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

WILLIAM KELLY,

Plaintiff,

vs.

PFIZER, INC. and ELI LILLY AND  
 COMPANY,

Defendants.

Case No.: \_\_\_\_\_

**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**

Plaintiff, William Kelly, individually alleges:

**BACKGROUND**

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

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 and Eli Lilly are citizens of a state other than the state in which Plaintiff is a  
12 citizen.

13 2. On April 7, 2016 the Judicial Panel on Multidistrict Litigation (JPML) entered a  
14 Transfer Order consolidating all such related matters before this Honorable Court in the  
15 Northern District of California. *See In re: Viagra (Sildenafil Citrate) Products Liability*  
16 *Litigation*, Case No: 3:16-md-02691-RS.

17 3. Related Viagra and Cialis actions are pending in this and other federal judicial  
18 districts throughout the United States. Plaintiff reserves the right to assert all of his legal claims  
19 under Alabama substantive law in that Plaintiff resides in the County of Jefferson, State of  
20 Alabama (hereinafter “Plaintiff’s Home Forum”). For purposes of remand and trial, venue is  
21 proper in the Plaintiff’s Home Forum, the Northern District Court of Alabama, and also in MDL  
22 No. 2691, the United States District Court for the Northern District of California, for the  
23 purpose of consolidated proceedings.

24 4. Plaintiff’s Home Forum is the United States District Court for the Northern  
25 District of Alabama. Plaintiff was domiciled in Alabama when he was prescribed Viagra and  
26 Cialis, when he was exposed to Viagra and Cialis, and when he sustained his injuries.

27 5. Venue in this judicial district is proper under 28 U.S.C. § 1391(a) as Defendants  
28 are subject to this Court’s personal jurisdiction.



1 and/or instructions for Viagra in California, Plaintiff's Home Forum, and throughout the United  
2 States.

3 11. Defendant Eli Lilly is a corporation organized and existing under the laws of the  
4 State of Indiana. Defendant maintains its principal place of business at Lilly Corporate Center,  
5 located in Indianapolis, Indiana 46285. Eli Lilly's registered agent is National Registered  
6 Agents, Inc., 150 West Market Street, Suite 800, Indianapolis, Indiana 46204. Eli Lilly may also  
7 be served through its Registered Agent as identified at the California Secretary of State,  
8 National Registered Agents, Inc., 818 West Seventh Street, Suite 930, Los Angeles, California  
9 90017.

10 12. At all relevant times Eli Lilly, including its owners, employees, parent  
11 companies, subsidiaries, affiliates, and agents, were engaged in the business of designing,  
12 testing, manufacturing, packaging, marketing, distributing, promoting, selling, and providing  
13 warnings and/or instructions for Cialis in California, Plaintiff's Home Forum, and throughout  
14 the United States.

### 15 **FACTS**

#### 16 **A. Background - Viagra**

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

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

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

28 16. Viagra treats erectile dysfunction by inhibiting the secretion of

phosphodiesterase type 5 ("PDE5"), an enzyme responsible for the degradation of cyclic guanosine monophosphate ("cGMP"). When the cGMP is not degraded by the PDE5, smooth muscles in the corpus cavernosum relax; this, in turn, permits an inflow of blood to the corpus cavernosum, creating an erection.

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

#### B. Prevalence of Viagra in Market

18. 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.

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

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

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

#### C. Background – Cialis

22. On November 21, 2003, the U.S. Food and Drug Administration approved new drug application ("NDA") 021368 from Lilly ICOS LLC for the manufacture and sale of tadalafil.<sup>5</sup>

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

<sup>2</sup> 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>.

<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>.

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

<sup>5</sup> The initial FDA approval for tadalafil was issued to the entity Lilly ICOS LLC. From 1998 to 2006, Eli Lilly and ICOS Corporation were partners in the joint venture known as Lilly ICOS LLC. This joint venture was responsible for the manufacture, marketing, and sale of Cialis from the drug's FDA approval in 2003 until Eli Lilly acquired ICOS Corporation in October of 2006. Press Release, Eli Lilly and Company, Lilly Announces Acquisition of ICOS Corporation (Oct. 17, 2006), <https://investor.lilly.com/releasedetail.cfm?ReleaseID=214900>. Mr. Fleming did not

1           23.     Tadalafil, sold under the brand name Cialis, is an oral tablet prescribed to men  
2 with erectile dysfunction.

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

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

14           26.     Since FDA approval of Cialis in 2003, Eli Lilly has engaged in a continuous and  
15 expensive multimedia campaign to market Cialis to men worldwide as a symbol of regaining  
16 and enhancing one's virility.

17 **D.     Prevalence of Cialis in Market**

18           27.     In 2012, Cialis was the second largest drug in the global market of erectile  
19 dysfunction drugs accounting for over \$1,926,000,000 in revenue.

20           28.     In its 2013 Annual Report, Eli Lilly reported revenue exceeding \$2,159,000,000  
21 from worldwide sales of Cialis, a 12% increase in sales from 2012 to 2013.

22           29.     Upon information and belief, as of May 2014 approximately 45 million men  
23 have taken Cialis.

24 **E.     Defendants' Knowledge of Defect**

25           30.     Unbeknownst to most Viagra and Cialis users, and not mentioned in any of the  
26 advertising proliferated by Defendants, recent studies have shown that the cellular activity  
27

28 begin taking Cialis until after the acquisition, rendering the entity Lilly ICOS LLC relevant only  
for explanatory purposes here.

1 providing the mechanism of action for these drugs may also be associated with the development  
2 and/or exacerbation of melanoma.

3 31. The American Cancer Society states that melanoma is “the most serious type of  
4 skin cancer.”<sup>6</sup>

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

9 33. Several studies have linked the mechanism of action for Viagra and Cialis to cell  
10 mutation cultivating melanomagenesis, or the creation of melanocytes which develop into  
11 melanoma.

12 34. A study published in 2011 found that treatment with Viagra and Cialis can  
13 promote melanoma cell invasion.<sup>8</sup> Specifically, by inhibiting PDE5, Viagra mimics an effect of  
14 gene activation and therefore may potentially function as a trigger for the creation of melanoma  
15 cells.

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

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

23 <sup>6</sup> American Cancer Society, *Skin Cancer Facts*, last revised March 19, 2014, available at:  
24 <http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts>.

25 <sup>7</sup> National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 2011, available at:  
<http://www.cancer.gov/cancertopics/wyntk/skin/page4>.

26 <sup>8</sup> I. Arozarena, et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating  
The cGMP-Specific Phosphodiesterase PDE5A*, 19 CANCER CELL 45 (2011).

27 <sup>9</sup> X Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Through the PKG Pathway in  
B16 Melanoma Cells*, 113 J. CELL BIOCHEM. 2738 (2012).

28 <sup>10</sup> F.P. Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation  
Requires Melanin Pigment*, 3 NATURE COMMUNICATIONS 884 (2012).

1 melanoma development in men in the United States.<sup>11</sup> The JAMA study was published in the  
2 journal's June 2014 edition.

3 37. Among 25,848 participants, the JAMA study reported that recent sildenafil users  
4 at baseline had a significantly elevated risk of invasive melanoma, with a "hazard ratio" of 1.84;  
5 in other words, the study participants who had recently used sildenafil exhibited an 84%  
6 increase in risk of developing or encouraging invasive melanoma.<sup>12</sup>

7 38. The JAMA study did not specifically study the effects of Cialis use on  
8 melanomagenesis, as Cialis had not yet been approved by the FDA for treatment of erectile  
9 dysfunction. However, its central mechanism of action, the inhibition of PDE5, is the same  
10 mechanism of action that renders sildenafil citrate effective in treating erectile dysfunction.

