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**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA**

DENNIS BJORGE	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	<b>Case No.:</b>
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	

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**COMPLAINT**

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1. This is an action for personal injuries and damages suffered by Plaintiff Dennis Bjorge (“Plaintiff”) as a direct and proximate result of Eli Lilly and Company’s negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of tadalafil tablets sold under the brand name Cialis® (“Cialis”).

**PARTIES**

2. Plaintiff Dennis Bjorge is and was at all relevant times an adult resident citizen of the United States residing in the County of Washtenaw, State of Michigan.



1 8. On November 21, 2003, the U.S. Food and Drug Administration approved new  
2 drug application (“NDA”) 021368 from Lilly ICOS LLC for the manufacture and sale of  
3 tadalafil.<sup>1</sup>

4 9. Tadalafil, sold under the brand name Cialis, is an oral tablet prescribed to men  
5 with erectile dysfunction.

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

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

19 12. The National Institutes of Health estimate that erectile dysfunction affects as  
20 many as thirty million men in the United States.<sup>2</sup>

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24 <sup>1</sup> The initial FDA approval for tadalafil was issued to the entity Lilly ICOS LLC. From 1998 to  
25 2006, Eli Lilly and ICOS Corporation were partners in the joint venture known as Lilly ICOS  
26 LLC. This joint venture was responsible for the manufacture, marketing, and sale of Cialis from  
27 the drug’s FDA approval in 2003 until Eli Lilly acquired ICOS Corporation in October of 2006.  
28 Press Release, Eli Lilly and Company, Lilly Announces Acquisition of ICOS Corporation (Oct.  
17, 2006), <https://investor.lilly.com/releasedetail.cfm?ReleaseID=214900>. Plaintiff did not  
begin taking Cialis until after the acquisition, rendering the entity Lilly ICOS LLC relevant only  
for explanatory purposes here.

<sup>2</sup> NIH Consensus Development Panel on Impotence (July 7, 1993).

1 13. Since Cialis's FDA approval in 2003, Defendant has engaged in a continuous  
2 and expensive multimedia advertising campaign to market Cialis to men worldwide as a symbol  
3 of regaining and enhancing one's virility.

4 B. Prevalence of Cialis in Market

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

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

9 16. Upon information and belief, as of May 2014 approximately 45 million men  
10 have taken Cialis.

11 C. Defendant's Knowledge of Defect

12 17. Unbeknownst to most Cialis users, and not mentioned in any of the advertising  
13 proliferated by Defendant, recent studies have shown that the cellular activity providing the  
14 mechanism of action for Cialis may also be associated with the development and/or  
15 exacerbation of melanoma.  
16

17 18. The American Cancer Society states that melanoma is "the most serious type of  
18 skin cancer."<sup>3</sup>  
19

20 19. According to the National Cancer Institute, part of the National Institute of  
21 Health, melanoma is more likely than other skin cancers to spread to other parts of the body,  
22 thereby causing further tissue damage and complicating the potential for effective treatment and  
23 eradication of the cancerous cells.<sup>4</sup>  
24

25  
26  
27 <sup>3</sup> American Cancer Society, *Skin Cancer Facts*, last revised March 19, 2014, available at:  
<http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts>.

28 <sup>4</sup> National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 2011, available at:  
<http://www.cancer.gov/cancertopics/wyntk/skin/page4>.

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

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

7           22. A 2012 study published in the Journal of Cell Biochemistry also found that  
8 PDE5 inhibitors were shown to promote melanin synthesis,<sup>6</sup> which may exacerbate melanoma  
9 development.<sup>7</sup>

10           23. On April 7, 2014, an original study (“the JAMA study”) was published on the  
11 website for the *Journal of the American Medical Association Internal Medicine* which, in light  
12 of the previous studies, sought to examine the direct relationship between the use of PDE5  
13 inhibitors and melanoma development in men in the United States.<sup>8</sup> The JAMA study was  
14 published in the journal’s June 2014 edition.

15           24. Among 25,848 participants, the JAMA study reported that recent users of  
16 another PDE5 inhibitor, sildenafil citrate, at baseline had a significantly elevated risk of  
17 invasive melanoma, with a “hazard ratio” of 1.84; in other words, the study participants who  
18 had recently used sildenafil exhibited an 84% increase in risk of developing or encouraging  
19 invasive melanoma.<sup>9</sup>

20  
21  
22  
23  
24 <sup>5</sup> I. Aozarena, et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating The*  
*cGMP-Specific Phosphodiesterase PDE5A*, 19 *CANCER CELL* 45 (2011).

25 <sup>6</sup> X Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Through the PKG Pathway in*  
*B16 Melanoma Cells*, 113 *J. CELL BIOCHEM.* 2738 (2012).

26 <sup>7</sup> F.P. Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation*  
*Requires Melanin Pigment*, 3 *NATURE COMMUNICATIONS* 884 (2012).

27 <sup>8</sup> Wen-Qing Li, Abrar A. Qureshi, Kathleen C. Robinson, & Jiali Han, *Sildenafil Use and*  
*Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*, 174 *JAMA*  
28 *INTERNAL MEDICINE* 964 (2014).

<sup>9</sup> *Id.*

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

5  
6           26.     On March 22, 2016, a study was published in *Cell Reports* which determined  
7 that PDE5 inhibition leads to increased tumor growth.<sup>10</sup> Specifically, melanoma cells express a  
8 cGMP pathway involving PDE5 and such pathway promotes MAPK signaling and melanoma  
9 cell growth and migration.<sup>11</sup> PDE5A (uninhibited) degrades cGMP, acting as a brake on the  
10 melanoma growth-promoting cGMP pathway.<sup>12</sup> Viagra, however, inhibits PDE5, thereby  
11 stopping it from degrading cGMP.<sup>13</sup> Without such degradation, Viagra leads to increased  
12 melanoma tumor growth.<sup>14</sup>

13  
14           27.     The *Cell Reports* study did not specifically study the effects of Cialis. However,  
15 its central mechanism of action, the inhibition of PDE5, is the same mechanism of action that  
16 renders Viagra effective in treating erectile dysfunction.

