal claims under Kentucky substantive law in that Plaintiff resides in the County of  
25 Madison, State of Kentucky (hereinafter “Plaintiff’s Home Forum”). For purposes of remand  
26 and trial, venue is proper in the Plaintiff’s Home Forum, the Eastern District of Kentucky.



1 manufacture and sale of sildenafil citrate.

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

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

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

15 15. The National Institutes of Health estimate that erectile dysfunction affects as  
16 many as thirty million men in the United States.<sup>1</sup>

17 B. Prevalence of Viagra in Market

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

22 17. Viagra holds approximately 45% of the United States market share for erectile  
23 dysfunction medications.<sup>2</sup>

24 18. Pfizer estimates that Viagra has been prescribed to more than 35 million men  
25 worldwide.<sup>3</sup>

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

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

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

1 19. In 2012 alone, physicians wrote approximately eight million prescriptions for  
2 Viagra.<sup>4</sup>

3 C. Pfizer's Knowledge of Defect

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

10 21. In the same FDA report, mice studies were not carried to completion due to  
11 increased mortality.<sup>6</sup> Groups receiving a 30 mg/kg dose of sildenafil were near or below 20  
12 percent survival and were terminated after 13-15 months of treatment. Groups receiving a 10  
13 mg/kg dose of sildenafil were near 20 percent survival and were terminated after 19-22 months  
14 of treatment.

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

18 23. The American Cancer Society states that melanoma is “the most serious type of  
19 skin cancer.”<sup>7</sup>

20 24. According to the National Cancer Institute, part of the National Institutes of  
21 Health, melanoma is more likely than other skin cancers to spread to other parts of the body,  
22  
23  
24

---

25 <sup>4</sup> Wilson, *supra* note 4.

26 <sup>5</sup> *Carcinogenicity Assessment Report and FDA-CDER Rodent Carcinogenicity Database*  
27 *Factsheet*, NDA #20-895 (1997), available at:  
[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/98/viagra/carcin\\_rep.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/98/viagra/carcin_rep.pdf).

28 <sup>6</sup> *Id.*

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

1 thereby causing further tissue damage and complicating the potential for effective treatment and  
2 eradication of the cancerous cells.<sup>8</sup>

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

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

8 27. A 2012 study published in the *Journal of Cell Biochemistry* also found that  
9 PDE5 inhibitors were shown to promote melanin synthesis,<sup>10</sup> which may exacerbate melanoma  
10 development.<sup>11</sup>

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

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

20 D. Consumer Expectations

21  
22 <sup>8</sup> National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 2011, available at:  
23 <http://www.cancer.gov/cancertopics/wyntk/skin/page4>.

24 <sup>9</sup> I. Arozarena, et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating*  
25 *The cGMP-Specific Phosphodiesterase PDE5A*, 19 *CANCER CELL* 45 (2011).

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

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

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

<sup>13</sup> *Id.*

1 30. Since Viagra's FDA approval in 1998, Pfizer has engaged in a continuous,  
2 expensive, and aggressive advertising campaign to market Viagra to men worldwide as a  
3 symbol of regaining and enhancing one's virility.

4 31. Viagra has engaged in increasingly aggressive marketing techniques and  
5 strategies to promote the use of Viagra in the face of increasing pharmaceutical competition. By  
6 means of demonstration, a 2004 article in The Chicago Tribune cited industry reports stating  
7 that Viagra spent "tens of millions of dollars each month on direct-to-consumer advertising [  
8 ]."<sup>14</sup>

9 32. Pfizer has also been criticized by regulators, physicians and consumer groups for  
10 its attempts to target younger men in its advertising. Doctors and federal regulators stated that  
11 "such ads sen[t] a confusing message to patients who might really benefit from the drug."<sup>15</sup>

12 33. While designing and formulating Viagra, Pfizer discovered or should have  
13 discovered that the drug's mechanism of action, the inhibition of PDE5, also presented a  
14 significant risk of exacerbating melanoma.

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

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

20 36. Prescribing physicians would not have had the same level of access to the  
21 research and development conducted by Pfizer prior to its decision to manufacture Viagra for  
22 general public use.  
23  
24  
25

---

26 <sup>14</sup> Bruce Japsen, *Viagra's 2 Rivals Grab Market Share In A Year*, CHICAGO TRIBUNE, Sept. 23,  
27 2004, available at [http://articles.chicagotribune.com/2004-09-23/business/0409230283\\_1\\_viagra-erectile-levitra](http://articles.chicagotribune.com/2004-09-23/business/0409230283_1_viagra-erectile-levitra).

28 <sup>15</sup> Bruce Japsen, *Toned-Down Advertising Credited for Viagra Gains*, CHICAGO TRIBUNE, Feb.  
8, 2007, available at [http://articles.chicagotribune.com/2007-02-08/business/0702080063\\_1\\_viagra-erectile-pfizer-spokesman](http://articles.chicagotribune.com/2007-02-08/business/0702080063_1_viagra-erectile-pfizer-spokesman).

1 37. Pfizer failed to communicate to the general public that the inhibition of PDE5  
2 inherently necessary to the efficacy of Viagra would also present a significant risk of one's  
3 development or exacerbation of cancerous cells.

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

7 39. Pfizer expected or should have expected individuals who suffered from erectile  
8 dysfunction to ingest Viagra as a means to treat their condition.

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

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

14 E. Risks and Benefits of Viagra Use

15 42. At all times relevant hereto, Viagra was useful to some members of the  
16 population; namely, men diagnosed with erectile dysfunction.

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

20 44. Viagra also encourages the development of melanoma in the body of a user,  
21 thereby placing them at a significant health risk.

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

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



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

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

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

10 F. Facts Regarding Plaintiff

11 50. Plaintiff began pharmaceutical treatment for erectile dysfunction in January of  
12 2013, when his physician, Dr. Terence O'Neill at Lexington Clinic, prescribed Viagra.

13 51. Plaintiff continued to fill his Viagra prescriptions from Dr. O'Neill and take the  
14 drug regularly until at least June of 2015.

15 52. On March 10, 2015, Dr. Joseph Bark of Dermatology Consultants conducted a  
16 biopsy of a skin lesion on Plaintiff's left cheek. On March 17, 2015, the biopsied skin was  
17 diagnosed as superficial spreading malignant melanoma. Plaintiff's melanoma was categorized  
18 as 0.70 mm Breslow thickness, Clark's level IV.