11 39. On March 22, 2016, a study was published in *Cell Reports* which determined  
12 that PDE5 inhibition leads to increased tumor growth.<sup>13</sup> Specifically, melanoma cells express a  
13 cGMP pathway involving PDE5 and such pathway promotes MAPK signaling and melanoma  
14 cell growth and migration.<sup>14</sup> PDE5A (uninhibited) degrades cGMP, acting as a brake on the  
15 melanoma growth-promoting cGMP pathway.<sup>15</sup> Viagra, however, inhibits PDE5, thereby  
16 stopping it from degrading cGMP.<sup>16</sup> Without such degradation, Viagra leads to increased  
17 melanoma tumor growth.<sup>17</sup>

18 40. Defendants purposefully downplayed, understated and outright ignored the  
19 melanoma-related health hazards and risks associated with using Viagra® and Cialis®.  
20 Defendants also deceived potential Viagra® and Cialis® users by relaying positive information  
21 about the drugs' benefits through the press, while downplaying known, adverse, serious health  
22 effects.

23  
24 <sup>11</sup> Wen-Qing Li, Abrar A. Qureshi, Kathleen C. Robinson, & Jiali Han, *Sildenafil Use and*  
25 *Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*, 174 JAMA  
INTERNAL MEDICINE 964 (2014).

26 <sup>12</sup> *Id.*

27 <sup>13</sup> Dhayade et al., *Sildenafil Potentiates a cGMP-Dependent Pathway to Promote Melanoma*  
*Growth*, 14 Cell Reports 1 (2016).

28 <sup>14</sup> *Id.* at 3-4.

<sup>15</sup> *Id.* at 5-9.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*



F. Consumer Expectations

41. Since the FDA's approval of Viagra 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.

42. Since the FDA's approval of Cialis in 2003, Eli Lilly has engaged in a continuous, expensive, and aggressive advertising campaign to market Cialis to men worldwide as a symbol of regaining and enhancing one's virility.

43. Pfizer has engaged in increasingly aggressive marketing techniques and strategies to promote the use of Viagra in the face of increasing pharmaceutical competition. By means of demonstration, a 2004 article in The Chicago Tribune cited industry reports stating that Pfizer spent "tens of millions of dollars each month on direct-to-consumer advertising [ ]."<sup>18</sup>

44. 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."<sup>19</sup>

45. For example, none of the informational documents proliferated to patients using and physicians prescribing Viagra and Cialis since the FDA's approval of the drugs make any mention of the risk of melanoma associated with ingestion of Viagra and Cialis.

46. As another example, none of the commercials or print advertisements promoting the prescription and use of Viagra and Cialis since the drugs were approved by the FDA mention any melanoma-related risks associated with using the drugs.

47. While designing and formulating Viagra and Cialis, Defendants discovered or should have discovered that the drugs' mechanism of action, the inhibition of PDE5, also presented a significant risk of exacerbating melanoma.

<sup>18</sup> Bruce Japsen, *Viagra's 2 Rivals Grab Market Share In A Year*, CHICAGO TRIBUNE, Sept. 23, 2004, available at [http://articles.chicagotribune.com/2004-09-23/business/0409230283\\_1\\_viagra-erectile-levitra](http://articles.chicagotribune.com/2004-09-23/business/0409230283_1_viagra-erectile-levitra).

<sup>19</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        48. Despite these significant findings, Defendants have made no efforts in their  
2 ubiquitous Viagra and Cialis advertisements to warn users about the potential risk of developing  
3 melanoma that has been scientifically linked to these drugs.

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

6        50. Prescribing physicians would not have had the same level of access to the  
7 research and development conducted by Pfizer and/or Eli Lilly prior to their decision to  
8 manufacture Viagra and/or Cialis for general public use.

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

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

15        53. Defendants expected or should have expected individuals who suffered from  
16 erectile dysfunction to ingest Viagra and/or Cialis as a means to treat their condition.

17        54. Defendants expected or should have expected physicians treating erectile  
18 dysfunction to prescribe Viagra and/or Cialis as a means to treat the condition.

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

23 **G. Risks and Benefits of Viagra and Cialis Use**

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

27        57. At all times relevant hereto, Viagra and Cialis were useful to some members of  
28 the population; namely, men diagnosed with erectile dysfunction.

1           58.     However, Viagra and Cialis also encourage the development of melanoma in the  
2 body of a user, thereby placing them at a significant health risk.

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

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

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

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

17          63.     Because the risk of using Viagra and Cialis so greatly outweighs the benefits of  
18 such use, the drugs present an unreasonably dangerous risk when used in its intended condition.

19 **F.     Facts Regarding Plaintiff**

20          64.     Plaintiff began pharmaceutical treatment of erectile dysfunction in 2000 when  
21 his physician prescribed Viagra.

22          65.     Plaintiff continued to fill his Viagra prescriptions and take the drug until at least  
23 2012

24          66.     Plaintiff began a different pharmaceutical treatment for erectile dysfunction in  
25 August 2010 when his physician prescribed Cialis.

26          67.     Plaintiff regularly ingested Cialis until approximately 2012.

27          68.     On November 29, 2011 Plaintiff underwent a biopsy of a skin lesion on his left  
28 leg. The biopsied skin was diagnosed as malignant melanoma.

1           69. In December 2011 Plaintiff underwent an excision for his left leg melanoma. He  
2 underwent a further excision of residual malignant melanoma on April 20, 2012.

3           70. Since first being diagnosed with melanoma, Plaintiff has undergone multiple  
4 surgeries and has had to remain vigilant in monitoring his skin for lesions.

5           71. As a direct, proximate, and legal result of Defendants' negligence and wrongful  
6 conduct, and the unreasonably dangerous and defective characteristics of Viagra and Cialis,  
7 Plaintiff suffered severe and permanent physical and emotional injuries. His physical injuries  
8 have included melanoma as well as the multiple surgeries necessitated by his skin cancer  
9 diagnosis. Plaintiff has endured not only physical pain and suffering but also economic loss,  
10 including significant expenses for medical care and treatment. Because of the nature of his  
11 diagnosis, he will certainly continue to incur such medical expenses in the future. As a result of  
12 these damages, Plaintiff seeks actual and punitive damages from Defendants.

13 G. Summary

14           72. At all times relevant to this lawsuit, Defendants engaged in the business of  
15 researching, licensing, designing, formulating, compounding, testing, manufacturing,  
16 producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting,  
17 packaging and/or advertising for sale or selling the prescription drugs Viagra and Cialis in  
18 California, Plaintiff's Home Forum, and throughout the United States.

19           73. For the duration of these efforts, Defendants directed their advertising efforts to  
20 consumers located across the nation, including consumers in the State of California, Plaintiff's  
21 Home Forum, and throughout the United States. Such efforts were also aimed at prescribing  
22 physicians across the nation, including prescribing physicians in the State of California,  
23 Plaintiff's Home Forum, and throughout the United States.

24           74. At all times mentioned in this Complaint, Defendants' officers and directors  
25 participated in, authorized, and directed the production and aggressive promotion of Viagra and  
26 Cialis when they knew, or with the exercise of reasonable care should have known, of the risk  
27 of developing melanoma associated with Viagra and Cialis use. In doing so, these officers and  
28

1 directors actively participated in the tortious conduct which resulted in the injuries suffered by  
2 many Viagra and Cialis users, including Plaintiff.