17  
18     D.     Consumer Expectations

19           28.     Since the FDA's approval of Cialis in 2003, Eli Lilly has engaged in a  
20 continuous, expensive, and aggressive advertising campaign to market Cialis to men worldwide  
21 as a symbol of regaining and enhancing one's virility.  
22  
23  
24  
25

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26 <sup>10</sup> Dhayade et al., *Sildenafil Potentiates a cGMP-Dependent Pathway to Promote Melanoma*  
27 *Growth*, 14 *Cell Reports* 1 (2016).

28 <sup>11</sup> *Id.* at 3-4.

<sup>12</sup> *Id.* at 5-9.

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

<sup>14</sup> *Id.*

1 29. For example, none of the informational documents proliferated to patients using  
2 and physicians prescribing Cialis since the FDA's approval of the drug make any mention of the  
3 risk of melanoma associated with ingestion of Cialis.

4 30. As another example, none of the commercials or print advertisements promoting  
5 the prescription and use of Cialis, since its approval by the FDA, mention any melanoma-related  
6 risks associated with using the drug.

7 31. While designing and formulating Cialis, Defendant discovered or should have  
8 discovered that the drugs' mechanism of action, the inhibition of PDE5, also presented a  
9 significant risk of exacerbating melanoma.  
10

11 32. Despite these significant findings, Defendant has made no efforts in its  
12 ubiquitous Cialis advertisements to warn users about the potential risk of developing melanoma  
13 that has been scientifically linked to these drugs.  
14

15 33. Members of the general public had no plausible means through which they could  
16 have discovered the significant risk of melanomagenesis associated with PDE5 inhibition.  
17

18 34. Prescribing physicians would not have had the same level of access to the  
19 research and development conducted by Defendant prior to its decision to manufacture Cialis  
20 for general public use.  
21

22 35. Defendant failed to communicate to the general public that the inhibition of  
23 PDE5 inherently necessary to the efficacy of Cialis would also present a significant risk of  
24 one's development or exacerbation of cancerous cells.  
25

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

1 37. Defendant expected or should have expected individuals who suffered from  
2 erectile dysfunction to ingest Cialis as a means to treat their condition.

3 38. Defendant expected or should have expected physicians treating erectile  
4 dysfunction to prescribe Cialis as a means to treat the condition.

5  
6 39. The risk presented by ingesting Cialis would be present from the moment of  
7 manufacture; that is, the user would not need to change or alter the drug itself or the means by  
8 which it was ingested in order for the drug to carry the same risk of harm as described herein.

9  
10 40. At all times relevant to this lawsuit, Defendant engaged in the business of  
11 researching, licensing, designing, formulating, compounding, testing, manufacturing,  
12 producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting,  
13 packaging and/or advertising for sale or selling the prescription drug Cialis for use among the  
14 general public.

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

22 E. Risks and Benefits of Cialis Use

23  
24 42. 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.



1 43. At all times relevant hereto, Cialis was useful to some members of the  
2 population; namely, men diagnosed with erectile dysfunction.

3 44. However, Cialis also encourages the development of melanoma in the body of a  
4 user, thereby placing them at a significant health risk.

5  
6 45. Defendant manufactured, marketed and sold Cialis as a PDE5 inhibitor;  
7 however, the mechanism of action that made the drug effective in treating erectile dysfunction  
8 simultaneously enhanced the risk of the user developing melanoma.

9  
10 46. Through the testing and formulating of Cialis, and before the initiation of the  
11 drug's mass manufacture, Defendant knew or should have known in the exercise of ordinary  
12 care that the chemical reactions inherent to the mechanism of action for Cialis would present a  
13 cancer-related health hazard to potential future users.

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

18  
19 48. Because the risk of using Cialis so greatly outweighs the benefits of such use, the  
20 drug presents an unreasonably dangerous risk when used in its intended condition.

21 F. Facts Regarding Plaintiff

22 49. Plaintiff began pharmaceutical treatment for erectile dysfunction with Cialis in  
23 December of 2007.

24  
25 50. Plaintiff continued to fill his Cialis prescriptions and take the drug regularly until  
26 at least December of 2013.

27 51. On January 2, 2013, Plaintiff underwent a biopsy of a lesion on the left of his  
28 neck.

1 52. The results of that biopsy revealed malignant melanoma.

2 53. Since first being diagnosed with melanoma, Plaintiff has had to remain vigilant  
3 in monitoring his skin for lesions and other symptoms of melanoma, including surgical therapy  
4 on January 23, 2013, to test for residual melanoma.

5 54. Had Defendant properly disclosed the melanoma-related risks associated with  
6 Cialis, Plaintiff would have avoided the risk of developing melanoma by not using Cialis at all;  
7 severely limiting the dosage and length of its use; and/or more closely monitoring the degree to  
8 which the Cialis was adversely affecting his health.

9  
10 55. Furthermore, had Defendant properly disclosed the melanoma-related risks  
11 associated with Cialis, Plaintiff's physician would have avoided such risk to his patient by not  
12 prescribing Cialis to him; severely limited the dosage he prescribed to Plaintiff; and/or closely  
13 monitored the length to which the Cialis was adversely affecting Plaintiff's health.