19 53. On April 15, 2015, Plaintiff underwent a wide local excision of his left cheek  
20 melanoma at Saint Joseph Hospital.

21 54. Since first being diagnosed with melanoma, Plaintiff has had to remain vigilant  
22 in monitoring his skin for lesions.

23 55. As a direct, proximate, and legal result of Pfizer's negligence and wrongful  
24 conduct, and the unreasonably dangerous and defective characteristics of the drug Viagra,  
25 Plaintiff suffered severe and permanent physical and emotional injuries. His physical injuries  
26 have included melanoma as well as the multiple surgeries necessitated by his skin cancer  
27 diagnosis. Plaintiff has endured not only physical pain and suffering but also economic loss,  
28 including significant expenses for medical care and treatment. Because of the nature of his

1 diagnosis, he will certainly continue to incur such medical expenses in the future. As a result of  
2 these damages, Plaintiff seeks actual and punitive damages from Pfizer.

3 G. Summary

4 56. At all times relevant to this lawsuit, Pfizer engaged in the business of  
5 researching, licensing, designing, formulating, compounding, testing, manufacturing,  
6 producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting,  
7 packaging and/or advertising for sale or selling the prescription drug Viagra in California,  
8 Plaintiff's Home Forum, and throughout the United States.

9 57. For the duration of these efforts, Pfizer directed its advertising efforts to  
10 consumers located across the nation, including consumers in the State of California, Plaintiff's  
11 Home Forum, and throughout the United States. Such efforts were also aimed at prescribing  
12 physicians across the nation, including prescribing physicians in the State of California,  
13 Plaintiff's Home Forum, and throughout the United States.

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

20 59. Pfizer purposefully downplayed, understated and outright ignored the melanoma-  
21 related health hazards and risks associated with using Viagra. Pfizer also deceived potential  
22 Viagra users by relaying positive information through the press, including testimonials from  
23 retired, popular United States politicians, while downplaying known adverse and serious health  
24 effects.

25 60. Pfizer concealed material information related to melanoma development from  
26 potential Viagra users.



1 to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers like  
2 Plaintiff and his physicians, Pfizer engaged in and continues to engage in unfair conduct under  
3 Cal. Bus. & Prof. Code §17200 and applicable statutes and laws of Plaintiff's Home Forum.  
4 Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized evidence of the  
5 pattern of omission and concealment perpetrated by Pfizer against Plaintiff.

6 67. As a result of Pfizer's violations of the UCL and applicable statutes and laws of  
7 Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable relief and monetary relief  
8 in the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well as an  
9 award of attorneys' fees, costs, and expenses for prosecuting this action.

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

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

17 69. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
18 herein.

19 70. California Business & Professions Code Section 17200 ("Unfair Competition  
20 Law" or "UCL") and applicable statutes and laws of Plaintiff's Home Forum preclude unfair  
21 competition: *i.e.*, the employment of any unlawful, unfair or fraudulent business acts or  
22 practices; and, any unfair, deceptive, untrue or misleading advertising (Cal. Bus. & Prof. Code  
23 Section 17500). This prohibition extends to any act, omission, or conduct affecting the rights of  
24 consumers.

25 71. Pfizer has designed and continues to design, manufacture, market, sell, and place  
26 into the stream of commerce the Viagra purchased and used in California, Plaintiff's Home  
27 Forum, and throughout the United States. Pfizer has failed and continues to fail to disclose and  
28 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

1 should not be purchased or used for that purpose.

2 72. Pfizer has been and remains obligated to disclose this material safety hazard  
3 because reasonable consumers like Plaintiff expect Viagra to perform its only intended and  
4 reasonably expected function and purpose of allowing them to achieve and maintain an erection.  
5 In failing to disclose this critical safety hazard, known to Pfizer but not to reasonable consumers  
6 like Plaintiff or his physicians, Pfizer engaged in and continues to engage in fraudulent conduct  
7 by omission under Cal. Bus. & Prof. Code §17200 and applicable statutes and laws in Plaintiff's  
8 Home Forum. Plaintiff incorporates herein paragraphs 1 and 25-57, *supra*, as particularized  
9 evidence of the pattern of omission and concealment perpetrated by Pfizer against Plaintiff.

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

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

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

21 75. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
22 herein.

23 76. Pfizer's conduct is unlawful under the UCL because it violates Cal. Civ. Code §  
24 1750, *et seq.* (hereinafter "Consumer Legal Remedies Act" or "CLRA") and applicable statutes  
25 and laws in Plaintiff's Home Forum. Through omission and concealment, Pfizer has  
26 misrepresented and continues to misrepresent that Viagra: (a) has characteristics, uses or  
27 benefits that it does not have (Section 1770(a)(5)); and, (b) is of a particular standard, quality, or  
28 grade when they are of another (Section 1770(a)(7)). Plaintiff incorporates herein paragraphs 1

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

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

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

9 79. As a result of Pfizer's violations of the UCL and applicable statutes and laws in  
10 Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable relief and monetary relief  
11 in the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well as an  
12 award of attorneys' fees, costs, and expenses for prosecuting this action.

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

17 **FOURTH CAUSE OF ACTION**  
18 **(Strict Liability – Defective Design)**

19 81. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
20 herein.

21 82. Defendant has a duty to provide adequate warnings and instructions for Viagra,  
22 to use reasonable care to design a product that is not unreasonably dangerous to users, and to  
23 adequately test its product.

24 83. At all times relevant to this action, Defendant researched, designed, tested,  
25 manufactured, packaged, labeled, marketed, distributed, promoted, and sold Viagra, placing the  
26 drug into the stream of commerce.

27 84. At all times relevant to this action, Viagra was designed, tested, inspected,  
28 manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised,  
promoted, sold, packaged, supplied and/or distributed by Defendant in a condition that was

1 defective and unreasonably dangerous to consumers, including the Plaintiff.

2 85. Viagra is defective in its design and/or formulation in that it is not reasonably fit,  
3 suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits  
4 associated with its design and formulation.

5 86. Viagra was expected to reach, and did reach, users and/or consumers, including  
6 Plaintiff, without substantial change in the defective and unreasonably dangerous condition in  
7 which it was manufactured and sold.

8 87. Plaintiff used Viagra as prescribed and in the foreseeable manner normally  
9 intended, recommended, promoted, and marketed by Defendant.

10 88. Viagra was unreasonably dangerous in that, as designed, it failed to perform  
11 safely when used by ordinary consumers, including Plaintiff, when it was used as intended and  
12 in a reasonably foreseeable manner.