3 75. Defendants purposefully downplayed, understated and outright ignored the  
4 melanoma-related health hazards and risks associated with using Viagra and Cialis. Defendants  
5 also deceived potential Viagra and Cialis users by relaying positive information through the  
6 press, including testimonials from retired, popular United States politicians, while downplaying  
7 known adverse and serious health effects.

8 76. Defendants concealed material information related to melanoma development  
9 from potential Viagra and Cialis users.

10 77. In particular, Defendants fail to mention any potential risk for melanoma  
11 development and/or exacerbation associated with Viagra and Cialis use in the drug label,  
12 package inserts, and the warnings the company includes in its commercials, online and print  
13 advertisements.

14 78. As a result of Defendants' advertising and marketing, and representations about  
15 its product, men in the United States, including the Plaintiff, used Viagra and Cialis. If Plaintiff  
16 in this action had known the risks and dangers associated with taking Viagra and Cialis,  
17 Plaintiff would have elected not to take either drug and, consequently, would not have been  
18 subject to the increased risk of melanoma. Similarly, if Plaintiff's physicians had been aware of  
19 the risks and dangers associated with taking Viagra and Cialis, they would not have prescribed  
20 Viagra and Cialis to Plaintiff.

## 21 22 **CAUSES OF ACTION**

### 23 **FIRST CAUSE OF ACTION** 24 **Unfair and Deceptive Trade Practices** 25 **(Unfairness)**

26 79. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
27 herein.

28 80. California Business & Professions Code Section 17200 ("Unfair Competition  
Law" or "UCL") and applicable statutes and laws of Plaintiff's Home Forum preclude unfair

1 competition: *i.e.*, the employment of any unlawful, unfair or fraudulent business acts or  
 2 practices; and, any unfair, deceptive, untrue or misleading advertising (Cal. Bus. & Prof. Code  
 3 Section 17500). This prohibition extends to any act, omission, or conduct affecting the rights of  
 4 consumers.

5 81. Defendants have designed and continue to design, manufacture, market, sell, and  
 6 place into the stream of commerce the Viagra and Cialis purchased and used in California,  
 7 Plaintiff's Home Forum, and throughout the United States. Defendants have failed and  
 8 continue to fail to disclose and conceal the serious safety hazard posed by the design of Viagra  
 9 and Cialis—they do not warn Plaintiff or his physicians of the increased risk of developing  
 10 melanoma as a result of using either drug, and should not be purchased or used for that purpose.

11 82. Defendants have been and remain obligated to disclose this material safety  
 12 hazard because reasonable consumers expect Viagra and Cialis to perform its only intended and  
 13 reasonably expected function and purpose of allowing a user to achieve and maintain an  
 14 erection. In failing to disclose this critical safety hazard, known to Defendants but not to  
 15 reasonable consumers like Plaintiff and his physicians, Defendants engaged in and continue to  
 16 engage in unfair conduct under Cal. Bus. & Prof. Code §17200 and applicable statutes and laws  
 17 of Plaintiff's Home Forum. Plaintiff incorporates herein paragraphs 1 and 25-70, *supra*, as  
 18 particularized evidence of the pattern of omission and concealment perpetrated by Defendants  
 19 against Plaintiff.

20 83. As a result of Defendants' violations of the UCL and applicable statutes and laws  
 21 of Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable relief and monetary  
 22 relief in the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well  
 23 as an award of attorneys' fees, costs, and expenses for prosecuting this action.

24 84. **WHEREFORE**, Plaintiff demands judgment against Defendants 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  
**SECOND CAUSE OF ACTION**  
**Unfair and Deceptive Trade Practices**

**(Fraud)**

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

3           86. California Business & Professions Code Section 17200 (“Unfair Competition  
4 Law” or “UCL”) and applicable statutes and laws of Plaintiff’s Home Forum preclude unfair  
5 competition: *i.e.*, the employment of any unlawful, unfair or fraudulent business acts or  
6 practices; and, any unfair, deceptive, untrue or misleading advertising (Cal. Bus. & Prof. Code  
7 Section 17500). This prohibition extends to any act, omission, or conduct affecting the rights of  
8 consumers.

9           87. Defendants have designed and continue to design, manufacture, market, sell, and  
10 place into the stream of commerce the Viagra and Cialis purchased and used in California,  
11 Plaintiff’s Home Forum, and throughout the United States. Defendants have failed and continue  
12 to fail to disclose and conceal the serious safety hazard posed by the design of Viagra and  
13 Cialis—they did not warn Plaintiff or his physicians of the increased risk of developing  
14 melanoma as a result of using Viagra and Cialis, and should not be purchased or used for that  
15 purpose.

16           88. Defendants have been and remain obligated to disclose this material safety  
17 hazard because reasonable consumers like Plaintiff expect Viagra to perform its only intended  
18 and reasonably expected function and purpose of allowing them to achieve and maintain an  
19 erection. In failing to disclose this critical safety hazard, known to Pfizer but not to reasonable  
20 consumers like Plaintiff or his physicians, Defendants engaged in and continue to engage in  
21 fraudulent conduct by omission under Cal. Bus. & Prof. Code §17200 and applicable statutes  
22 and laws in Plaintiff’s Home Forum. Plaintiff incorporates herein paragraphs 1 and 25-70,  
23 *supra*, as particularized evidence of the pattern of omission and concealment perpetrated by  
24 Defendants against Plaintiff.

25           89. As a result of Defendants’ violations of the UCL and applicable statutes and laws  
26 in Plaintiff’s Home Forum, Plaintiff is entitled to appropriate equitable relief and monetary  
27 relief in the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well  
28 as an award of attorneys’ fees, costs, and expenses for prosecuting this action.

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

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

7        91.     Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
 8 herein.

9        92.     Defendants' conduct is unlawful under the UCL because it violates Cal. Civ.  
 10 Code § 1750, *et seq.* (hereinafter "Consumer Legal Remedies Act" or "CLRA") and applicable  
 11 statutes and laws in Plaintiff's Home Forum. Through omission and concealment, Defendants  
 12 have misrepresented and continues to misrepresent that Viagra and Cialis: (a) have  
 13 characteristics, uses or benefits that it does not have (Section 1770(a)(5)); and, (b) are of a  
 14 particular standard, quality, or grade when they are of another (Section 1770(a)(7)). Plaintiff  
 15 incorporates herein paragraphs 1 and 25-70, *supra*, as particularized evidence of the pattern of  
 16 misrepresentation by omission perpetrated by Defendants against Plaintiff.

17        93.     Were it not for Defendants' unlawful conduct, Plaintiff would not have  
 18 purchased Viagra and Cialis. Instead, he would have purchased safe and reliable erectile  
 19 dysfunction medication fit and safe for its intended purpose.

20        94.     Plaintiff has and will continue to suffer injury in fact and lose money as a direct  
 21 result of Defendants' unfair competition in that he has had to undergo multiple surgeries and  
 22 will continue to be required to undergo periodic skin checks to ensure against recurrence.

23        95.     As a result of Defendants' violations of the UCL and applicable statutes and laws  
 24 in Plaintiff's Home Forum, Plaintiff is entitled to appropriate equitable relief and monetary  
 25 relief in the form of restitution and interest. Plaintiff is also entitled to recover penalties, as well  
 26 as an award of attorneys' fees, costs, and expenses for prosecuting this action.

27        96.     **WHEREFORE**, Plaintiff demands judgment against Defendants and seeks  
 28 damages as detailed in the Global Prayer for Relief including: compensatory damages,



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

3 **FOURTH CAUSE OF ACTION**  
 4 **(Strict Liability – Defective Design)**

5 97. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
 6 herein.