14 56. As a direct, proximate, and legal result of Defendant's negligent and wrongful  
15 conduct, and the unreasonably dangerous and defective characteristics of the drug Cialis,  
16 Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff endured not  
17 only physical pain and suffering but also economic loss, including significant expenses for  
18 medical care and treatment. Because of the nature of his diagnosis, he will certainly continue to  
19 incur additional medical expenses in the future. As a result, Plaintiff seeks actual and punitive  
20 damages from Defendant.  
21

22 **CAUSES OF ACTION**

23  
24 **COUNT I**  
**(Strict Liability – Defective Design)**

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

28 58. Defendant has a duty to provide adequate warnings and instructions for Cialis, to

1 use reasonable care to design a product that is not unreasonably dangerous to users, and to  
2 adequately test its product.

3 59. At all times relevant to this action, Defendant researched, designed, tested,  
4 manufactured, packaged, labeled, marketed, distributed, promoted, and sold Cialis, placing the  
5 drug into the stream of commerce.  
6

7 60. At all times relevant to this action, Cialis was designed, tested, inspected,  
8 manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised,  
9 promoted, sold, packaged, supplied and/or distributed by Defendant in a condition that was  
10 defective and unreasonably dangerous to consumers, including the Plaintiff.  
11

12 61. Cialis is defective in its design and/or formulation in that it is not reasonably fit,  
13 suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits  
14 associated with its design and formulation.  
15

16 62. Cialis was expected to reach, and did reach, users and/or consumers, including  
17 Plaintiff, without substantial change in the defective and unreasonably dangerous condition in  
18 which it was manufactured and sold.  
19

20 63. Plaintiff used Cialis as prescribed and in the foreseeable manner normally  
21 intended, recommended, promoted, and marketed by Defendant.  
22

23 64. Cialis was unreasonably dangerous in that, as designed, it failed to perform  
24 safely when used by ordinary consumers, including Plaintiff, when it was used as intended and  
25 in a reasonably foreseeable manner.  
26

27 65. Cialis was unreasonably dangerous and defective in design or formulation for its  
28 intended use in that, when it left the hands of the manufacturers and/or supplier, it posed a risk

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

4 66. Cialis was insufficiently tested and caused harmful side effects that outweighed  
5 any potential utility.

7 67. Cialis, as manufactured and supplied, was defective due to inadequate warnings,  
8 and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the  
9 results of the clinical trials, testing and study.

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

19 69. In light of the potential and actual risk of harm associated with the drug's use, a  
20 reasonable person who had actual knowledge of this potential and actual risk of harm would  
21 have concluded that Cialis should not have been marketed in that condition.

23 70. As a direct and proximate cause of the Defendant's defective design of Cialis,  
24 including the lack of appropriate warnings, Plaintiff was prescribed and used the drug rather  
25 than alternative erectile dysfunction therapies with better and/or similar efficacy. Plaintiff  
26 suffered significant pain, injury, and economic damages incurred through cancer treatment from  
27 melanoma caused by Cialis use.  
28



1 through the exercise of reasonable care, the risks of serious injury and/or death associated with  
2 and/or caused by Cialis.

3 78. Defendant knew or had knowledge that the warnings that were given failed to  
4 properly warn of the increased risks of serious injury and/or death associated with and/or caused  
5 by Cialis.  
6

7 79. Plaintiff, individually and through his prescribing physicians, reasonably relied  
8 upon the skill, superior knowledge, and judgment of the Defendant.  
9

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

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

17 82. Safer alternatives were available that were just as effective and without the risks  
18 posed by Cialis.  
19

20 83. As a direct and proximate result of Defendant's failure to warn Plaintiff or his  
21 physician of the significant melanoma-related risks associated with Cialis's mechanism of  
22 action, Plaintiff suffered significant pain, injury, and economic damages incurred through  
23 cancer treatment from melanoma caused by Cialis use.  
24

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

**COUNT III**  
**(Failure to Test)**

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

5 86. Through the testing and formulating of Cialis, and before the initiation of the  
6 drug's mass manufacture, Defendant knew or should have known in the exercise of ordinary  
7 care that the chemical reactions inherent to Cialis's mechanism of action would present a  
8 cancer-related health hazard to potential future users like Plaintiff.  
9

10 87. Defendant failed to adequately test the safety of Cialis.

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

15 89. As a direct and proximate result of Defendant's failure to adequately test Cialis,  
16 Plaintiff suffered significant pain, injury, and economic damages incurred through cancer  
17 treatment from melanoma caused by Cialis use.  
18

19 90. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks  
20 damages as detailed in the Global Prayer for Relief including: compensatory damages,  
21 exemplary damages, and punitive damages, together with interest, the costs of suit and  
22 attorneys' fees, and such other and further relief as this Court deems just and proper.  
23

24 **COUNT IV**  
25 **(Negligence)**

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

92. Defendant owed Plaintiff a duty to exercise reasonable care when designing,

1 testing, manufacturing, labeling, marketing, advertising, promoting, distributing, and/or selling  
2 Cialis.

3 93. At all relevant times to this action, Defendant owed a duty to properly warn  
4 Plaintiff, physicians, consumers, and the public of the risks, dangers and adverse side effects of  
5 Cialis, including the increased risk of serious injury and death, when the drug was used as  
6 intended or in a way that Defendant could reasonably have anticipated.  
7

8 94. Defendant breached its duty by failing to exercise ordinary care in the  
9 preparation, design, research, testing, development, manufacturing, inspection, labeling,  
10 marketing, promotion, advertising and selling of Cialis, as set forth below.  
11

12 95. Defendant failed to exercise due care under the circumstances and therefore  
13 breached this duty in numerous ways, including the following:  
14

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



1 distributing, and selling Cialis to physicians and consumers, including Plaintiff,  
2 without an adequate warning of the significant and dangerous risks of Cialis and  
3 without proper instructions to avoid the harm that could foreseeably occur as a  
4 result of using the drug;