13 89. Viagra was unreasonably dangerous and defective in design or formulation for  
14 its intended use in that, when it left the hands of the manufacturers and/or supplier, it posed a  
15 risk of serious injury which could have been reduced or avoided by the adoption of a feasible  
16 reasonable alternative design. There were safer alternative methods and designs for the like  
17 product.

18 90. Viagra was insufficiently tested and caused harmful side effects that outweighed  
19 any potential utility.

20 91. Viagra, as manufactured and supplied, was defective due to inadequate warnings,  
21 and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the  
22 results of the clinical trials, testing and study.

23 92. Viagra as manufactured and supplied by the Defendant was defective due to  
24 inadequate post-marketing warnings or instructions because, after Defendant knew or should  
25 have known of the risk of injuries from use and/or ingestion and acquired additional knowledge  
26 and information confirming the defective and dangerous nature of Viagra, Defendant failed to  
27 provide adequate warnings to the medical community and the consumers, to whom Defendant  
28 was directly marketing and advertising; and, further, Defendant continued to affirmatively

1 promote Viagra as safe and effective.

2 93. In light of the potential and actual risk of harm associated with the drug's use, a  
3 reasonable person who had actual knowledge of this potential and actual risk of harm would  
4 have concluded that Viagra should not have been marketed in that condition.

5 94. As a direct and proximate cause of the Defendant's defective design of Viagra,  
6 including the lack of appropriate warnings, Plaintiff was prescribed and used the drug rather  
7 than alternative erectile dysfunction therapies with better and/or similar efficacy. As a result,  
8 Plaintiff has suffered significant pain, injury, harm, suffering, and economic damages incurred  
9 through cancer treatment necessitated by Viagra use.

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

14 **FIFTH CAUSE OF ACTION**  
15 **(Strict Liability – Failure to Warn)**

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

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

21 98. Viagra was defective and unreasonably dangerous when it left the possession of  
22 the Defendant in that it contained warnings insufficient to alert consumers, including Plaintiff,  
23 of the dangerous risks and reactions associated with the subject product, including but not  
24 limited to the development and/or exacerbation of melanoma.

25 99. Information given by Defendant to the medical community and to consumers  
26 concerning the safety and efficacy of Viagra, especially the information contained in the  
27 advertising and promotional materials, did not accurately reflect the serious and potentially fatal  
28 side effects.



1           100. Had adequate warnings and instructions been provided, Plaintiff would not have  
2 been prescribed or taken Viagra, and would not have been at risk of the harmful side effects  
3 described herein.

4           101. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned  
5 through the exercise of reasonable care, the risks of serious injury and/or death associated with  
6 and/or caused by Viagra.

7           102. Defendant knew or had knowledge that the warnings that were given failed to  
8 properly warn of the increased risks of serious injury and/or death associated with and/or caused  
9 by Viagra.

10           103. Plaintiff, individually and through his prescribing physicians, reasonably relied  
11 upon the skill, superior knowledge, and judgment of the Defendant.

12           104. Defendant expected Plaintiff, individually and through his prescribing physician,  
13 to rely upon the information contained in the subject product's package insert and other  
14 advertising and promotional materials.

15           105. Defendant had a continuing duty to warn Plaintiff and his prescribing physician  
16 of the risk of development and/or exacerbation of melanoma directly associated with Viagra  
17 use.

18           106. Safer alternatives were available that were just as effective and without the risks  
19 posed by Viagra.

20           107. As a direct and proximate result of Pfizer's failure to warn Plaintiff or his  
21 physician of the significant melanoma-related risks associated with Viagra's mechanism of  
22 action, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred  
23 through cancer treatment from melanoma caused by Viagra use.

24           108. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks  
25 damages as detailed in the Global Prayer for Relief including: compensatory damages,  
26 exemplary damages, and punitive damages, together with interest, the costs of suit and  
27 attorneys' fees, and such other and further relief as this Court deems just and proper.  
28

1 **SIXTH CAUSE OF ACTION**

2 **(Failure to Test)**

3 109. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
4 herein.

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

9 111. Defendant failed to adequately test the safety of Viagra.

10 112. Had Defendant adequately tested relative efficacy of Viagra compared with other  
11 readily available, alternative erectile dysfunction therapies and disclosed those results to the  
12 medical community and the public, Plaintiff would not have purchased and used Viagra.

13 113. As a direct and proximate result of Pfizer's failure to adequately test Viagra,  
14 Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through  
15 cancer treatment from melanoma caused by Viagra use.

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

20 **SEVENTH CAUSE OF ACTION**

21 **(Negligence)**

22 115. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
23 herein.

24 116. Defendant owed Plaintiff a duty to exercise reasonable care when designing,  
25 testing, manufacturing, labeling, marketing, advertising, promoting, distributing, and/or selling  
26 Viagra.

27 117. At all relevant times to this action, Defendant owed a duty to properly warn  
28 Plaintiff, physicians, consumers, and the public of the risks, dangers and adverse side effects of

1 Viagra, including the increased risk of serious injury and death, when the drug was used as  
2 intended or in a way that Defendant could reasonably have anticipated.

3 118. Defendant breached its duty by failing to exercise ordinary care in the  
4 preparation, design, research, testing, development, manufacturing, inspection, labeling,  
5 marketing, promotion, advertising and selling of Viagra, as set forth below.

6 119. Defendant failed to exercise due care under the circumstances and therefore  
7 breached this duty in numerous ways, including the following:

- 8 a. failing to research and test Viagra properly and thoroughly before  
9 releasing the drug to the market;
- 10 b. failing to analyze properly and thoroughly the data resulting from the pre-  
11 marketing tests of Viagra;
- 12 c. failing to report to the FDA, the medical community, and the general  
13 public those data resulting from pre- and post-marketing tests of Viagra  
14 which indicated serious risks associated with its use;
- 15 d. failing to conduct adequate post-market monitoring and surveillance of  
16 Viagra;
- 17 e. failing to conduct adequate analysis of adverse event reports;
- 18 f. designing, manufacturing, marketing, promoting, advertising,  
19 distributing, and selling Viagra to physicians and consumers, including  
20 Plaintiff, without an adequate warning of the significant and dangerous  
21 risks of Viagra and without proper instructions to avoid the harm that  
22 could foreseeably occur as a result of using the drug;
- 23 g. failing to exercise due care when advertising and promoting Viagra;
- 24 h. negligently continuing to manufacture, market, advertise, and distribute  
25 Viagra after Defendant knew or should have known of the risks of serious  
26 injury and/or death associated with using the drug;
- 27 i. failing to use due care in the preparation and development of Viagra to  
28 prevent the aforementioned risk of injuries to individuals when the drug