7 98. Defendants have a duty to provide adequate warnings and instructions for Viagra  
 8 and Cialis, to use reasonable care to design a product that is not unreasonably dangerous to  
 9 users, and to adequately test their products.

10 99. At all times relevant to this action, Defendants researched, designed, tested,  
 11 manufactured, packaged, labeled, marketed, distributed, promoted, and sold Viagra and Cialis,  
 12 placing the drug into the stream of commerce.

13 100. At all times relevant to this action, Viagra and Cialis were designed, tested,  
 14 inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed,  
 15 advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a condition  
 16 that was defective and unreasonably dangerous to consumers, including the Plaintiff.

17 101. Viagra and Cialis are defective in their design and/or formulation in that they are  
 18 not reasonably fit, suitable, or safe for their intended purpose and/or their foreseeable risks  
 19 exceed the benefits associated with their design and formulation.

20 102. Viagra and Cialis were expected to reach, and did reach, users and/or consumers,  
 21 including Plaintiff, without substantial change in the defective and unreasonably dangerous  
 22 condition in which they were manufactured and sold.

23 103. Plaintiff used Viagra and Cialis as prescribed and in the foreseeable manner  
 24 normally intended, recommended, promoted, and marketed by Defendants.

25 104. Viagra and Cialis were unreasonably dangerous in that, as designed, they failed  
 26 to perform safely when used by ordinary consumers, including Plaintiff, when they were used as  
 27 intended and in a reasonably foreseeable manner.

28 105. Viagra and Cialis were unreasonably dangerous and defective in design or  
 formulation for their intended use in that, when they left the hands of the manufacturers and/or

1 supplier, they posed a risk of serious injury which could have been reduced or avoided by the  
2 adoption of a feasible reasonable alternative design. There were safer alternative methods and  
3 designs for the like products.

4 106. Viagra and Cialis were insufficiently tested and caused harmful side effects that  
5 outweighed any potential utility.

6 107. Viagra and Cialis, as manufactured and supplied, were defective due to  
7 inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate  
8 reporting regarding the results of the clinical trials, testing and study.

9 108. Viagra and Cialis as manufactured and supplied by the Defendants were  
10 defective due to inadequate post-marketing warnings or instructions because, after Defendants  
11 knew or should have known of the risk of injuries from use and/or ingestion and acquired  
12 additional knowledge and information confirming the defective and dangerous nature of Viagra  
13 and Cialis, Defendants failed to provide adequate warnings to the medical community and the  
14 consumers, to whom Defendants were directly marketing and advertising; and, further,  
15 Defendants continued to affirmatively promote Viagra and Cialis as safe and effective.

16 109. In light of the potential and actual risk of harm associated with the drugs' use, a  
17 reasonable person who had actual knowledge of this potential and actual risk of harm would  
18 have concluded that Viagra and Cialis should not have been marketed in that condition.

19 110. As a direct and proximate cause of the Defendants' defective design of Viagra  
20 and Cialis, including the lack of appropriate warnings, Plaintiff was prescribed and used the  
21 drugs rather than alternative erectile dysfunction therapies with better and/or similar efficacy.  
22 As a result, Plaintiff has suffered significant pain, injury, harm, suffering, and economic  
23 damages incurred through cancer treatment necessitated by Viagra and Cialis use.

24 111. **WHEREFORE**, Plaintiff demands judgment against Defendants 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 **FIFTH CAUSE OF ACTION**

**(Strict Liability – Failure to Warn)**

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

113. While designing and formulating Viagra and Cialis, Defendants discovered or should have discovered that the drugs' mechanism of action, the inhibition of PDE5, also presented a significant risk of exacerbating melanoma.

114. Viagra and Cialis were defective and unreasonably dangerous when they left the possession of the Defendants in that they 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.

115. Information given by Defendants to the medical community and to consumers concerning the safety and efficacy of Viagra and Cialis, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects.

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

117. 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 and Cialis.

118. Defendants 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 and Cialis.

119. Plaintiff, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendants.

120. Defendants expected Plaintiff, individually and through his prescribing physician, to rely upon the information contained in the subject product's package insert and other advertising and promotional materials.

1           121. Defendants had a continuing duty to warn Plaintiff and his prescribing physician  
2 of the risk of development and/or exacerbation of melanoma directly associated with Viagra and  
3 Cialis use.

4           122. Safer alternatives were available that were just as effective and without the risks  
5 posed by Viagra and Cialis.

6           123. As a direct and proximate result of Defendants' failure to warn Plaintiff or his  
7 physician of the significant melanoma-related risks associated with Viagra and Cialis'  
8 mechanism of action, Plaintiff suffered significant pain, injury, suffering, and economic  
9 damages incurred through cancer treatment from melanoma caused by Viagra and Cialis use.

10           124. **WHEREFORE**, Plaintiff demands judgment against Defendants 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                                   **SIXTH CAUSE OF ACTION**  
15                                   **(Failure to Test)**

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

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

22           127. Defendants failed to adequately test the safety of Viagra and Cialis.

23           128. Had Defendants adequately tested relative efficacy of Viagra and Cialis  
24 compared with other readily available, alternative erectile dysfunction therapies and disclosed  
25 those results to the medical community and the public, Plaintiff would not have purchased and  
26 used Viagra and Cialis.

129. As a direct and proximate result of Defendants' failure to adequately test Viagra and Cialis, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra and Cialis use.

130. **WHEREFORE**, Plaintiff demands judgment against Defendants 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)**

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

132. Defendants owed Plaintiff a duty to exercise reasonable care when designing, testing, manufacturing, labeling, marketing, advertising, promoting, distributing, and/or selling Viagra and Cialis.

133. At all relevant times to this action, Defendants owed a duty to properly warn Plaintiff, physicians, consumers, and the public of the risks, dangers and adverse side effects of Viagra and Cialis, including the increased risk of serious injury and death, when the drug was used as intended or in a way that Defendants could reasonably have anticipated.

134. Defendants breached their duty by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of Viagra and Cialis, as set forth below.

135. Defendants failed to exercise due care under the circumstances and therefore breached this duty in numerous ways, including the following:

- a. failing to research and test Viagra and Cialis properly and thoroughly before releasing the drugs to the market;
- b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of Viagra and Cialis;
- c. failing to report to the FDA, the medical community, and the general

- 1 public those data resulting from pre- and post-marketing tests of Viagra  
2 and Cialis which indicated serious risks associated with their use;
- 3 d. failing to conduct adequate post-market monitoring and surveillance of  
4 Viagra and Cialis;
- 5 e. failing to conduct adequate analysis of adverse event reports;
- 6 f. designing, manufacturing, marketing, promoting, advertising,  
7 distributing, and selling Viagra and Cialis to physicians and consumers,  
8 including Plaintiff, without an adequate warning of the significant and  
9 dangerous risks of Viagra and Cialis and without proper instructions to  
10 avoid the harm that could foreseeably occur as a result of using these  
11 drugs;
- 12 g. failing to exercise due care when advertising and promoting Viagra and  
13 Cialis;
- 14 h. negligently continuing to manufacture, market, advertise, and distribute  
15 Viagra and Cialis after Defendants knew or should have known of the  
16 risks of serious injury and/or death associated with using these drugs;
- 17 i. failing to use due care in the preparation and development of Viagra and  
18 Cialis to prevent the aforementioned risk of injuries to individuals when  
19 these drugs were ingested;
- 20 j. failing to use due care in the design of Viagra and Cialis to prevent the  
21 aforementioned risk of injuries to individuals when these drugs were  
22 ingested;
- 23 k. failing to conduct adequate pre-clinical testing and research to determine  
24 the safety of Viagra and Cialis;
- 25 l. failing to conduct adequate post-marketing surveillance and exposure  
26 studies to determine the safety of Viagra and Cialis, while Defendants  
27 knew or should have known that post-marketing surveillance would be  
28 the only means to determine the relative risk of Viagra and Cialis for