- 5
- 6 g. failing to exercise due care when advertising and promoting Cialis;
- 7
- 8 h. negligently continuing to manufacture, market, advertise, and distribute  
9 Cialis after Defendant knew or should have known of the risks of serious injury  
10 and/or death associated with using the drug;
- 11
- 12 i. failing to use due care in the preparation and development of Cialis to  
13 prevent the aforementioned risk of injuries to individuals when the drug was  
14 ingested;
- 15
- 16 j. failing to use due care in the design of Cialis to prevent the  
17 aforementioned risk of injuries to individuals when the drug was ingested;
- 18
- 19 k. failing to conduct adequate pre-clinical testing and research to determine  
20 the safety of Cialis;
- 21
- 22 l. failing to conduct adequate post-marketing surveillance and exposure  
23 studies to determine the safety of Cialis, while Defendant knew or should have  
24 known that post-marketing surveillance would be the only means to determine  
25 the relative risk of Cialis for causing serious injury and/or death in the absence of  
26 clinical trials, and that such surveillance would be necessary for a due diligence  
27 program that would alert Defendant of the need to change the drug's warnings or  
28 to withdraw it from the market altogether;

- 1 m. failing to completely, accurately and in a timely fashion, disclose the  
2 results of the pre-marketing testing and post-marketing surveillance and testing  
3 to Plaintiff, Plaintiff's physicians, other consumers, the medical community, and  
4 the FDA;
- 5  
6 n. failing to accompany Cialis with adequate and proper warnings regarding  
7 all possible adverse side effects, including serious injury (e.g., development  
8 and/or exacerbation of melanoma) associated with the use of the same and  
9 instructions on ways to safely use Cialis to avoid injury;
- 10  
11 o. failing to use due care in the manufacture, inspection, and labeling of  
12 Cialis to prevent the aforementioned risk of injuries to individuals who used the  
13 drug;
- 14  
15 p. failing to use due care in the promotion of Cialis to prevent the  
16 aforementioned risk of injuries to individuals when the drug was ingested;
- 17  
18 q. failing to use due care in the sale and marketing of Cialis to prevent the  
19 aforementioned risk of injuries to individuals when the drug was ingested;
- 20  
21 r. failing to use due care in the selling of Cialis to prevent the  
22 aforementioned risk of injuries to individuals when the drug was ingested;
- 23  
24 s. failing to provide adequate and accurate training and information to the  
25 sales representatives who sold the drug;
- 26  
27 t. failing to provide adequate and accurate training and information to  
28 healthcare providers for the appropriate use of Cialis;
- u. failing to conduct or fund research into the development of medications

1 of this type which would pose the least risk of causing serious injury and death  
2 as alleged herein, into the early detection of persons who might be most  
3 susceptible to such reactions, and into the development of better remedies and  
4 treatment for those who experience these tragic adverse reactions;

5  
6 v. failing to educate healthcare providers, patients, and the public about the  
7 safest use of the drug;

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

11 x. being otherwise reckless, careless and/or negligent.

12  
13 96. Despite the fact that Defendant knew or should have known that Cialis increased  
14 the risk of serious injury and/or death, Defendant continued to promote and market Cialis to  
15 doctors and to consumers, including Plaintiff, when safer and more effective methods of  
16 treatment were available.

17  
18 97. As a direct and proximate result of the negligence committed by Defendant in  
19 testing and ultimately selling Cialis, Plaintiff suffered significant pain, injury, and economic  
20 damages incurred through cancer treatment from melanoma caused by Cialis use.

21  
22 98. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks  
23 damages as detailed in the Global Prayer for Relief including: compensatory damages,  
24 exemplary damages, and punitive damages, together with interest, the costs of suit and  
25 attorneys' fees, and such other and further relief as this Court deems just and proper.  
26  
27  
28

**COUNT V**  
**(Gross Negligence)**

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

5           100. Defendant had a duty to exercise reasonable care in the warning about, design,  
6 testing, manufacture, marketing, labeling, sale, and/or distribution of Cialis, including a duty to  
7 ensure that Defendant's product, Cialis, did not cause users to suffer from unreasonable and  
8 dangerous side effects.  
9

10           101. Defendant failed to exercise reasonable care in the warning about, design,  
11 testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's product,  
12 Cialis, in that Defendant knew or should have known that taking Cialis caused unreasonable and  
13 life-threatening injuries, as alleged herein.  
14

15           102. Defendant was grossly negligent under the circumstances and breached its duty  
16 of care in numerous ways, including the following:  
17

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

- e. failing to conduct adequate analysis of adverse event reports;
- f. designing, manufacturing, marketing, advertising, distributing, and selling Cialis to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Cialis and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- g. failing to exercise due care when advertising and promoting Cialis;
- h. recklessly continuing to manufacture, market, advertise, and distribute Cialis after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;
- i. failing to use due care in the preparation and development of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- j. failing to use due care in the design of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;
- k. failing to conduct adequate pre-clinical testing and research to determine the safety of Cialis;
- l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Cialis, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of Cialis for causing serious injury and death

1 as alleged herein in the absence of clinical trials, and that such  
2 surveillance would be necessary for a due diligence program that would  
3 alert Defendant to the need to change the drug's warnings or to withdraw  
4 it from the market altogether;

- 5
- 6 m. failing to completely, accurately and in a timely fashion, disclose the  
7 results of the pre-marketing testing and post-marketing surveillance and  
8 testing to Plaintiff, his doctors, other consumers, the medical community,  
9 and the FDA;
- 10
- 11 n. failing to accompany Cialis with proper warnings regarding all possible  
12 adverse side effects associated with the use of the same;
- 13
- 14 o. failing to use due care in the manufacture, inspection, and labeling of  
15 Cialis to prevent the aforementioned risk of injuries to individuals who  
16 used the drug;
- 17
- 18 p. failing to use due care in the promotion of Cialis to prevent the  
19 aforementioned risk of injuries to individuals when the drug was  
20 ingested;
- 21
- 22 q. failing to use due care in the sale and marketing of Cialis to prevent the  
23 aforementioned risk of injuries to individuals when the drug was  
24 ingested;
- 25
- 26 r. failing to provide adequate and accurate training and information to the  
27 sales representatives who sold the drug;  
28

- s. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of 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 drug;
- v. failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and
- w. was otherwise grossly negligent.