1 was ingested;

2 j. failing to use due care in the design of Viagra to prevent the  
3 aforementioned risk of injuries to individuals when the drug was  
4 ingested;

5 k. failing to conduct adequate pre-clinical testing and research to determine  
6 the safety of Viagra;

7 l. failing to conduct adequate post-marketing surveillance and exposure  
8 studies to determine the safety of Viagra, while Defendant knew or  
9 should have known that post-marketing surveillance would be the only  
10 means to determine the relative risk of Viagra for causing serious injury  
11 and/or death in the absence of clinical trials, and that such surveillance  
12 would be necessary for a due diligence program that would alert  
13 Defendant of the need to change the drug's warnings or to withdraw it  
14 from the market altogether;

15 m. failing to completely, accurately and in a timely fashion, disclose the  
16 results of the pre-marketing testing and post-marketing surveillance and  
17 testing to Plaintiff, Plaintiff's physicians, other consumers, the medical  
18 community, and the FDA;

19 n. failing to accompany Viagra with adequate and proper warnings  
20 regarding all possible adverse side effects, including serious injury (e.g.,  
21 development and/or exacerbation of melanoma) associated with the use  
22 of the same and instructions on ways to safely use Viagra to avoid injury;

23 o. failing to use due care in the manufacture, inspection, and labeling of  
24 Viagra to prevent the aforementioned risk of injuries to individuals who  
25 used the drug;

26 p. failing to use due care in the promotion of Viagra to prevent the  
27 aforementioned risk of injuries to individuals when the drug was  
28 ingested;

- 1 q. failing to use due care in the sale and marketing of Viagra to prevent the
- 2 aforementioned risk of injuries to individuals when the drug was
- 3 ingested;
- 4 r. failing to use due care in the selling of Viagra to prevent the
- 5 aforementioned risk of injuries to individuals when the drug was
- 6 ingested;
- 7 s. failing to provide adequate and accurate training and information to the
- 8 sales representatives who sold the drug;
- 9 t. failing to provide adequate and accurate training and information to
- 10 healthcare providers for the appropriate use of Viagra;
- 11 u. failing to conduct or fund research into the development of medications
- 12 of this type which would pose the least risk of causing serious injury and
- 13 death as alleged herein, into the early detection of persons who might be
- 14 most susceptible to such reactions, and into the development of better
- 15 remedies and treatment for those who experience these tragic adverse
- 16 reactions;
- 17 v. failing to educate healthcare providers, patients, and the public about the
- 18 safest use of the drug;
- 19 w. failing to give patients and healthcare providers adequate information to
- 20 weigh the risks of serious injury and/or death for a given patient; and
- 21 x. being otherwise reckless, careless and/or negligent.

22 120. Despite the fact that Defendant knew or should have known that Viagra  
23 increased the risk of serious injury and/or death, Defendant continued to promote and market  
24 Viagra to doctors and to consumers, including Plaintiff, when safer and more effective methods  
25 of treatment were available.

26 121. As a direct and proximate result of the negligence committed by Pfizer in testing  
27 and ultimately selling Viagra, Plaintiff suffered significant pain, injury, suffering, and economic  
28 damages incurred through cancer treatment from melanoma caused by Viagra use.



- 1 f. designing, manufacturing, marketing, advertising, distributing, and  
2 selling Viagra to consumers, including Plaintiff, without an adequate  
3 warning of the significant and dangerous risks of Viagra and without  
4 proper instructions to avoid the harm which could foreseeably occur as a  
5 result of using the drug;
- 6 g. failing to exercise due care when advertising and promoting Viagra;
- 7 h. recklessly continuing to manufacture, market, advertise, and distribute  
8 Viagra after Defendant knew or should have known of the risks of serious  
9 injury and/or death associated with using the drug;
- 10 i. failing to use due care in the preparation and development of Viagra to  
11 prevent the aforementioned risk of injuries to individuals when the drug  
12 was ingested;
- 13 j. failing to use due care in the design of Viagra to prevent the  
14 aforementioned risk of injuries to individuals when the drug was  
15 ingested;
- 16 k. failing to conduct adequate pre-clinical testing and research to determine  
17 the safety of Viagra;
- 18 l. failing to conduct adequate post-marketing surveillance and exposure  
19 studies to determine the safety of Viagra, while Defendant knew or  
20 should have known that post-marketing surveillance would be the only  
21 means to determine the relative risk of Viagra for causing serious injury  
22 and death as alleged herein in the absence of clinical trials, and that such  
23 surveillance would be necessary for a due diligence program that would  
24 alert Defendant to the need to change the drug's warnings or to withdraw  
25 it from the market altogether;
- 26 m. failing to completely, accurately and in a timely fashion, disclose the  
27 results of the pre-marketing testing and post-marketing surveillance and  
28

1 testing to Plaintiff, her doctors, other consumers, the medical community,  
2 and the FDA;

3 n. failing to accompany Viagra with proper warnings regarding all possible  
4 adverse side effects associated with the use of the same;

5 o. failing to use due care in the manufacture, inspection, and labeling of  
6 Viagra to prevent the aforementioned risk of injuries to individuals who  
7 used the drug;

8 p. failing to use due care in the promotion of Viagra to prevent the  
9 aforementioned risk of injuries to individuals when the drug was  
10 ingested;

11 q. failing to use due care in the sale and marketing of Viagra to prevent the  
12 aforementioned risk of injuries to individuals when the drug was  
13 ingested;

14 r. failing to provide adequate and accurate training and information to the  
15 sales representatives who sold the drug;

16 s. failing to provide adequate and accurate training and information to  
17 healthcare providers for the appropriate use of Viagra;

18 t. failing to conduct or fund research into the development of medications  
19 of this type which would pose the least risk of causing such serious injury  
20 and death, as alleged herein, into the early detection of persons who  
21 might be most susceptible to such reactions, and into the development of  
22 better remedies and treatment for those who experience these tragic  
23 adverse reactions;

24 u. failing to educate healthcare providers and the public about the safest use  
25 of the drug;

26 v. failing to give healthcare providers adequate information to weigh the  
27 risks of serious injury and/or death for a given patient; and

28 w. was otherwise grossly negligent.