1 causing serious injury and/or death in the absence of clinical trials, and  
2 that such surveillance would be necessary for a due diligence program  
3 that would alert Defendants of the need to change the drugs' warnings or  
4 to withdraw them from the market altogether;

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

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

14 o. failing to use due care in the manufacture, inspection, and labeling of  
15 Viagra and Cialis to prevent the aforementioned risk of injuries to  
16 individuals who used these drugs;

17 p. failing to use due care in the promotion of Viagra and Cialis to prevent  
18 the aforementioned risk of injuries to individuals when the drugs were  
19 ingested;

20 q. failing to use due care in the sale and marketing of Viagra and Cialis to  
21 prevent the aforementioned risk of injuries to individuals when the drugs  
22 were ingested;

23 r. failing to use due care in the selling of Viagra and Cialis to prevent the  
24 aforementioned risk of injuries to individuals when the drugs were  
25 ingested;

26 s. failing to provide adequate and accurate training and information to the  
27 sales representatives who sold the drugs;

28 t. failing to provide adequate and accurate training and information to

healthcare providers for the appropriate use of Viagra and Cialis;

- 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 these drugs;
- 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.

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

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

138. **WHEREFORE**, Plaintiff demands judgment against Defendants 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)**

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



1           140. Defendants had a duty to exercise reasonable care in the warning about, design,  
2 testing, manufacture, marketing, labeling, sale, and/or distribution of Viagra and Cialis,  
3 including a duty to ensure that Defendants' products, Viagra and Cialis, did not cause users to  
4 suffer from unreasonable and dangerous side effects.

5           141. Defendants failed to exercise reasonable care in the warning about, design,  
6 testing, manufacture, marketing, labeling, sale, and/or distribution of Defendants' products,  
7 Viagra and Cialis, in that Defendants knew or should have known that taking Viagra and Cialis  
8 caused unreasonable and life-threatening injuries, as alleged herein.

9           142. Defendants were grossly negligent under the circumstances and breached their  
10 duty of care in numerous ways, including the following:

- 11           a. failing to test Viagra and Cialis properly and thoroughly before releasing  
12           the drugs to the market;
- 13           b. failing to analyze properly and thoroughly the data resulting from the pre-  
14           marketing tests of Viagra and Cialis;
- 15           c. failing to report to the FDA, the medical community, and the general  
16           public those data resulting from pre- and post-marketing tests of Viagra  
17           and Cialis which indicated risks associated with their use;
- 18           d. failing to conduct adequate post-market monitoring and surveillance of  
19           Viagra and Cialis;
- 20           e. failing to conduct adequate analysis of adverse event reports;
- 21           f. designing, manufacturing, marketing, advertising, distributing, and  
22           selling Viagra and Cialis to consumers, including Plaintiff, without an  
23           adequate warning of the significant and dangerous risks of Viagra and  
24           Cialis and without proper instructions to avoid the harm which could  
25           foreseeably occur as a result of using the drugs;
- 26           g. failing to exercise due care when advertising and promoting Viagra and  
27           Cialis;

- h. recklessly continuing to manufacture, market, advertise, and distribute Viagra and Cialis after Defendants knew or should have known of the risks of serious injury and/or death associated with using the drugs;
- i. failing to use due care in the preparation and development of Viagra and Cialis to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- j. failing to use due care in the design of Viagra and Cialis to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- k. failing to conduct adequate pre-clinical testing and research to determine the safety of Viagra and Cialis;
- l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Viagra and Cialis, while Defendants knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of Viagra and Cialis 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 Defendants to the need to change the drugs' 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, his doctors, other consumers, the medical community, and the FDA;
- n. failing to accompany Viagra and Cialis with proper warnings regarding all possible adverse side effects associated with the use of the same;
- o. failing to use due care in the manufacture, inspection, and labeling of Viagra and Cialis to prevent the aforementioned risk of injuries to individuals who used the drugs;

- p. failing to use due care in the promotion of Viagra and Cialis to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- q. failing to use due care in the sale and marketing of Viagra and Cialis to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- r. failing to provide adequate and accurate training and information to the sales representatives who sold the drugs;
- s. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of Viagra and Cialis;
- 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;
- u. failing to educate healthcare providers and the public about the safest use of the drugs;
- 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.

143. Although Defendants knew, or recklessly disregarded, the fact that Defendants' products, Viagra and Cialis, caused serious and potentially fatal side effects, Defendants continued to market Viagra and Cialis to consumers, including Plaintiff, without disclosing these side effects including the risks of serious injury and/or death.

144. Defendants knew and/or consciously or recklessly disregarded the fact that consumers such as Plaintiff would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

1        145. Defendants knew of, or recklessly disregarded the defective nature of  
 2 Defendants' products, Viagra and Cialis, as set forth herein, but continued to design,  
 3 manufacture, market, and sell Viagra and Cialis, so as to maximize sales and profits at the  
 4 expense of the health and safety of the public, including Plaintiff, in conscious and/or reckless  
 5 disregard of the foreseeable harm caused by Viagra and Cialis.

6        146. As a direct and proximate result of Defendants' gross negligence, Plaintiff  
 7 suffered significant pain, injury, suffering, and economic damages incurred through cancer  
 8 treatment from melanoma caused by Viagra and Cialis use.

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

13                                    **NINTH CAUSE OF ACTION**  
 14                                    **(Negligence Per Se)**

15        148. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
 16 herein.

17        149. At all times herein mentioned, Defendants had an obligation not to violate the  
 18 law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the  
 19 manufacture, design, formulation, compounding, testing, production, processing, assembling,  
 20 inspection, research, promotion, advertising, distribution, marketing, promotion, labeling,  
 21 packaging, preparation for use, consulting, sale, warning, and post-sale warning and other  
 22 communications of the risks and dangers of Viagra and Cialis.

23        150. By reason of its conduct as alleged herein, Defendants violated provisions of  
 24 statutes and regulations, including, but not limited to, the following:

- 25                    a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§  
 26                    331 and 352, by misbranding Viagra and Cialis;

151. As a direct and proximate result of Defendants' statutory and regulatory violations, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Viagra and Cialis use.

152. **WHEREFORE**, Plaintiff demands judgment against Defendants 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.

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

WILLIAM KELLY COMPLAINT

1 authorized agents or sales representatives, orally and in publications, package inserts and other  
2 written materials intended for physicians, medical patients and the general public, that Viagra  
3 and Cialis are safe, effective, and proper for their intended use.

4 155. Defendants breached expressed warranties with respect to Viagra and Cialis in  
5 the following particulars:

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

18 156. Viagra and Cialis do not conform to Defendants' express representations because  
19 its mechanism of action, the inhibition of the PDE5 enzyme, also increases the risk of the  
20 development and/or exacerbation of melanoma.

21 157. At all relevant times, Viagra and Cialis did not perform as safely as an ordinary  
22 consumer would expect when used as intended or in a reasonably foreseeable manner.

23 158. Plaintiff, Plaintiff's physicians, other consumers, and the medical community  
24 relied upon Defendants' express warranties, resulting in Plaintiff's ingestion of the drug.