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

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

105. Defendant knew of, or recklessly disregarded the defective nature of Defendant's product, Cialis, as set forth herein, but continued to design, manufacture, market, and sell Cialis,

1 so as to maximize sales and profits at the expense of the health and safety of the public,  
2 including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by  
3 Cialis.

4  
5 106. As a direct and proximate result of Defendant's gross negligence, Plaintiff  
6 suffered significant pain, injury, and economic damages incurred through cancer treatment from  
7 melanoma caused by Cialis use.

8  
9 107. **WHEREFORE**, Plaintiff demands judgment against Defendant 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  
14 **COUNT VI**  
**(Negligence Per Se)**

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

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

24  
25 110. By reason of its conduct as alleged herein, Defendant violated provisions of  
26 statutes and regulations, including, but not limited to, the following:  
27  
28



- 1 a. Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§  
2 331 and 352, by misbranding Cialis;
- 3 b. Defendant failed to follow the “[g]eneral requirements on content and format  
4 of labeling for human prescription drugs” in violation of 21 C.F.R. § 201.56;
- 5 c. Defendant failed to follow the “[s]pecific requirements on content and format  
6 of labeling for human prescription drugs” in violation of 21 C.F.R. § 201.57;  
7 and
- 8 d. Defendant advertised and promoted Cialis in violation of 21 C.F.R. § 202.1;  
9 and
- 10 e. Defendant violated 21 C.F.R. § 201.57(e) by failing to timely and adequately  
11 change the Cialis label to reflect the evidence of an association between  
12 Cialis and the development and/or exacerbation of melanoma suffered by  
13 Plaintiff.  
14 Plaintiff.

15  
16 These statutes and regulations impose a standard of conduct designed to protect  
17 consumers of drugs, including Plaintiff. Defendant’s violations of these statutes and regulations  
18 constitute negligence per se.

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

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

**COUNT VII**  
**(Breach of Express Warranty)**

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

5 114. At all times relevant hereto, Defendant expressly represented and warranted to  
6 Plaintiff and his healthcare providers, by and through statements made by Defendant or its  
7 authorized agents or sales representatives, orally and in publications, package inserts and other  
8 written materials intended for physicians, medical patients, and the general public, that Cialis is  
9 safe, effective, and proper for its intended use.  
10

11 115. Defendant breached expressed warranties with respect to Cialis in the following  
12 particulars:  
13

14 a. Defendant represented through its labeling, advertising, marketing materials,  
15 seminar presentations, publications, notice letters, and regulatory  
16 submissions that Cialis was safe, and fraudulently withheld and concealed  
17 information about the substantial risks of serious injury and/or death  
18 associated with using Cialis;  
19

20 b. Defendant represented that Cialis was as safe, and/or safer than other  
21 alternative medications and fraudulently concealed information that  
22 demonstrated that Cialis was not safer than alternatives available on the  
23 market; and  
24

25 c. Defendant represented that Cialis was more efficacious than other alternative  
26 medications and fraudulently concealed information regarding the true  
27 efficacy of the drug.  
28

1 116. Cialis does not conform to Defendant's express representations because its  
2 mechanism of action, the inhibition of the PDE5 enzyme, also increases the risk of the  
3 development and/or exacerbation of melanoma.

4 117. At all relevant times, Cialis did not perform as safely as an ordinary consumer  
5 would expect when used as intended or in a reasonably foreseeable manner.  
6

7 118. Plaintiff, Plaintiff's physicians, other consumers, and the medical community  
8 relied upon Defendant's express warranties, resulting in Plaintiff's ingestion of the drug.  
9

10 119. As a direct and proximate result of the breach of warranty committed by  
11 Defendant, Plaintiff suffered significant pain, injury, and economic damages incurred through  
12 cancer treatment from melanoma caused by Cialis use.  
13

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

19 **COUNT VIII**  
20 **(Breach of Implied Warranty)**

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

23 122. At all relevant and material times, Defendant manufactured, distributed,  
24 advertised, promoted, and sold Cialis.  
25

26 123. At all relevant times, Defendant intended that Cialis be used in the manner that  
27 Plaintiff in fact used it.  
28

1           124. Defendant impliedly warranted Cialis to be of merchantable quality, safe and fit  
2 for the use for which Defendant intended it, and Plaintiff in fact used it.

3           125. Defendant was aware that consumers, including Plaintiff, would use Cialis to  
4 achieve and maintain an erection; which is to say that Plaintiff was a foreseeable user of  
5 Defendant's product Cialis.  
6

7           126. Defendant knew, or had reason to know, that Plaintiff's physician would rely on  
8 Defendant's judgment and skill in providing Cialis for its intended use.  
9

10           127. Plaintiff and his physician reasonably relied upon the skill and judgment of  
11 Defendant as to whether Cialis was of merchantable quality, safe and fit for its intended use.  
12

13           128. The drug was expected to reach and did in fact did reach consumers, including  
14 Plaintiff, without substantial change in the condition in which it was manufactured and sold by  
15 Defendant.  
16

17           129. Defendant breached various implied warranties with respect to Cialis including  
18 the following particulars:

19           a. Defendant represented through its labeling, advertising, marketing materials,  
20 seminar presentations, publications, notice letters, and regulatory  
21 submissions that Cialis was safe and fraudulently withheld and concealed  
22 information about the substantial risks of serious injury and/or death  
23 associated with using Cialis;  
24

25           b. Defendant represented that Cialis was as safe, and/or safer than other  
26 alternative medications and fraudulently concealed information that  
27 demonstrated that Cialis was not safer than alternatives available on the  
28

1 market; and

2 c. Defendant represented that Cialis was more efficacious than other alternative  
3 medications and fraudulently concealed information regarding the true  
4 efficacy of the drug.  
5

6 130. In reliance upon Defendant's implied warranty, Plaintiff used Cialis as  
7 prescribed and in the foreseeable manner normally intended, recommended, promoted, and  
8 marketed by Defendant.  
9

10 131. Cialis was neither safe for its intended use nor of merchantable quality, as had  
11 been implicitly warranted by Defendant, in that Cialis's mechanism of action, the inhibition of  
12 PDE5, inherently presented a significant increase in the user's risk of developing and/or  
13 exacerbating melanoma.  
14

15 132. Defendant breached its implied warranty to Plaintiff in that Cialis is  
16 unreasonably dangerous, defective, and unfit for the ordinary purposes for which Cialis was  
17 used. It was not of merchantable quality, safe and fit for its intended use, or adequately tested.  
18

19 133. As a direct and proximate result of the falsity of the warranties implicated by  
20 Defendant's actions and omissions, Plaintiff suffered significant pain, injury, and economic  
21 damages incurred through cancer treatment from melanoma caused by Cialis use.  
22

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

**COUNT IX**  
**(Fraudulent Misrepresentation and Concealment)**

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

4  
5 136. Defendant intentionally and fraudulently misrepresented to consumers and  
6 physicians, including Plaintiff, Plaintiff's physicians, and the public in general, that Cialis had  
7 been tested and found to be safe, well-tolerated and/or more efficacious than alternative  
8 medications and/or methods of erectile dysfunction therapy and that Cialis's benefits  
9 outweighed its risks when used as instructed, when, in fact, Defendant knew, or should have  
10 known, and fraudulently concealed that Cialis is dangerous to patients and that the benefits of  
11 its use are far outweighed by the risks for Plaintiff and many others.

12  
13 137. At all relevant times, Defendant knew of the use for which Cialis was intended  
14 and expressly and/or impliedly warranted its drug was of merchantable quality and safe and fit  
15 for such use.

16 138. Defendant had sole access to material facts concerning the dangers and  
17 unreasonable risks of Cialis.

18  
19 139. Defendant's superior knowledge and expertise, its relationship of trust and  
20 confidence with doctors and the public, its specific knowledge regarding the risks and dangers  
21 of Cialis and its intentional dissemination of promotional and marketing information about  
22 Cialis for the purpose of maximizing its sales, each gave rise to the affirmative duty to  
23 meaningfully disclose and provide all material information about the risks and harms associated  
24 with the drug.

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

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

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

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

11 143. Defendant 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 Cialis.

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

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

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

1 b. Defendant fraudulently represented that Cialis was as safe and/or safer and/or  
2 more efficacious than other alternative erectile dysfunction therapies, and  
3 fraudulently concealed information that demonstrated that Cialis was not  
4 safer and/or more efficacious than alternatives available on the market.

5 146. Defendant knew, had reason to know, or should have known, that these  
6 representations and actively concealed adverse information were false, and that Cialis had  
7 defects and was unreasonably dangerous. Yet, Defendant willfully, wantonly, and recklessly  
8 disregarded its obligation to provide truthful representations regarding the safety and risk of  
9 Cialis to consumers, including Plaintiff, and to the medical community.  
10

11 147. Defendant did not have adequate proof upon which to base such representations,  
12 and in fact, given Defendant's knowledge about Cialis's pharmacology and reported adverse  
13 events, Defendant knew, or should have known, that these representations, omissions and/or  
14 concealments were false and fraudulent. Specifically, Defendant knew of, possessed evidence  
15 and/or had reason to know that Cialis had defects and was unreasonably dangerous, causing the  
16 development and/or exacerbation of melanoma, as detailed herein.  
17

18 148. Defendant's misrepresentations were made with the intent that physicians and  
19 patients, including Plaintiff, would rely upon them and were made with the intent of defrauding  
20 and deceiving Plaintiff, other consumers, and the medical community to induce and encourage  
21 the sale of Cialis.  
22

23 149. Plaintiff, Plaintiff's physicians, and others, did rely upon and/or were induced by  
24 the misrepresentations, omissions and/or active concealment of the dangers of Cialis to the  
25 detriment of the Plaintiff.  
26

27 150. Defendant's fraudulent representations and concealments evince its callous,  
28 reckless, willful, and depraved indifference to the health, safety, and welfare of consumers,  
including Plaintiff.



1 151. In selecting treatment, Plaintiff's physicians and Plaintiff relied on and were  
2 induced by Defendant's misrepresentations concerning the dangers of Cialis.

3 152. As detailed herein, Defendant made these fraudulent misrepresentations,  
4 omissions and concealments through statements and comments to the press, labeling,  
5 advertising, marketing and promotion materials, seminar presentations, publications, Dear  
6 Doctor letters, and regulatory submissions.

7 153. Plaintiff and the treating medical community did not know that the  
8 representations, omissions, and/or concealments made by Defendant were false and were  
9 justified in reasonably relying upon Defendant's representations.  
10

11 154. Had Defendant not fraudulently misrepresented and concealed such information,  
12 Plaintiff would not have ingested Cialis and suffered resulting harm.

13 155. Defendant made the aforesaid representations and concealments intentionally  
14 and in the course of Defendant's business as designers, manufacturers, and distributors of Cialis  
15 despite having no reasonable basis for the assertion that these representations were true, without  
16 having accurate or sufficient information concerning the aforesaid representations and/or  
17 knowing these representations were false. Defendant was aware that without such information it  
18 could not accurately make the aforesaid representations.  
19

20 156. At the time Defendant made the aforesaid representations and at the time  
21 Plaintiff received Cialis, Plaintiff, Plaintiff's physicians, and the public in general reasonably  
22 believed them to be true. At the time that Plaintiff received Cialis, Defendant failed to  
23 adequately inform Plaintiff and/or his prescribing doctors that Cialis use increased the risk of  
24 the development and/or exacerbation of melanoma, despite Defendant being in possession of  
25 such evidence. Plaintiff received no adequate warnings, either written or verbal, that Cialis  
26 caused these side effects, and relied on these omissions and concealments.  
27  
28

1 157. As a direct and proximate consequence of Defendant's fraudulent  
2 misrepresentations, omissions, and intentional concealment of material facts, upon which  
3 Plaintiff reasonably relied, Plaintiff sustained significant pain, injury, harm, suffering, and  
4 economic damages incurred through cancer treatment from melanoma caused by Cialis use.

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

10 **COUNT X**  
11 **(Negligent Misrepresentation and Concealment)**

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

14 160. At all relevant times, Defendant designed, tested, manufactured, packaged,  
15 marketed, distributed, promoted, and sold Cialis.

16 161. At all relevant times, Defendant knew of the use for which Cialis was intended  
17 and expressly and/or impliedly warranted that the drug was of merchantable quality and safe  
18 and fit for such use.  
19

20 162. Defendant's 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 Cialis, and its intentional dissemination of promotional and marketing information about  
23 Cialis for the purpose of maximizing its sales, each gave rise to the affirmative duty to disclose  
24 and provide all material information about the risks and harms associated with the drug.  
25

26 163. Defendant recklessly, and/or negligently represented to Plaintiff, Plaintiff's  
27 physicians, and other persons and professionals whom Defendant knew would rely, that Cialis  
28

1 was safe to ingest and that the utility of this product outweighed any risk in use for their  
2 intended purposes.

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

7 165. Defendant led Plaintiff to rely upon the safety of the product in its use.

8 166. The false representations of the Defendant were recklessly and/or negligently  
9 made in that Cialis in fact caused injury, was unsafe, and the benefits of its use were far  
10 outweighed by the risk associated with use thereof.

11 167. Defendant committed acts of reckless and/or negligent misrepresentation and  
12 reckless and/or negligent concealment by suppressing material facts relating to the dangers and  
13 injuries associated with, and caused by, the use of Cialis.

14 168. Defendant knew or should have known that its representations and/or omissions  
15 were false. Defendant made such false, negligent and/or reckless representations with the intent  
16 or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations, leading  
17 to the use of Cialis by Plaintiff.

18 169. Defendant recklessly and/or negligently misrepresented, and/or omitted  
19 information with respect to Cialis in the following particulars:

- 20 a. Defendant represented through its labeling, advertising, marketing materials,  
21 seminar presentations, publications, notice letters, and regulatory  
22 submissions that Cialis was safe and fraudulently withheld and concealed  
23 information about the substantial risks of serious injury and/or death  
24 associated with using Cialis;  
25  
26  
27  
28

1 b. Defendant represented that Cialis was as safe and/or safer than other  
2 alternative erectile dysfunction therapies and fraudulently concealed  
3 information, which demonstrated that Cialis was not safer than alternatives  
4 available on the market; and

5 c. Defendant represented that Cialis was more efficacious than other alternative  
6 erectile dysfunction therapies and fraudulently concealed information,  
7 regarding the true efficacy of the drug.  
8

9 170. Defendant made affirmative misrepresentations and recklessly and/or negligently  
10 omitted material adverse information regarding the safety and effectiveness of Cialis.

11 171. Defendant made these misrepresentations and/or omissions at a time when  
12 Defendant knew or had reason to know that Cialis had defects and was unreasonably dangerous  
13 and was not what Defendant had represented to the medical community, the FDA and the  
14 consuming public, including Plaintiff.

15 172. Defendant omitted, suppressed, and/or concealed material facts concerning the  
16 dangers and risk of injuries associated with the use of Cialis including, serious injury and death.  
17 Furthermore, Defendant was willfully blind to, ignored, downplayed, avoided, and/or otherwise  
18 understated the serious nature of the risks associated with the use of Cialis in order to increase  
19 sales.  
20

21 173. Defendant's misrepresentations and/or omissions were undertaken by Defendant  
22 with an intent that doctors and patients, including Plaintiff, rely upon them.  
23

24 174. Defendant's misrepresentations and/or omissions were undertaken with the intent  
25 of defrauding and/or deceiving Plaintiff, other consumers, and the medical community to induce  
26 and encourage the sale of Cialis.  
27  
28

1 175. Defendant's misrepresentations and/or omissions evinced the Defendant's  
2 callous, reckless, willful, and depraved indifference to the health, safety, and welfare of  
3 consumers, including Plaintiff.

4 176. Plaintiff's physician and Plaintiff relied on and were induced by Defendant's  
5 misrepresentations, omissions, and/or active concealment of the dangers of Cialis in selecting  
6 treatment.

7 177. Plaintiff and Plaintiff's physicians did not know that the representations made by  
8 Defendant were false and were justified in relying upon Defendant's representations.

9 178. Had Plaintiff been aware of the increased risk of side effects associated with  
10 Cialis and the relative efficacy of Cialis compared with other readily available alternative  
11 erectile dysfunction therapies, Plaintiff would not have taken Cialis.

12 179. As a direct and proximate consequence of Defendant's misrepresentations,  
13 Plaintiff sustained injuries and damages alleged herein including specifically those alleged  
14 herein.

15 180. Plaintiff relied on the misrepresentations made by Defendant in purchasing and  
16 using Cialis.

17 181. Plaintiff's reliance on Defendant's misrepresentations was justified because such  
18 misrepresentations were made by entities that were in a position to know of and disclose any  
19 potentially harmful information concerning the use of Cialis.

20 182. If Plaintiff had known of the information concealed by Defendant regarding the  
21 melanoma-related risks posed by Cialis, Plaintiff would not have purchased and subsequently  
22 used Cialis.

23 183. As a direct and proximate result of the negligent misrepresentations by  
24 Defendant, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred  
25 through cancer treatment from melanoma caused by Cialis use.





1 and dangerous risks of Cialis and without proper instructions to avoid the harm  
2 which could foreseeably occur as a result of using the drug;

- 3 g. failed to exercise due care when advertising and promoting Cialis;
- 4 h. willfully and wantonly continued to manufacture, market, advertise, and  
5 distribute Cialis after Defendant knew or should have known of the risks of  
6 serious injury and/or death associated with using the drug;
- 7 i. willfully and wantonly failed to use due care in the preparation and development  
8 of Cialis to prevent the aforementioned risk of injuries to individuals when the  
9 drug was ingested;
- 10 j. willfully and wantonly failed to use due care in the design of Cialis to prevent  
11 the aforementioned risk of injuries to individuals when the drug was ingested;
- 12 k. failed to conduct adequate pre-clinical testing and research to determine the  
13 safety of Cialis;
- 14 l. failed to conduct adequate post-marketing surveillance and exposure studies to  
15 determine the safety of Cialis, while Defendant knew or should have known that  
16 post-marketing surveillance would be the only means to determine the relative  
17 risk of Cialis for causing such serious injury and death as alleged herein in the  
18 absence of clinical trials, and that such surveillance would be necessary for a due  
19 diligence program that would alert Defendant to the need to change the drug's  
20 warnings or to withdraw it from the market altogether;
- 21 m. failed to completely, accurately and in a timely fashion, disclose the results of  
22 the pre-marketing testing and post-marketing surveillance and testing to Plaintiff,  
23 Plaintiff's physicians, other consumers, the medical community, and the FDA;
- 24 n. failed to accompany Cialis with proper warnings regarding all possible adverse  
25 side effects associated with the use of the same;  
26  
27  
28



- 1 o. willfully and wantonly failed to use due care in the manufacture, inspection, and  
2 labeling of Cialis to prevent the aforementioned risk of injuries to individuals  
3 who used the drug;
- 4 p. willfully and wantonly failed to use due care in the promotion of Cialis to  
5 prevent the aforementioned risk of injuries to individuals when the drug was  
6 ingested;
- 7 q. willfully and wantonly failed to use due care in the sale and marketing of Cialis  
8 to prevent the aforementioned risk of injuries to individuals when the drug was  
9 ingested;
- 10 r. willfully and wantonly failed to use due care in the selling of Cialis to prevent  
11 the aforementioned risk of injuries to individuals when the drug was ingested;
- 12 s. failed to provide adequate and accurate training and information to the sales  
13 representatives who sold the drug;
- 14 t. failed to provide adequate and accurate training and information to healthcare  
15 providers for the appropriate use of Cialis;
- 16 u. failed to conduct or fund research into the development of medications of this  
17 type which would pose the least risk of causing serious injury and death as  
18 alleged herein, into the early detection of persons who might be most susceptible  
19 to such reactions, and into the development of better remedies and treatment for  
20 those who experience these tragic adverse reactions;
- 21 v. failed to educate healthcare providers and the public about the safest use of the  
22 drug;
- 23 w. failed to give healthcare providers adequate information to weigh the risks of  
24 serious injury and/or death for a given patient; and
- 25 x. otherwise behaved willfully, wantonly, and maliciously.
- 26  
27  
28







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.)

<p><b>I. (a) PLAINTIFFS</b></p> <p>DENNIS BJORGE</p> <p><b>(b)</b> County of Residence of First Listed Plaintiff <input type="checkbox"/> WASHTEAW <i>(EXCEPT IN U.S. PLAINTIFF CASES)</i></p> <p><b>(c)</b> Attorneys <i>(Firm Name, Address, and Telephone Number)</i></p> <p>Trevor B. Rockstad, Esq., Davis &amp; Crump, P.C., 2601 14th Street, Gulfport, MS 39501; (228) 863-6000; trevor.rockstad@daviscrump.com</p>	<p><b>DEFENDANTS</b></p> <p>ELI LILLY AND COMPANY</p> <p>County of Residence of First Listed Defendant <input type="checkbox"/> MARION <i>(IN U.S. PLAINTIFF CASES ONLY)</i></p> <p>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED Attorneys <i>(If Known)</i></p>
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<p><b>II. BASIS OF JURISDICTION</b> <i>(Place an "X" in One Box Only)</i></p> <p><input type="checkbox"/> 1 U.S. Government Plaintiff</p> <p><input type="checkbox"/> 2 U.S. Government Defendant</p> <p><input type="checkbox"/> 3 Federal Question <i>(U.S. Government Not a Party)</i></p> <p><input checked="" type="checkbox"/> 4 Diversity <i>(Indicate Citizenship of Parties in Item III)</i></p>	<p><b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> <i>(Place an "X" in One Box for Plaintiff and One Box for Defendant)</i></p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td></td> <td style="text-align: center;">PTF</td> <td style="text-align: center;">DEF</td> <td></td> <td style="text-align: center;">PTF</td> <td style="text-align: center;">DEF</td> </tr> <tr> <td>Citizen of This State</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF		PTF	DEF	Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
	PTF	DEF		PTF	DEF																				
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Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

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

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

**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 drug 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: 01/13/2017   SIGNATURE OF ATTORNEY OF RECORD: /s/ Trevor B. Rockstad