1 127. Although Defendant knew, or recklessly disregarded, the fact that Defendant's  
2 product, Viagra, caused serious and potentially fatal side effects, Defendant continued to market  
3 Viagra to consumers, including Plaintiff, without disclosing these side effects including the  
4 risks of serious injury and/or death.

5 128. Defendant knew and/or consciously or recklessly disregarded the fact that  
6 consumers such as Plaintiff would suffer injury as a result of Defendant's failure to exercise  
7 reasonable care as described above.

8 129. Defendant knew of, or recklessly disregarded the defective nature of Defendant's  
9 product, Viagra, as set forth herein, but continued to design, manufacture, market, and sell  
10 Viagra, so as to maximize sales and profits at the expense of the health and safety of the public,  
11 including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by  
12 Viagra.

13 130. As a direct and proximate result of Pfizer's gross negligence, Plaintiff suffered  
14 significant pain, injury, suffering, and economic damages incurred through cancer treatment  
15 from melanoma caused by Viagra use.

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

20 **NINTH CAUSE OF ACTION**  
21 **(Negligence Per Se)**

22 132. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
23 herein.

24 133. At all times herein mentioned, Defendant had an obligation not to violate the  
25 law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the  
26 manufacture, design, formulation, compounding, testing, production, processing, assembling,  
27 inspection, research, promotion, advertising, distribution, marketing, promotion, labeling,  
28 packaging, preparation for use, consulting, sale, warning, and post-sale warning and other

1 communications of the risks and dangers of Viagra.

2 134. By reason of its conduct as alleged herein, Defendant violated provisions of  
3 statutes and regulations, including, but not limited to, the following:

- 4 a. Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§  
5 331 and 352, by misbranding Viagra;
- 6 b. Defendant failed to follow the “[g]eneral requirements on content and format  
7 of labeling for human prescription drugs” in violation of 21 C.F.R. § 201.56;
- 8 c. Defendant failed to follow the “[s]pecific requirements on content and format  
9 of labeling for human prescription drugs” in violation of 21 C.F.R. § 201.57;  
10 and
- 11 d. Defendant advertised and promoted Viagra in violation of 21 C.F.R. § 202.1;  
12 and
- 13 e. Defendant violated 21 C.F.R. § 201.57(e) by failing to timely and adequately  
14 change the Viagra label to reflect the evidence of an association between  
15 Viagra and the development and/or exacerbation of melanoma suffered by  
16 Plaintiff.  
17

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

21 135. As a direct and proximate result of Defendant’s statutory and regulatory  
22 violations, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred  
23 through cancer treatment from melanoma caused by Viagra use.

24 136. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks  
25 damages as detailed in the Global Prayer for Relief including: compensatory damages,  
26 exemplary damages, and punitive damages, together with interest, the costs of suit and  
27 attorneys’ fees, and such other and further relief as this Court deems just and proper.  
28

**TENTH CAUSE OF ACTION**  
**(Breach of Express Warranty)**

1  
2 137. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
3 herein.

4 138. At all times relevant hereto, Pfizer expressly represented and warranted to  
5 Plaintiff and his healthcare providers, by and through statements made by Pfizer or its  
6 authorized agents or sales representatives, orally and in publications, package inserts and other  
7 written materials intended for physicians, medical patients and the general public, that Viagra is  
8 safe, effective, and proper for its intended use.

9 139. Defendant breached expressed warranties with respect to Viagra in the following  
10 particulars:

- 11 a. Defendant represented through its labeling, advertising, marketing  
12 materials, seminar presentations, publications, notice letters, and  
13 regulatory submissions that Viagra was safe, and fraudulently withheld  
14 and concealed information about the substantial risks of serious injury  
15 and/or death associated with using Viagra;
- 16 b. Defendant represented that Viagra was as safe, and/or safer than other  
17 alternative medications and fraudulently concealed information that  
18 demonstrated that Viagra was not safer than alternatives available on the  
19 market; and
- 20 c. Defendant represented that Viagra was more efficacious than other  
21 alternative medications and fraudulently concealed information regarding  
22 the true efficacy of the drug.

23 140. Viagra does not conform to Defendant's express representations because its  
24 mechanism of action, the inhibition of the PDE5 enzyme, also increases the risk of the  
25 development and/or exacerbation of melanoma.

26 141. At all relevant times, Viagra did not perform as safely as an ordinary consumer  
27 would expect when used as intended or in a reasonably foreseeable manner.

28 142. Plaintiff, Plaintiff's physicians, other consumers, and the medical community

1 relied upon Defendant's express warranties, resulting in Plaintiff's ingestion of the drug.

2 143. As a direct and proximate result of the breach of warranty committed by Pfizer,  
3 Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through  
4 cancer treatment from melanoma caused by Viagra use.

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

9 **ELEVENTH CAUSE OF ACTION**  
10 **(Breach of Implied Warranty)**

11 145. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
12 herein.

13 146. At all relevant and material times, Defendant manufactured, distributed,  
14 advertised, promoted, and sold Viagra.

15 147. At all relevant times, Defendant intended that Viagra be used in the manner that  
16 Plaintiff in fact used it.

17 148. Defendant impliedly warranted Viagra to be of merchantable quality, safe and fit  
18 for the use for which Defendant intended it, and Plaintiff in fact used it.

19 149. Defendant was aware that consumers, including Plaintiff, would use Viagra to  
20 achieve and maintain an erection; which is to say that Plaintiff was a foreseeable user of  
21 Defendant's product Viagra.

22 150. Defendant knew, or had reason to know, that Plaintiff's physician would rely on  
23 Defendant's judgment and skill in providing Viagra for its intended use.

24 151. Plaintiff and his physician reasonably relied upon the skill and judgment of  
25 Defendant as to whether Viagra was of merchantable quality, safe and fit for its intended use.

26 152. The drug was expected to reach and did in fact did reach consumers, including  
27 Plaintiff, without substantial change in the condition in which it was manufactured and sold by  
28 Defendant.

1           153. Defendant breached various implied warranties with respect to Viagra including  
2 the following particulars:

3                   a. Defendant represented through its labeling, advertising, marketing  
4 materials, seminar presentations, publications, notice letters, and  
5 regulatory submissions that Viagra was safe and fraudulently withheld  
6 and concealed information about the substantial risks of serious injury  
7 and/or death associated with using Viagra;

8                   b. Defendant represented that Viagra was as safe, and/or safer than other  
9 alternative medications and fraudulently concealed information that  
10 demonstrated that Viagra was not safer than alternatives available on the  
11 market; and

12                   c. Defendant represented that Viagra was more efficacious than other  
13 alternative medications and fraudulently concealed information regarding  
14 the true efficacy of the drug.