25 159. As a direct and proximate result of the breach of warranty committed by  
26 Defendants, Plaintiff suffered significant pain, injury, suffering, and economic damages  
27 incurred through cancer treatment from melanoma caused by Viagra and Cialis use.  
28

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

5                           **ELEVENTH CAUSE OF ACTION**  
6                           **(Breach of Implied Warranty)**

7           161.   Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
8 herein.

9           162.   At all relevant and material times, Defendants manufactured, distributed,  
10 advertised, promoted, and sold Viagra and Cialis.

11           163.   At all relevant times, Defendants intended that Viagra and Cialis be used in the  
12 manner that Plaintiff in fact used it.

13           164.   Defendants impliedly warranted Viagra and Cialis to be of merchantable quality,  
14 safe and fit for the use for which Defendants intended it, and Plaintiff in fact used it.

15           165.   Defendants were aware that consumers, including Plaintiff, would use Viagra  
16 and Cialis to achieve and maintain an erection; which is to say that Plaintiff was a foreseeable  
17 user of Defendants' products Viagra and Cialis.

18           166.   Defendants knew, or had reason to know, that Plaintiff's physician would rely on  
19 Defendants' judgment and skill in providing Viagra and Cialis for its intended use.

20           167.   Plaintiff and his physician reasonably relied upon the skill and judgment of  
21 Defendants as to whether Viagra and Cialis were of merchantable quality, safe and fit for their  
22 intended use.

23           168.   The drugs were expected to reach and in fact did reach consumers, including  
24 Plaintiff, without substantial change in the condition in which it was manufactured and sold by  
25 Defendants.

26           169.   Defendants breached various implied warranties with respect to Viagra and  
27 Cialis including the following particulars:

28                   a.   Defendants represented through their labeling, advertising, marketing

1 materials, seminar presentations, publications, notice letters, and  
2 regulatory submissions that Viagra and Cialis were safe and fraudulently  
3 withheld and concealed information about the substantial risks of serious  
4 injury and/or death associated with using Viagra and Cialis;

5 b. Defendants represented that Viagra and Cialis were as safe, and/or safer  
6 than other alternative medications and fraudulently concealed  
7 information that demonstrated that Viagra and Cialis were not safer than  
8 alternatives available on the market; and

9 c. Defendants represented that Viagra and Cialis were more efficacious than  
10 other alternative medications and fraudulently concealed information  
11 regarding the true efficacy of the drugs.

12 170. In reliance upon Defendants' implied warranty, Plaintiff used Viagra and Cialis  
13 as prescribed and in the foreseeable manner normally intended, recommended, promoted, and  
14 marketed by Defendants.

15 171. Viagra and Cialis were neither safe for their intended use nor of merchantable  
16 quality, as had been implicitly warranted by Defendants, in that Viagra and Cialis' mechanism  
17 of action – the inhibition of PDE5 – inherently presented a significant increase in the user's risk  
18 of developing and/or exacerbating melanoma.

19 172. Defendants breached their implied warranty to Plaintiff in that Viagra and Cialis  
20 are unreasonably dangerous, defective, and unfit for the ordinary purposes for which Viagra and  
21 Cialis were used. It was not of merchantable quality, safe and fit for their intended use, or  
22 adequately tested.

23 173. As a direct and proximate result of the falsity of the warranties implicated by  
24 Defendants' actions and omissions, Plaintiff suffered significant pain, injury, suffering, and  
25 economic damages incurred through cancer treatment from melanoma caused by Viagra and  
26 Cialis use.

27 174. **WHEREFORE**, Plaintiff demands judgment against Defendants and seeks  
28 damages as detailed in the Global Prayer for Relief including: compensatory damages,



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

3 **TWELFTH CAUSE OF ACTION**  
4 **(Fraudulent Misrepresentation and Concealment)**

5 175. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
6 herein.

7 176. Defendants intentionally and fraudulently misrepresented to consumers and  
8 physicians, including Plaintiff, Plaintiff's physicians and the public in general, that Viagra and  
9 Cialis had been tested and found to be safe, well-tolerated and/or more efficacious than  
10 alternative medications and/or methods of erectile dysfunction therapy and that Viagra and  
11 Cialis' benefits outweighed their risks when used as instructed, when, in fact, Defendants knew,  
12 or should have known, and fraudulently concealed that Viagra and Cialis are dangerous to  
13 patients and that the benefits of its use are far outweighed by the risks for Plaintiff and many  
14 others.

15 177. At all relevant times, Defendants knew of the use for which Viagra and Cialis  
16 were intended and expressly and/or impliedly warranted their drugs were of merchantable  
17 quality and safe and fit for such use.

18 178. Defendants had sole access to material facts concerning the dangers and  
19 unreasonable risks of Viagra and Cialis.

20 179. Defendants' superior knowledge and expertise, its relationship of trust and  
21 confidence with doctors and the public, its specific knowledge regarding the risks and dangers  
22 of Viagra and Cialis and their intentional dissemination of promotional and marketing  
23 information about Viagra and Cialis for the purpose of maximizing their sales, each gave rise to  
24 the affirmative duty to meaningfully disclose and provide all material information about the  
25 risks and harms associated with the drugs.

26 180. Defendants made false affirmative representations, omissions and/or fraudulently  
27 concealed material adverse information regarding the dangers, risks, safety, benefits, utility and  
28 effectiveness of Viagra and Cialis in order to induce Plaintiff, Plaintiff's physicians, and the

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

5 181. Defendants had a duty to disclose such information, arising from Defendants'  
6 actions of making, marketing, promoting, labeling, distributing and selling pharmaceutical  
7 products to Plaintiff and others.

8 182. Defendants' false representations and concealments were fraudulently made, in  
9 that Viagra and Cialis in fact caused injury, was unsafe, and the benefits of their use were far  
10 outweighed by the risk associated with use thereof.

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

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

17 185. Defendants made fraudulent affirmative misrepresentations and omissions and  
18 fraudulent concealments of material facts regarding the safety and effectiveness of Viagra and  
19 Cialis and of the dangers and risks of injuries associated with Viagra and Cialis, including:

- 20 a. Defendants fraudulently represented through its labeling, advertising,  
21 marketing materials, seminar presentations, publications, notice letters,  
22 and regulatory submissions that Viagra and Cialis had been adequately  
23 tested and found to be safe and effective for erectile dysfunction, and  
24 fraudulently concealed information about the substantial risks of serious  
25 injury and/or death associated with using Viagra and Cialis; and  
26 b. Defendants fraudulently represented that Viagra and Cialis were as safe  
27 and/or safer and/or more efficacious than other alternative erectile  
28 dysfunction therapies, and fraudulently concealed information that

1 demonstrated that Viagra and Cialis were not safer and/or more  
2 efficacious than alternatives available on the market.

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

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

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

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

21 190. Defendants' fraudulent representations and concealments evince its callous,  
22 reckless, willful, and depraved indifference to the health, safety, and welfare of consumers,  
23 including Plaintiff.

24 191. In selecting treatment, Plaintiff's physicians and Plaintiff relied on and were  
25 induced by Defendants' misrepresentations concerning the dangers of Viagra and Cialis.

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

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

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

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

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

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

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

27 198. **WHEREFORE**, Plaintiff demands judgment against Defendants and seeks  
28 damages as detailed in the Global Prayer for Relief including: compensatory damages,

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

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

5 199. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
6 herein.

7 200. At all relevant times, Defendants designed, tested, manufactured, packaged,  
8 marketed, distributed, promoted, and sold Viagra and Cialis.

9 201. At all relevant times, Defendants knew of the use for which Viagra and Cialis  
10 were intended and expressly and/or impliedly warranted that the drugs were of merchantable  
11 quality and safe and fit for such use.

12 202. Defendants' superior knowledge and expertise, its relationship of trust and  
13 confidence with doctors and the public, its specific knowledge regarding the risks and dangers  
14 of Viagra and Cialis and its intentional dissemination of promotional and marketing information  
15 about Viagra and Cialis for the purpose of maximizing its sales, each gave rise to the  
16 affirmative duty to disclose and provide all material information about the risks and harms  
17 associated with the drugs.

18 203. Defendants recklessly, and/or negligently represented to Plaintiff, Plaintiff's  
19 physicians, and other persons and professionals whom Defendants knew would rely, that Viagra  
20 and Cialis were safe to ingest and that the utility of this product outweighed any risk in use for  
21 their intended purposes.

22 204. Defendants recklessly and/or negligently failed to disclose to Plaintiff, and  
23 others, important safety and efficacy information, thereby suppressing material facts about the  
24 drugs, while having a duty to disclose such information, which duty arose from its actions of  
25 making, marketing, promoting, distributing and selling pharmaceutical products to Plaintiff and  
26 others.

27 205. Defendants led Plaintiff to rely upon the safety of the products in their use.  
28

1       206. The false representations of the Defendants were recklessly and/or negligently  
2 made in that Viagra and Cialis in fact caused injury, were unsafe, and the benefits of their use  
3 were far outweighed by the risk associated with use thereof.

4       207. Defendants committed acts of reckless and/or negligent misrepresentation and  
5 reckless and/or negligent concealment by suppressing material facts relating to the dangers and  
6 injuries associated with, and caused by, the use of Viagra and Cialis.

7       208. Defendants knew or should have known that its representations and/or omissions  
8 were false. Defendants made such false, negligent and/or reckless representations with the  
9 intent or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations,  
10 leading to the use of Viagra and Cialis by Plaintiff.

11       209. Defendants recklessly and/or negligently misrepresented, and/or omitted  
12 information with respect to Viagra and Cialis in the following particulars:

- 13           a. Defendants represented through their labeling, advertising, marketing  
14 materials, seminar presentations, publications, notice letters, and  
15 regulatory submissions that Viagra and Cialis were safe and fraudulently  
16 withheld and concealed information about the substantial risks of serious  
17 injury and/or death associated with using Viagra and Cialis;
- 18           b. Defendants represented that Viagra and Cialis were as safe and/or safer  
19 than other alternative erectile dysfunction therapies and fraudulently  
20 concealed information, which demonstrated that Viagra and Cialis were  
21 not safer than alternatives available on the market; and
- 22           c. Defendants represented that Viagra and Cialis were more efficacious than  
23 other alternative erectile dysfunction therapies and fraudulently  
24 concealed information, regarding the true efficacy of the drugs.

25       210. Defendants made affirmative misrepresentations and recklessly and/or  
26 negligently omitted material adverse information regarding the safety and effectiveness of  
27 Viagra and Cialis.

1           211. Defendants made these misrepresentations and/or omissions at a time when  
2 Defendants knew or had reason to know that Viagra and Cialis had defects and were  
3 unreasonably dangerous and were not what Defendants had represented to the medical  
4 community, the FDA and the consuming public, including Plaintiff.

5           212. Defendants omitted, suppressed, and/or concealed material facts concerning the  
6 dangers and risk of injuries associated with the use of Viagra and Cialis including, serious  
7 injury and death. Furthermore, Defendants were willfully blind to, ignored, downplayed,  
8 avoided, and/or otherwise understated the serious nature of the risks associated with the use of  
9 Viagra and Cialis in order to increase sales.

10           213. Defendants' misrepresentations and/or omissions were undertaken by  
11 Defendants with an intent that doctors and patients, including Plaintiff, rely upon them.

12           214. Defendants' misrepresentations and/or omissions were undertaken with the intent  
13 of defrauding and/or deceiving Plaintiff, other consumers, and the medical community to induce  
14 and encourage the sale of Viagra and Cialis.

15           215. Defendants' misrepresentations and/or omissions evinced the Defendants'  
16 callous, reckless, willful, and depraved indifference to the health, safety, and welfare of  
17 consumers, including Plaintiff.

18           216. Plaintiff's physician and Plaintiff relied on and were induced by Defendants'  
19 misrepresentations, omissions, and/or active concealment of the dangers of Viagra and Cialis in  
20 selecting treatment.

21           217. Plaintiff and Plaintiff's physicians did not know that the representations made by  
22 Defendants were false and were justified in relying upon Defendants' representations.

23           218. Had Plaintiff been aware of the increased risk of side effects associated with  
24 Viagra and Cialis and the relative efficacy of Viagra and Cialis compared with other readily  
25 available alternative erectile dysfunction therapies, Plaintiff would not have taken Viagra and  
26 Cialis.

27           219. As a direct and proximate consequence of Defendants' misrepresentations,  
28 Plaintiff sustained injuries and damages including specifically those alleged herein.

1           220. Plaintiff relied on the misrepresentations made by Defendants in purchasing and  
2 using Viagra and Cialis.

3           221. Plaintiff's reliance on Defendants' misrepresentations was justified because such  
4 misrepresentations were made by entities that were in a position to know of and disclose any  
5 potentially harmful information concerning the use of Viagra and Cialis.

6           222. If Plaintiff had known of the information concealed by Defendants regarding the  
7 melanoma-related risks posed by Viagra and Cialis, Plaintiff would not have purchased and  
8 subsequently used Viagra and Cialis.

9           223. As a direct and proximate result of the negligent misrepresentations by  
10 Defendants, Plaintiff suffered significant pain, injury, suffering, and economic damages  
11 incurred through cancer treatment from melanoma caused by Viagra and Cialis use.

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

16                           **FOURTEENTH CAUSE OF ACTION**  
17                           **(Fraud and Deceit)**

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

20           226. At all times relevant hereto, Defendants conducted a sales and marketing  
21 campaign to promote the sale of Viagra and Cialis and willfully deceive Plaintiff, Plaintiff's  
22 healthcare providers, and the general public as to the benefits, health risks, and consequences of  
23 using Viagra and Cialis.

24           227. While conducting its sales and marketing campaign, Defendants knew that  
25 Viagra and Cialis are neither safe nor fit for human consumption; that using Viagra and Cialis  
26 are hazardous to health; and that Viagra and Cialis have a propensity to cause serious injuries,  
27 such as those suffered by Plaintiff.  
28



1           228. From the time the company first marketed and distributed Viagra and Cialis until  
2 the present, Defendants willfully deceived Plaintiff by concealing from him, his healthcare  
3 providers, and the general public the risks and dangers concerning the use of Viagra and Cialis.

4           229. Defendants intentionally concealed and suppressed the facts concerning Viagra  
5 and Cialis' melanoma-related risks with the intent to defraud potential consumers, as  
6 Defendants knew that healthcare providers would not prescribe Viagra and Cialis, and  
7 consumers like Plaintiff would not use Viagra and Cialis, if they were aware of the dangers  
8 posed by using Viagra and Cialis.

9           230. As a direct and proximate result of Defendants' fraudulent and deceitful conduct,  
10 Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through  
11 cancer treatment from melanoma caused by Viagra and Cialis use.

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

16                               **FIFTEENTH CAUSE OF ACTION**  
17                               **(Willful, Wanton, and Malicious Conduct)**

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

20           233. Defendants directly or indirectly, maliciously and wantonly made, created,  
21 manufactured, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed,  
22 advertised, warned, and/or sold Viagra and Cialis.

23           234. Defendants breached their duty and were wanton and malicious in their actions,  
24 misrepresentations, and omissions in that they:

- 25                   a. failed to test Viagra and Cialis properly and thoroughly before releasing
- 26                   the drugs to the market;
- 27                   b. failed to analyze properly and thoroughly the data resulting from the pre-
- 28                   marketing tests of Viagra and Cialis;

- 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 and Cialis which indicated risks associated with their use;
- d. failed to conduct adequate post-market monitoring and surveillance of Viagra and Cialis;
- e. failed to conduct adequate analysis of adverse event reports;
- f. designed, manufactured, marketed, advertised, distributed, and sold Viagra and Cialis to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Viagra and Cialis and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drugs;
- g. failed to exercise due care when advertising and promoting Viagra and Cialis;
- h. willfully and wantonly continued to manufacture, market, advertise, and distribute Viagra and Cialis after Defendants knew or should have known of the risks of serious injury and/or death associated with using the drugs;
- i. willfully and wantonly failed to use due care in the preparation and development of Viagra and Cialis to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- j. willfully and wantonly failed to use due care in the design of Viagra and Cialis to prevent the aforementioned risk of injuries to individuals when the drugs were ingested;
- k. failed to conduct adequate pre-clinical testing and research to determine the safety of Viagra and Cialis;
- l. failed to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Viagra and Cialis, while Defendants knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of Viagra and Cialis for

1 causing such serious injury and death as alleged herein in the absence of  
2 clinical trials, and that such surveillance would be necessary for a due  
3 diligence program that would alert Defendants to the need to change the  
4 drugs' warnings or to withdraw them from the market altogether;

5 m. failed to completely, accurately and in a timely fashion, disclose the  
6 results of the pre-marketing testing and post-marketing surveillance and  
7 testing to Plaintiff, Plaintiff's physicians, other consumers, the medical  
8 community, and the FDA;

9 n. failed to accompany Viagra and Cialis with proper warnings regarding all  
10 possible adverse side effects associated with the use of the same;

11 o. willfully and wantonly failed to use due care in the manufacture,  
12 inspection, and labeling of Viagra and Cialis to prevent the  
13 aforementioned risk of injuries to individuals who used the drugs;

14 p. willfully and wantonly failed to use due care in the promotion of Viagra  
15 and Cialis to prevent the aforementioned risk of injuries to individuals  
16 when the drugs were ingested;

17 q. willfully and wantonly failed to use due care in the sale and marketing of  
18 Viagra and Cialis to prevent the aforementioned risk of injuries to  
19 individuals when the drugs were ingested;

20 r. willfully and wantonly failed to use due care in the selling of Viagra and  
21 Cialis to prevent the aforementioned risk of injuries to individuals when  
22 the drugs were ingested;

23 s. failed to provide adequate and accurate training and information to the  
24 sales representatives who sold the drugs;

25 t. failed to provide adequate and accurate training and information to  
26 healthcare providers for the appropriate use of Viagra and Cialis;

27 u. failed to conduct or fund research into the development of medications of  
28 this type which would pose the least risk of causing serious injury and

1 death as alleged herein, into the early detection of persons who might be  
 2 most susceptible to such reactions, and into the development of better  
 3 remedies and treatment for those who experience these tragic adverse  
 4 reactions;

5 v. failed to educate healthcare providers and the public about the safest use  
 6 of the drugs;

7 w. failed to give healthcare providers adequate information to weigh the  
 8 risks of serious injury and/or death for a given patient; and

9 x. otherwise behaved willfully, wantonly, and maliciously.

10 235. Defendants knew or should have known that Viagra and Cialis were  
 11 unreasonably dangerous and could cause serious injuries, including death.

12 236. As a direct and proximate result of the wanton and malicious acts and omissions  
 13 of Defendants, the Plaintiff sustained injuries and damages alleged herein.

14 237. As a direct and proximate result of Defendants' willful, wanton and malicious  
 15 conduct, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred  
 16 through cancer treatment from melanoma caused by Viagra and Cialis use.

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

21 **SIXTEENTH CAUSE OF ACTION**  
 22 **(Unjust Enrichment)**

23 239. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully  
 24 herein.

25 240. At all times relevant to this action, Defendants designed, advertised, marketed,  
 26 promoted, manufactured, distributed, supplied, and/or sold Viagra and Cialis.

27 241. Plaintiff purchased Viagra and Cialis for the purpose of achieving and  
 28 maintaining an erection.

242. Defendants have accepted payment from Plaintiff for the purchase of Viagra and Cialis.

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

244. It is inequitable and unjust for Defendants to retain this money because the Plaintiff did not in fact receive the product Defendants represented Viagra and Cialis to be.

245. Based on the foregoing, Plaintiff is entitled to equitable relief against Defendants on account of their unjust enrichment.

246. **WHEREFORE**, Plaintiff demands judgment against Defendants 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.

## **PUNITIVE DAMAGES**

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

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

249. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Viagra and Cialis knowing these actions would expose persons to serious danger in order to advance the company's market share and profits.

250. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint, were willful and malicious.

251. Defendants' unconscionable conduct warrants an award of exemplary and punitive damages against the company.

**GLOBAL PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff prays judgment against Defendants as follows:

A. Declare, adjudge and decree the conduct of Defendants 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 William Kelly demands a trial by jury.

Dated: August 9, 2016.

DAVIS & CRUMP, P.C.

/s/ Trevor B. Rockstad

Trevor B. Rockstad (SBN277274)  
2601 14<sup>th</sup> Street  
Gulfport, MS 39503  
Telephone: (228) 863-6000  
Facsimile: (228) 864-0907  
Email: trevor.rockstad@daviscrump.com

JS-CAND 44 (Rev 07/16)

**CIVIL COVER SHEET**

The JS-CAND 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 in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**I. (a) PLAINTIFFS**

WILLIAM KELLY

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

Trevor B. Rockstad, Esq., Davis & Crump, P.C., 2601 14th  
Street, Gulfport, MS 39501; (228) 863-6000;  
trevor.rockstad@daviscrump.com

**DEFENDANTS**

PFIZER, INC., and ELI LILLY AND COMPANY

County of Residence of First Listed Defendant ☐ New York  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF  
THE TRACT OF LAND INVOLVED.  
Attorneys (If Known)

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

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

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

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

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

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment Of Veteran's Benefits <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input checked="" type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC § 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC § 158 <input type="checkbox"/> 423 Withdrawal 28 USC § 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC § 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC § 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities-Employment <input type="checkbox"/> 446 Amer. w/Disabilities-Other <input type="checkbox"/> 448 Education	<b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee-Conditions of Confinement			

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

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation-Transfer ☐ 8 Multidistrict Litigation-Direct File

**VI. CAUSE OF ACTION**

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

Brief description of cause:

Product liability claim involving prescription drugs Viagra and Cialis

**VII. REQUESTED IN COMPLAINT:**

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, Fed. R. Civ. P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S), IF ANY** (See instructions):

JUDGE Honorable Richard Seeborg

DOCKET NUMBER 3:16-md-02691

**IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)**

(Place an "X" in One Box Only)

☒ SAN FRANCISCO/OAKLAND ☐ SAN JOSE ☐ EUREKA-MCKINLEYVILLE

DATE: 08/09/2016

SIGNATURE OF ATTORNEY OF RECORD: /s/ Trevor B. Rockstad