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

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

22           156. Defendant breached its implied warranty to Plaintiff in that Viagra is  
23 unreasonably dangerous, defective, and unfit for the ordinary purposes for which Viagra was  
24 used. It was not of merchantable quality, safe and fit for its intended use, or adequately tested.

25           157. As a direct and proximate result of the falsity of the warranties implicated by  
26 Pfizer's actions and omissions, Plaintiff suffered significant pain, injury, suffering, and  
27 economic damages incurred through cancer treatment from melanoma caused by Viagra use.  
28



1 effectiveness of Viagra in order to induce Plaintiff, Plaintiff's physicians, and the public in  
2 general to rely upon such representations and to use Viagra. By failing to disclose important  
3 safety and injury information and suppressing material facts about Viagra to Plaintiff, Plaintiff's  
4 physicians and the public in general, Defendant further led Plaintiff and Plaintiff's physicians to  
5 rely upon the safety of Viagra.

6 165. Defendant had a duty to disclose such information, arising from Defendant's  
7 actions of making, marketing, promoting, labeling, distributing and selling pharmaceutical  
8 products to Plaintiff and others.

9 166. Defendant's false representations and concealments were fraudulently made, in  
10 that Viagra in fact caused injury, was unsafe, and the benefits of its use were far outweighed by  
11 the risk associated with use thereof.

12 167. Defendant committed acts of intentional misrepresentation and intentional  
13 concealment by suppressing material facts relating to the dangers and substantial risks of  
14 serious injuries and/or death associated with, and caused by, the use of Viagra.

15 168. Defendant made such false representations, omissions and concealments with the  
16 intent or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations,  
17 leading to the use of Viagra by Plaintiff.

18 169. Defendant made fraudulent affirmative misrepresentations and omissions and  
19 fraudulent concealments of material facts regarding the safety and effectiveness of Viagra and  
20 of the dangers and risks of injuries associated with Viagra, including:

21 a. Defendant fraudulently represented through its labeling, advertising,  
22 marketing materials, seminar presentations, publications, notice letters,  
23 and regulatory submissions that Viagra had been adequately tested and  
24 found to be safe and effective for erectile dysfunction, and fraudulently  
25 concealed information about the substantial risks of serious injury and/or  
26 death associated with using Viagra; and

27 b. Defendant fraudulently represented that Viagra was as safe and/or safer  
28 and/or more efficacious than other alternative erectile dysfunction

1 therapies, and fraudulently concealed information that demonstrated that  
2 Viagra was not safer and/or more efficacious than alternatives available on  
3 the market.

4 170. Defendant knew, had reason to know, or should have known that these  
5 representations and actively concealed adverse information were false, and that Viagra had  
6 defects and was unreasonably dangerous. Yet, Defendant willfully, wantonly, and recklessly  
7 disregarded its obligation to provide truthful representations regarding the safety and risk of  
8 Viagra to consumers, including Plaintiff, and to the medical community.

9 171. Defendant did not have adequate proof upon which to base such representations,  
10 and in fact, given Defendant's knowledge about Viagra's pharmacology and reported adverse  
11 events, Defendant knew or should have known that these representations, omissions and/or  
12 concealments were false and fraudulent. Specifically, Defendant knew of, possessed evidence  
13 and/or had reason to know that Viagra had defects and was unreasonably dangerous, causing the  
14 development and/or exacerbation of melanoma, as detailed herein.

15 172. Defendant's misrepresentations were made with the intent that physicians and  
16 patients, including Plaintiff, would rely upon them and were made with the intent of defrauding  
17 and deceiving Plaintiff, other consumers, and the medical community to induce and encourage  
18 the sale of Viagra.

19 173. Plaintiff, Plaintiff's physicians, and others, did rely upon and/or were induced by  
20 the misrepresentations, omissions and/or active concealment of the dangers of Viagra to the  
21 detriment of the Plaintiff.

22 174. Defendant's fraudulent representations and concealments evince its callous,  
23 reckless, willful, and depraved indifference to the health, safety, and welfare of consumers,  
24 including Plaintiff.

25 175. In selecting treatment, Plaintiff's physicians and Plaintiff relied on and were  
26 induced by Defendant's misrepresentations concerning the dangers of Viagra.

27 176. As detailed herein, Defendant made these fraudulent misrepresentations,  
28 omissions and concealments through statements and comments to the press, labeling,



1 advertising, marketing and promotion materials, seminar presentations, publications, Dear  
2 Doctor letters and regulatory submissions.

3 177. Plaintiff and the treating medical community did not know that the  
4 representations, omissions, and/or concealments made by Defendant were false and were  
5 justified in reasonably relying upon Defendant's representations.

6 178. Had Defendant not fraudulently misrepresented and concealed such information,  
7 Plaintiff would not have ingested Viagra and suffered resulting harm.

8 179. Defendant made the aforesaid representations and concealments intentionally  
9 and in the course of Defendant's business as designers, manufacturers, and distributors of  
10 Viagra despite having no reasonable basis for the assertion that these representations were true,  
11 without having accurate or sufficient information concerning the aforesaid representations  
12 and/or knowing these representations were false. Defendant was aware that without such  
13 information it could not accurately make the aforesaid representations.

14 180. At the time Defendant made the aforesaid representations and at the time  
15 Plaintiff received Viagra, Plaintiff, Plaintiff's physicians, and the public in general reasonably  
16 believed them to be true. At the time that Plaintiff received Viagra, Defendant failed to  
17 adequately inform Plaintiff and/or his prescribing doctors that Viagra use increased the risk of  
18 the development and/or exacerbation of melanoma, despite Defendant being in possession of  
19 such evidence. Plaintiff received no adequate warnings, either written or verbal, that Viagra  
20 caused these side effects, and relied on these omissions and concealments.

21 181. As a direct and proximate consequence of Defendant's fraudulent  
22 misrepresentations, omissions and intentional concealment of material facts, upon which  
23 Plaintiff reasonably relied, Plaintiff sustained significant pain, injury, harm, suffering, and  
24 economic damages incurred through cancer treatment from melanoma caused by Viagra use.

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

**THIRTEENTH CAUSE OF ACTION**  
**(Negligent Misrepresentation and Concealment)**

1  
2  
3 183. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
4 herein.

5 184. At all relevant times, Defendant designed, tested, manufactured, packaged,  
6 marketed, distributed, promoted, and sold Viagra.

7 185. At all relevant times, Defendant knew of the use for which Viagra was intended  
8 and expressly and/or impliedly warranted that the drug was of merchantable quality and safe  
9 and fit for such use.

10 186. Defendant's superior knowledge and expertise, its relationship of trust and  
11 confidence with doctors and the public, its specific knowledge regarding the risks and dangers  
12 of Viagra and its intentional dissemination of promotional and marketing information about  
13 Viagra for the purpose of maximizing its sales, each gave rise to the affirmative duty to disclose  
14 and provide all material information about the risks and harms associated with the drug.

15 187. Defendant recklessly, and/or negligently represented to Plaintiff, Plaintiff's  
16 physicians, and other persons and professionals whom Defendant knew would rely, that Viagra  
17 was safe to ingest and that the utility of this product outweighed any risk in use for their  
18 intended purposes.

19 188. Defendant recklessly and/or negligently failed to disclose to Plaintiff, and others,  
20 important safety and efficacy information, thereby suppressing material facts about the drug,  
21 while having a duty to disclose such information, which duty arose from its actions of making,  
22 marketing, promoting, distributing and selling pharmaceutical products to Plaintiff and others.

23 189. Defendant led Plaintiff to rely upon the safety of the product in its use.

24 190. The false representations of the Defendant were recklessly and/or negligently  
25 made in that Viagra in fact caused injury, was unsafe, and the benefits of its use were far  
26 outweighed by the risk associated with use thereof.

1           191. Defendant committed acts of reckless and/or negligent misrepresentation and  
2 reckless and/or negligent concealment by suppressing material facts relating to the dangers and  
3 injuries associated with, and caused by, the use of Viagra.

4           192. Defendant knew or should have known that its representations and/or omissions  
5 were false. Defendant made such false, negligent and/or reckless representations with the intent  
6 or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations, leading  
7 to the use of Viagra by Plaintiff.

8           193. Defendant recklessly and/or negligently misrepresented, and/or omitted  
9 information with respect to Viagra in the following particulars:

10                   a. Defendant represented through its labeling, advertising, marketing  
11 materials, seminar presentations, publications, notice letters, and  
12 regulatory submissions that Viagra was safe and fraudulently withheld  
13 and concealed information about the substantial risks of serious injury  
14 and/or death associated with using Viagra;

15                   b. Defendant represented that Viagra was as safe and/or safer than other  
16 alternative erectile dysfunction therapies and fraudulently concealed  
17 information, which demonstrated that Viagra was not safer than  
18 alternatives available on the market; and

19                   c. Defendant represented that Viagra was more efficacious than other  
20 alternative erectile dysfunction therapies and fraudulently concealed  
21 information, regarding the true efficacy of the drug.

22           194. Defendant made affirmative misrepresentations and recklessly and/or negligently  
23 omitted material adverse information regarding the safety and effectiveness of Viagra.

24           195. Defendant made these misrepresentations and/or omissions at a time when  
25 Defendant knew or had reason to know that Viagra had defects and was unreasonably  
26 dangerous and was not what Defendant had represented to the medical community, the FDA  
27 and the consuming public, including Plaintiff.

28

1           196. Defendant omitted, suppressed, and/or concealed material facts concerning the  
2 dangers and risk of injuries associated with the use of Viagra including, serious injury and  
3 death. Furthermore, Defendant was willfully blind to, ignored, downplayed, avoided, and/or  
4 otherwise understated the serious nature of the risks associated with the use of Viagra in order  
5 to increase sales.

6           197. Defendant's misrepresentations and/or omissions were undertaken by Defendant  
7 with an intent that doctors and patients, including Plaintiff, rely upon them.

8           198. Defendant's misrepresentations and/or omissions were undertaken with the intent  
9 of defrauding and/or deceiving Plaintiff, other consumers, and the medical community to induce  
10 and encourage the sale of Viagra.

11           199. Defendant's misrepresentations and/or omissions evinced the Defendant's  
12 callous, reckless, willful, and depraved indifference to the health, safety, and welfare of  
13 consumers, including Plaintiff.

14           200. Plaintiff's physician and Plaintiff relied on and were induced by Defendant's  
15 misrepresentations, omissions, and/or active concealment of the dangers of Viagra in selecting  
16 treatment.

17           201. Plaintiff and Plaintiff's physicians did not know that the representations made by  
18 Defendant were false and were justified in relying upon Defendant's representations.

19           202. Had Plaintiff been aware of the increased risk of side effects associated with  
20 Viagra and the relative efficacy of Viagra compared with other readily available alternative  
21 erectile dysfunction therapies, Plaintiff would not have taken Viagra.

22           203. As a direct and proximate consequence of Defendant's misrepresentations,  
23 Plaintiff sustained injuries and damages alleged herein including specifically those alleged  
24 herein.

25           204. Plaintiff relied on the misrepresentations made by Pfizer in purchasing and using  
26 Viagra.



1 healthcare providers would not prescribe Viagra, and consumers like Plaintiff would not use  
2 Viagra, if they were aware of the dangers posed by using Viagra.

3 214. As a direct and proximate result of Pfizer's fraudulent and deceitful conduct,  
4 Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through  
5 cancer treatment from melanoma caused by Viagra use.

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

10 **FIFTEENTH CAUSE OF ACTION**  
11 **(Willful, Wanton, and Malicious Conduct)**

12 216. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
13 herein.

14 217. Pfizer directly or indirectly, maliciously and wantonly made, created,  
15 manufactured, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed,  
16 advertised, warned, and/or sold Viagra.

17 218. Pfizer breached its duty and was wanton and malicious in its actions,  
18 misrepresentations, and omissions in that it:

- 19 a. failed to test Viagra properly and thoroughly before releasing the drug to  
20 the market;
- 21 b. failed to analyze properly and thoroughly the data resulting from the pre-  
22 marketing tests of Viagra;
- 23 c. failed to report to the FDA, the medical community, and the general  
24 public those data resulting from pre- and post-marketing tests of Viagra  
25 which indicated risks associated with its use;
- 26 d. failed to conduct adequate post-market monitoring and surveillance of  
27 Viagra;
- 28 e. failed to conduct adequate analysis of adverse event reports;

- 1 f. designed, manufactured, marketed, advertised, distributed, and sold  
2 Viagra to consumers, including Plaintiff, without an adequate warning of  
3 the significant and dangerous risks of Viagra and without proper  
4 instructions to avoid the harm which could foreseeably occur as a result  
5 of using the drug;
- 6 g. failed to exercise due care when advertising and promoting Viagra;
- 7 h. willfully and wantonly continued to manufacture, market, advertise, and  
8 distribute Viagra after Defendant knew or should have known of the risks  
9 of serious injury and/or death associated with using the drug;
- 10 i. willfully and wantonly failed to use due care in the preparation and  
11 development of Viagra to prevent the aforementioned risk of injuries to  
12 individuals when the drug was ingested;
- 13 j. willfully and wantonly failed to use due care in the design of Viagra to  
14 prevent the aforementioned risk of injuries to individuals when the drug  
15 was ingested;
- 16 k. failed to conduct adequate pre-clinical testing and research to determine  
17 the safety of Viagra;
- 18 l. failed to conduct adequate post-marketing surveillance and exposure  
19 studies to determine the safety of Viagra, while Defendant knew or  
20 should have known that post-marketing surveillance would be the only  
21 means to determine the relative risk of Viagra for causing such serious  
22 injury and death as alleged herein in the absence of clinical trials, and that  
23 such surveillance would be necessary for a due diligence program that  
24 would alert Defendant to the need to change the drug's warnings or to  
25 withdraw it from the market altogether;
- 26 m. failed to completely, accurately and in a timely fashion, disclose the  
27 results of the pre-marketing testing and post-marketing surveillance and  
28

1 testing to Plaintiff, Plaintiff's physicians, other consumers, the medical  
2 community, and the FDA;

3 n. failed to accompany Viagra with proper warnings regarding all possible  
4 adverse side effects associated with the use of the same;

5 o. willfully and wantonly failed to use due care in the manufacture,  
6 inspection, and labeling of Viagra to prevent the aforementioned risk of  
7 injuries to individuals who used the drug;

8 p. willfully and wantonly failed to use due care in the promotion of Viagra  
9 to prevent the aforementioned risk of injuries to individuals when the  
10 drug was ingested;

11 q. willfully and wantonly failed to use due care in the sale and marketing of  
12 Viagra to prevent the aforementioned risk of injuries to individuals when  
13 the drug was ingested;

14 r. willfully and wantonly failed to use due care in the selling of Viagra to  
15 prevent the aforementioned risk of injuries to individuals when the drug  
16 was ingested;

17 s. failed to provide adequate and accurate training and information to the  
18 sales representatives who sold the drug;

19 t. failed to provide adequate and accurate training and information to  
20 healthcare providers for the appropriate use of Viagra;

21 u. failed to conduct or fund research into the development of medications of  
22 this type which would pose the least risk of causing serious injury and  
23 death as alleged herein, into the early detection of persons who might be  
24 most susceptible to such reactions, and into the development of better  
25 remedies and treatment for those who experience these tragic adverse  
26 reactions;

27 v. failed to educate healthcare providers and the public about the safest use  
28 of the drug;



- 1 w. failed to give healthcare providers adequate information to weigh the  
2 risks of serious injury and/or death for a given patient; and  
3 x. otherwise behaved willfully, wantonly, and maliciously.

4 219. Pfizer knew or should have known that Viagra was unreasonably dangerous and  
5 could cause serious injuries, including death.

6 220. As a direct and proximate result of the wanton and malicious acts and omissions  
7 of Pfizer, the Plaintiff sustained injuries and damages alleged herein.

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

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

15 **SIXTEENTH CAUSE OF ACTION**  
16 **(Unjust Enrichment)**

17 223. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
18 herein.

19 224. At all times relevant to this action, Defendant designed, advertised, marketed,  
20 promoted, manufactured, distributed, supplied, and/or sold Viagra.

21 225. Plaintiff purchased Viagra for the purpose of achieving and maintaining an  
22 erection.

23 226. Defendant has accepted payment from Plaintiff for the purchase of Viagra.

24 227. Plaintiff did not receive the safe and effective pharmaceutical product for which  
25 Plaintiff intended to purchase.

26 228. It is inequitable and unjust for Defendant to retain this money because the  
27 Plaintiff did not in fact receive the product Defendant represented Viagra to be.

28 229. Based on the foregoing, Plaintiff is entitled to equitable relief against Defendant  
on account of its unjust enrichment.



1 D. Other, further, and different relief as the nature of the case may require or  
2 as may be determined to be just, equitable, and proper by this Court.

3 **DEMAND FOR JURY TRIAL**

4 Plaintiff Terrence Hayes demands a trial by jury.

5  
6  
7 Dated: March 3, 2016.

LEVIN SIMES, LLP

8  
9 /s/Rachel Abrams \_\_\_\_\_

10 Rachel Abrams  
11 LEVIN SIMES, LLP  
12 44 Montgomery Street, 32<sup>nd</sup> Floor  
13 San Francisco, CA, 94104  
14 Telephone: (415) 426-3000  
15 Facsimile: (415) 426-3001  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS
TERRENCE HAYES
(b) County of Residence of First Listed Plaintiff Madison County, KY
(c) Attorneys (Firm Name, Address, and Telephone Number)
Rachel Abrams
Levin Simes, LLP: 44 Montgomery St, 32nd Fl, San Francisco, CA
94104; (415) 426-3000

DEFENDANTS
PFIZER, INC.
County of Residence of First Listed Defendant NY
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.
Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)
1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country
PTF DEF
1 1
2 2
3 3
Incorporated or Principal Place of Business In This State
Incorporated and Principal Place of Business In Another State
Foreign Nation
PTF DEF
4 4
5 5
6 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)
CONTRACT
PERSONAL INJURY
REAL PROPERTY
CIVIL RIGHTS
PRISONER PETITIONS
FORFEITURE/PENALTY
LABOR
IMMIGRATION
BANKRUPTCY
PROPERTY RIGHTS
SOCIAL SECURITY
FEDERAL TAX SUITS
OTHER STATUTES

V. ORIGIN (Place an "X" in One Box Only)
1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from another district (specify)
6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
Brief description of cause:
Product Liability

VII. REQUESTED IN COMPLAINT:
CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND \$ More than \$75,000
CHECK YES only if demanded in complaint:
JURY DEMAND: X Yes [ ] No

VIII. RELATED CASE(S) IF ANY (See instructions):
JUDGE Hon. Richard Seeborg
DOCKET NUMBER 3:15-cv-04884

DATE 03/03/2016
SIGNATURE OF ATTORNEY OF RECORD /s/ Rachel Abrams

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE