

1 ARATI C. FURNESS (CA SBN: 225435)  
 afurness@fnlawfirm.com  
 2 PATRICK A. LUFF (TX SBN: 24092728)  
*Application for Admission Pro Hac Vice Anticipated*  
 3 pluff@fnlawfirm.com  
 4 **FEARS NACHAWATI, PLLC**  
 5473 Blair Road  
 5 Dallas, Texas 75231  
 Telephone: (214) 890-0711  
 6 Facsimile: (214) 890-0712  
 7 *Attorneys for Plaintiff*

8  
 9 **UNITED STATES DISTRICT COURT**  
 10 **FOR THE EASTERN DISTRICT OF CALIFORNIA**

11		)	
12	IRIS SMITH	)	Case No.: 2:20-at-01181
13		)	
	Plaintiff,	)	
14		)	
	vs.	)	<b><u>ORIGINAL COMPLAINT</u></b>
15	JANSSEN PHARMACEUTICALS, INC. f/k/a	)	
16	JANSSEN PHARMACEUTICA INC. f/k/a	)	<b>JURY TRIAL DEMANDED</b>
17	ORTHO-MCNEIL-JANSSEN	)	
18	PHARMACEUTICALS, INC.; JANSSEN	)	
19	ORTHO LLC; JANSSEN RESEARCH &	)	
20	DEVELOPMENT LLC f/k/a JOHNSON AND	)	
21	JOHNSON PHARMACEUTICAL RESEARCH	)	
22	AND DEVELOPMENT LLC; ORTHO-MCNEIL	)	
23	PHARMACEUTICALS, LLC; JOHNSON &	)	
24	JOHNSON COMPANY; TEVA BRANDED	)	
25	PHARMACEUTICAL PRODUCTS R&D, INC.;	)	
26	AND TEVA PHARMACEUTICALS USA, INC.	)	
27		)	
28	Defendants.	)	

1 Plaintiff Iris Smith, upon information and belief, files this Original Complaint, and would  
2 respectfully show as follows:

3 **JURISDICTION AND VENUE**

4 1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because  
5 the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and because there  
6 is complete diversity between Plaintiff and Defendants.

7 2. This Court has personal jurisdiction over Defendants consistent with the U.S.  
8 Constitution because Plaintiff's claims arise out of Defendants' transaction of business and the  
9 tortious acts within the State of California, and by virtue of Defendants' substantial, continuous,  
10 and systematic contacts with the State of California unrelated to Plaintiff's claims.

11 **NATURE OF THE CASE**

12 3. This is an action for damages suffered by Plaintiff as a direct and proximate result  
13 of Defendants' negligent and wrongful conduct in connection with the design, development,  
14 manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of  
15 Elmiron for the relief of bladder pain or discomfort associated with interstitial cystitis.

16 4. Defendants Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica Inc. f/k/a  
17 Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Janssen Ortho LLC; Janssen Research &  
18 Development LLC f/k/a Johnson and Johnson Pharmaceutical Research and Development LLC;  
19 Johnson & Johnson Company; Ortho-McNeil Pharmaceuticals, LLC; Teva Branded  
20 Pharmaceutical Products R&D, Inc.; and Teva Pharmaceuticals USA, Inc. (hereinafter collectively  
21 referred to as "Defendants") concealed, and continue to conceal, their knowledge of Elmiron's  
22 unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

23 5. As a result of the defective nature of Elmiron, persons who were prescribed and  
24 ingested Elmiron, including Plaintiff Iris Smith, have suffered and may continue to suffer severe  
25 and permanent personal injuries, including but not limited to retinal pigmentary changes, vision  
26 changes, and potentially irreversible vision damage.

1 6. After beginning treatment with Elmiron, and as a direct and proximate result of  
2 Defendants' actions and inaction, Plaintiff Iris Smith suffered retinal pigmentary changes. Plaintiff  
3 Iris Smith's ingestion of the defective and unreasonably dangerous drug Elmiron has caused and  
4 will continue to cause her injury and damage.

5 7. Plaintiff brings this action for personal injuries suffered as a proximate result of  
6 Plaintiff Iris Smith being prescribed and ingesting Elmiron. Plaintiff accordingly seeks  
7 compensatory and punitive damages, monetary restitution, and all other available remedies as a  
8 result of injuries caused by Elmiron.

9 **PLAINTIFF**

10 8. Plaintiff, Iris Smith, is a citizen and resident of the State of California.

11 9. Plaintiff Iris Smith began taking Elmiron in or about 2000.

12 10. As result of using Defendants' Elmiron, Plaintiff Iris Smith, was caused to suffer  
13 retinal pigmentary changes.

14 11. As a result of using Defendants' Elmiron, Plaintiff Iris Smith was caused to sustain  
15 severe and permanent personal injuries, pain, suffering, and emotional distress.

16 12. The injuries and damages sustained by Plaintiff were caused by Defendants'  
17 Elmiron.

18 **DEFENDANTS**

19 13. Upon information and belief, Defendant Janssen Pharmaceuticals, Inc. f/k/a  
20 Janssen Pharmaceutica Inc. f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. (hereinafter  
21 referred to as "Janssen Pharm") is a Pennsylvania corporation, having a principal place of business  
22 at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560, and is a wholly owned subsidiary  
23 of Defendant Johnson & Johnson Company.

24 14. As part of its business, Defendant Janssen Pharm is involved in the research,  
25 development, design, licensing, manufacture, distribution, supply, sales and/or marketing, and  
26 introduction into interstate commerce, either directly or indirectly through third parties or related  
27 entities, of pharmaceutical products including Elmiron and pentosan polysulfate sodium.

1 15. Upon information and belief, Defendant Janssen Pharm has transacted and  
2 conducted business in the State of New Jersey and the State of California.

3 16. Upon information and belief, Defendant Janssen Pharm, has derived substantial  
4 revenue from goods and products used in the State of California.

5 17. Upon information and belief, Defendant Janssen Pharm expected or should have  
6 expected its acts to have consequence within the United States of America and the State of  
7 California and derived substantial revenue from interstate commerce within the United States and  
8 the State of California.

9 18. Upon information and belief, and at all relevant times, Defendant Janssen Pharm  
10 was in the business of and did design, research, manufacture, test, advertise, promote, market, sell,  
11 and distribute the drug Elmiron for the relief of bladder pain or discomfort associated with  
12 interstitial cystitis.

13 19. Upon information and belief, Defendant Janssen Ortho LLC (hereinafter referred  
14 to as “Janssen Ortho”) is a limited liability company organized under the laws of Delaware, having  
15 a principal place of business at Stateroad 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778.  
16 Defendant Janssen Ortho is a subsidiary of Johnson & Johnson.

17 20. As part of its business, Defendant Janssen Ortho is involved in the research,  
18 development, sales, and marketing of pharmaceutical products including Elmiron and pentosan  
19 polysulfate sodium.

20 21. Upon information and belief, Defendant Janssen Ortho has transacted and  
21 conducted business in the State of California.

22 22. Upon information and belief, Defendant Janssen Ortho has derived substantial  
23 revenue from goods and products used in the State of California.

24 23. Upon information and belief, Defendant Janssen Ortho expected or should have  
25 expected its acts to have consequence within the United States and the State of California and  
26 derived substantial revenue from interstate commerce within the United States and the State of  
27 California.

1 24. Upon information and belief, and at all relevant times, Defendant Janssen Ortho  
2 was in the business of and did design, research, manufacture, test, advertise, promote, market, sell,  
3 and distribute the drug Elmiron for the relief of bladder pain or discomfort associated with  
4 interstitial cystitis.

5 25. Upon information and belief, Defendant Janssen Research & Development LLC  
6 f/k/a Johnson and Johnson Research and Development LLC (hereinafter referred to as “Janssen  
7 R&D”) is a limited liability company organized under the laws of New Jersey, with a principal  
8 place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New  
9 Jersey 08933. Defendant Janssen R&D’s sole member, Centocor Research & Development, Inc.,  
10 is a Pennsylvania corporation with a principal place of business in Pennsylvania. Accordingly,  
11 Janssen R&D is a citizen of Pennsylvania and New Jersey for purposes of 28 U.S.C. § 1332.

12 26. Upon information and belief, Defendant Janssen R&D has transacted and  
13 conducted business in the State of California.

14 27. Upon information and belief, Defendant Janssen R&D has derived substantial  
15 revenue from good and products used in the State of California.

16 28. Upon information and belief, Defendant Janssen R&D expected or should have  
17 expected its acts to have consequence within the United States and the State of California and  
18 derived substantial revenue from interstate commerce within the United States and the State of  
19 California.

20 29. Upon information and belief, and at all relevant times, Defendant Janssen R&D  
21 was in the business of and did design, research, manufacture, test, advertise, promote, market, sell,  
22 and distribute the drug Elmiron for the relief of bladder pain or discomfort associated with  
23 interstitial cystitis.

24 30. Upon information and belief, Defendant Ortho-McNeil Pharmaceuticals, Inc.  
25 (hereinafter referred to as “Ortho Pharma”) is a corporation organized under the laws of Delaware  
26 with its principal place of business at 1000 US Highway 202, Raritan, New Jersey 08869, and is a  
27 wholly owned subsidiary of Defendant Johnson & Johnson Company.

1 31. Upon information and belief, Defendant Ortho Pharma has transacted and  
2 conducted business in the State of California.

3 32. Upon information and belief, Defendant Ortho Pharma has derived substantial  
4 revenue from good and products used in the State of California.

5 33. Upon information and belief, Defendant Ortho Pharma expected or should have  
6 expected its acts to have consequence within the United States and the State of California and  
7 derived substantial revenue from interstate commerce within the United States and the State of  
8 California.

9 34. Upon information and belief, and at all relevant times, Defendant Ortho Pharma  
10 was in the business of and did design, research, manufacture, test, advertise, promote, market, sell,  
11 and distribute the drug Elmiron for the relief of bladder pain or discomfort associated with  
12 interstitial cystitis.

13 35. Upon information and belief, Defendant Johnson & Johnson Company (“J&J”) is  
14 a corporation organized under the laws of New Jersey with its principal place of business at One  
15 Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

16 36. Upon information and belief, and at all relevant times, Defendants Janssen Pharm,  
17 Ortho Pharma, and Janssen R&D are wholly owned subsidiaries of Defendant J&J.

18 37. As part of its business, Defendant J&J is and at all relevant times was, involved in  
19 the research, development, design, licensing, manufacture, distribution, supply, packaging,  
20 labeling, sales, and/or marketing and introduction into interstate commerce, either directly or  
21 indirectly through third parties or related entities, of pharmaceutical products including Elmiron.  
22 Defendant J&J manufactures, markets, and sells a wide range of pharmaceutical products  
23 including Elmiron and pentosan polysulfate sodium.

24 38. Upon information and belief, Defendant J&J has transacted and conducted business  
25 in the State of California.

26 39. Upon information and belief, Defendant J&J has derived substantial revenue from  
27 goods and products used in the State of California.

1 40. Upon information and belief, Defendant J&J expected or should have expected its  
2 acts to have consequence within the United States and the State of California and derived  
3 substantial revenue from interstate commerce within the United States and the State of California.

4 41. Upon information and belief, and at all relevant times, Defendant J&J was in the  
5 business of and did design, research, manufacture, test, advertise, promote, market, sell, and  
6 distribute the drug Elmiron for the relief of bladder pain or discomfort associated with interstitial  
7 cystitis.

8 42. Upon information and belief, Defendant Teva Branded Pharmaceutical Products  
9 R&D, Inc. (hereinafter referred to as “Teva R&D”) is a corporation organized under the laws of  
10 Delaware, having a principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

11 43. As part of its business, Defendant Teva R&D is involved in the research,  
12 development, sales, and marketing of pharmaceutical products including Elmiron and pentosan  
13 polysulfate sodium.

14 44. Upon information and belief, Defendant Teva R&D has transacted and conducted  
15 business in the State of New Jersey and the State of California.

16 45. Upon information and belief, Defendant Teva R&D has derived substantial revenue  
17 from goods and products used in the State of New Jersey and the State of California.

18 46. Upon information and belief, Defendant Teva R&D expected or should have  
19 expected its acts to have consequence within the United States and the State of California and  
20 derived substantial revenue from interstate commerce within the United States and the State of  
21 California.

22 47. Upon information and belief, and at all relevant times, Defendant Teva R&D was  
23 in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and  
24 distribute the drug Elmiron for the relief of bladder pain or discomfort associated with interstitial  
25 cystitis.

26 48. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. (“Teva  
27 USA”) is a corporation organized under the laws of Delaware with its principal place of business

1 at 400 Interpace Parkway, Parsippany, NJ 07054.

2 49. As part of its business, Defendant Teva USA is involved in the research,  
3 development, sales, and marketing of pharmaceutical products including Elmiron and pentosan  
4 polysulfate sodium.

5 50. Upon information and belief, Defendant Teva USA has transacted and conducted  
6 business in the State of New Jersey and the State of California.

7 51. Upon information and belief, Defendant Teva USA has derived substantial revenue  
8 from goods and products used in the State of New Jersey and the State of California.

9 52. Upon information and belief, Defendant Teva USA expected or should have  
10 expected its acts to have consequence within the United States of America and the State of New  
11 Jersey and the State of California and derived substantial revenue from interstate commerce within  
12 the United States and the State of New Jersey and the State of California, more particularly.

13 53. Upon information and belief, and at all relevant times, Defendant Teva USA was  
14 in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and  
15 distribute the drug Elmiron for the relief of bladder pain or discomfort associated with interstitial  
16 cystitis.

17 **FACTUAL BACKGROUND**

18 54. Pentosan polysulfate sodium (hereinafter referred to as “PPS”) is a semi-  
19 synthetically produced low molecular weight heparin-like compound and is marketed in the United  
20 States by Defendants under the name Elmiron.

21 55. Upon information and belief, Defendant TEVA R&D licenses Elmiron to  
22 Defendant Janssen Pharm, a wholly owned subsidiary of Defendant J&J, for manufacture,  
23 marketing, advertising, distribution, and sale of Elmiron in the United States, including in the State  
24 of New Jersey and the State of California.

25 56. Upon information and belief, the original New Drug Application (hereinafter  
26 referred to as “NDA”) for Elmiron was submitted by Baker Norton Pharmaceuticals, Inc.  
27 (hereinafter referred to as “the sponsor”), which was owned by Ivax Corporation. Ivax Corporation



1 licensed Elmiron to Ortho-McNeil Pharmaceutical, Inc. n/k/a Defendant Janssen Pharm.  
2 Defendant TEVA R&D then purchased Ivax Corporation and continued to license Elmiron to  
3 Defendant Janssen Pharm.

4 57. Elmiron sales in the United States total more than \$150 million each year.

5 58. Elmiron was the first oral medication approved for use to relieve bladder pain or  
6 discomfort associated with interstitial cystitis.

7 59. Interstitial cystitis is a chronic bladder condition affecting millions of people,  
8 mainly women, in the United States that causes increased bladder pressure, bladder pain, and even  
9 pelvic pain that can often be severe. There is currently no cure for interstitial cystitis.

10 60. On August 7, 1985, the United States Food and Drug Administration (hereinafter  
11 referred to as “FDA”) designated Elmiron an orphan drug product due to the rarity of interstitial  
12 cystitis.

13 61. The sponsor submitted its first NDA for approval on June 11, 1991 which included  
14 data from two clinical trials (referred to as study 001 and 002).

15 62. On January 27, 1993, FDA issued its first non-approval letter due to numerous  
16 problems with the clinical trial analyses and results, as well as interaction between the clinical trial  
17 investigators. Specifically, FDA stated that the NDA lacked the requisite two (2) adequate and  
18 well-controlled studies for determining the effects of Elmiron. FDA requested that the sponsor  
19 conduct another well-controlled, ideally blinded and randomized, clinical trial and to exclude  
20 certain investigators.

21 63. In response, the sponsor declined to perform an additional clinical trial and instead  
22 re-analyzed the data from the two pivotal studies already submitted.

23 64. On October 28, 1994, FDA issued a second non-approval letter due to insufficient  
24 clinical trial evidence to establish efficacy. Once again, the FDA emphasized that the studies could  
25 not be considered independent due to issues with the investigators. In removing the data generated  
26 by those investigators, neither study was powered to show statistical significance for any of the  
27 primary efficacy endpoints. While FDA did find that study 002 provide some evidence of efficacy,

1 it once again encouraged the sponsor to perform another well-controlled, sufficiently powered  
2 clinical trial and to exclude any investigators involved in study 002.

3 65. The sponsor continued to decline to perform an additional clinical trial and instead  
4 proposed an analysis of the database from its Compassionate Use program established in 1986,  
5 which it submitted to FDA on August 31, 1995.

6 66. Ultimately, for its third resubmission of the NDA, the sponsor relied on two clinical  
7 studies. The first study (study 002) was a blinded, randomized, placebo-controlled trial that  
8 evaluated only 151 patients for three (3) months. Of the patients receiving Elmiron, 38% reported  
9 greater than 50% improvement in bladder pain compared to 18% of the placebo patients. FDA  
10 noted that the study indicated a statistically significant treatment effect for only two (2) of six (6)  
11 identified efficacy endpoints – the patient’s evaluation of bladder pain and the investigator’s  
12 evaluation of overall improvement – both of which allow for bias that undermines the validity of  
13 the results. Further, FDA also noted that one investigator in particular influenced the results, and  
14 when the data from that investigator were removed, the results still favored Elmiron over placebo  
15 but were no longer statistically significant.

16 67. The second clinical trial was an unblinded retrospective analysis of 2,499 patients,  
17 mostly women, in the Elmiron Compassionate Use program. After three (3) months, over half of  
18 the patients dropped out or were deemed ineligible for the trial; importantly, 31% of those patients  
19 reported lack of efficacy and 17% reported an adverse event. The number of patients reporting  
20 improvement in pain after three (3) months of treatment was 61% but dropped to only 13% after  
21 six (6) months of treatment.

22 68. In reviewing the NDA for a third time, FDA accepted the Compassionate Use data  
23 in lieu of a randomized controlled clinical trial, the typical gold standard. However, FDA noted  
24 that only a subset of the patients was analyzed, and any observed efficacy from Elmiron use could  
25 be enhanced by placebo effect since the study was unblinded and uncontrolled.

26 69. In reviewing the clinical trial data overall, FDA noted that 75% of interstitial  
27 cystitis patients could be classified as non-responders to Elmiron therapy and recommended a three

1 (3) month trial period after drug initiation to determine if a patient will respond to Elmiron.

2 70. On September 26, 1996, FDA ultimately approved the NDA for Elmiron based on  
3 these two studies despite the significant concerns. The FDA reviewers noted that, while the studies  
4 had fatal flaws, the unique situation of interstitial cystitis, the apparent lack of significant clinical  
5 safety concerns based on these short-term studies, and the appearance of efficacy in a subset of  
6 patients resulted in a small risk/benefit ratio provided the sponsor agreed to an indication with a  
7 three-month initial treatment trial and continued to monitor the safety and efficacy of Elmiron.

8 71. Following approval in 1996, Defendants have received multiple Adverse Event  
9 Reports (hereinafter referred to as “AERs”) detailing injuries including serious visual symptoms  
10 and/or damage both in the United States and internationally.

11 72. Then, in Spring of 2018, a team at Emory Eye Center submitted a letter to the editor  
12 of the Journal of Urology reporting findings of unusual retinal pigmentary changes or maculopathy  
13 (i.e., any condition affecting the macula at the center of the retina) in six (6) female patients on  
14 long-term Elmiron treatment (median use of 15.5 years) *that did not resemble any other type of*  
15 *retinal disease.*<sup>1</sup> That case series was published online at the end of April 2018.<sup>2</sup> None of the  
16 patients had family history of retinal disease or any pathogenic process that would predispose them  
17 to such a disease. Of the six (6), five (5) had received 400mg daily of Elmiron (but two reduced  
18 their dose to 200mg pe day after 17 years of treatment), and one (1) received 300mg daily. The  
19 youngest patient was 23 years old when diagnosed with interstitial cystitis, began showing visual  
20 symptoms at 30, and by 37 had the most severe eye damage in the study. The authors also

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25 <sup>1</sup> Pearce WA, et al. *Re: FDA BRUDAC 2018 Criteria for Interstitial Cystitis/Bladder Pain Syndrome Clinical*  
26 *Trials: Future Direction for Research.* J Urol 2018;200(5):1122-1123.

27 <sup>2</sup> Pearce WA, et al. *Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate*  
28 *Sodium.* Ophthalmology. 2018 May 22.

1 highlighted the results of the Compassionate Use study that showed vision related adverse events,  
2 including optic neuritis, amblyopia, and retinal hemorrhage.

3 73. In May 2019, the same Emory team presented an update to their study at the  
4 American Urological Association annual meeting in Chicago. The study identified 10 patients with  
5 pigmentary maculopathy at the Emory Eye Center. The patients ranged in age from 38 to 68 and  
6 once again had a median treatment duration of 15.5 years (with the shortest duration of a little over  
7 two (2) years). The poster presentation concluded:

8 We describe a potentially avoidable retinal degeneration phenomenon associated  
9 with chronic PPS exposure. Structural changes occur at the level of the retinal  
10 pigment epithelium, manifesting as characteristic pigmentary changes. While it  
11 remains unclear whether drug cessation will alter the course of retinal disease, we  
12 encourage affected patients to discontinue use, and patients with suggestive visual  
13 symptoms to undergo a comprehensive ophthalmic examination with OCT and  
14 FAF imaging.<sup>3</sup>

15 74. The Emory researchers also presented at the Association for Research in Vision  
16 and Ophthalmology Annual Meeting at the end of Spring 2019 where they reported results from a  
17 retrospective cross-sectional study that included all patients at Emory Eye Center who had been  
18 diagnosed with interstitial cystitis within a four (4)-year period. The authors found 14 cases of this  
19 characteristic maculopathy in 80 patients exposed to Elmiron and no cases in 139 unexposed  
20 patients. The only statistically significant risk factor was Elmiron exposure, with median use of  
21 18.3 years in affected patients. The authors thereby concluded a strong association between  
22 Elmiron exposure and this specific type of vision-threatening maculopathy.<sup>4</sup>

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25 <sup>3</sup> Foote, et al. 2019. *Chronic Exposure to Pentosan Polysulfate Sodium is Associated with Retinal Pigmentary  
Changes and Vision Loss*. AUA 2019 Abstract MP47-03.

26 <sup>4</sup> Hanif AM, et al. *Strength of Association between Pentosan Polysulfate and a Novel Maculopathy*.  
27 *Ophthalmology*. 2019 Oct;126(10):1464-1466.

1           75.     The Emory research group then teamed with researchers at other institutions to  
2 conduct a multi-institutional case series published in September 2019 that analyzed 35 patients  
3 with Elmiron-associated maculopathy. The median duration of use was 14.5 years at a median  
4 dose of 300mg per day. The most common referral diagnosis was macular or pattern dystrophy  
5 and/or age-related macular degeneration, and the most common symptoms included blurred vision  
6 and prolonged dark adaptation. This study focused on diagnostic methods (i.e., multimodal  
7 imaging) and presentation of this specific form of maculopathy, which proved distinctive from  
8 other retinal diseases and conditions.<sup>5</sup>

9           76.     In October 2019, a research team at Kaiser Permanente in Oakland, CA found that  
10 out of 140 patients currently using Elmiron for an average of 15 years (and a minimum of five (5)  
11 years), 24% had eye damage and/or retinal toxicity that increased with the total amount of Elmiron  
12 taken. That team presented their research at the 2019 Annual meeting for the American Academy  
13 of Ophthalmology in San Francisco.<sup>6</sup> The researchers then performed multimodal image screening  
14 on 117 patients exposed to Elmiron, of which 23% had definite indications of maculopathy and  
15 demonstrated a dose-response relationship. Specifically, approximately one quarter of patients  
16 with an intake of greater than 500g developed retinal changes consistent with Elmiron-associated  
17 maculopathy.<sup>7</sup>

18           77.     Another presentation at the October 2019 AAO meeting was “the first study to  
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23           <sup>5</sup> Hanif A, et al. *Phenotypic Spectrum of Pentosan Polysulfate Sodium-Associated Maculopathy: A*  
24 *Multicenter Study*. JAMA Ophthalmol. 2019;137(11):1275-1282.

25           <sup>6</sup> “More Evidence Linking Common Bladder Medication to a Vision-threatening Eye Condition.” AAO Press  
26 Release. Oct. 12, 2019.

27           <sup>7</sup> Vora RA, et al. *Prevalence of Maculopathy Associated with Long-Term Pentosan Polysulfate Therapy*.  
28 Ophthalmology. 2020 June;127(6):835-836.

1 demonstrate a *dose-response correlation* between exposure to [Elmiron] and retinal toxicity.”<sup>8</sup>

2 78. In November 2019, the Emory Eye Center team released results from a U.S.  
3 retrospective cohort study using a medical claims database from 2002 to 2016 comparing Elmiron  
4 users to matched controls at five and seven years of use. At the seven-year follow-up, Elmiron  
5 users had *significantly increased risk* of developing atypical maculopathy and age-related macular  
6 degeneration. Therefore, this study concluded that Elmiron “exposure was associated with a new  
7 diagnosis of macular disease at the 7-year follow-up in a large national cohort.”<sup>9</sup>

8 79. Also in November 2019, a researcher at Harvard published a case study of Elmiron-  
9 associated maculopathy that progressed over six years after discontinuing the medication. The  
10 female patient used 200mg per day for 18 years. She first presented with a year of visual symptoms  
11 at the age of 62 and stopped using Elmiron shortly thereafter. She continued to be seen for  
12 increasing visual damage over the course of the next six years and was determined to have retinal  
13 atrophy and damage that could not be associated with any genetic or other potential cause. Upon  
14 release of the Emory case study in 2018, her treaters determined her case was consistent with  
15 Elmiron-associated maculopathy. The authors stated that this case, “adds a new layer of concern  
16 by demonstrating progressive maculopathy continuing for up to 6 years after the cessation of  
17 [Elmiron],” and called for screening that “balances the demands of patients and physicians with  
18 the importance of prompt identification of early toxicity.”<sup>10</sup>

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22 <sup>8</sup> Schaal, S. and Hadad, A. “Qualitative and Quantitative Analysis of Pentosan Polysulfate Sodium Retinal  
23 Toxicity Demonstrates a Dose-Response Curve.” AAO PA068 – 2.

24 <sup>9</sup> Jain N, et al. 2019. *Association of macular disease with long-term use of pentosan polysulfate sodium:  
25 findings from a US cohort.* Br. J. Ophthalmol. 2019 Nov 6.

26 <sup>10</sup> Huckfeldt R, et al. *Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium.*  
27 *Ophthalmic Surgery, Lasers & Imaging Retina.* 2019;50(10):656-659. Similar screening guidelines have been  
28 established for another drug, hydroxychloroquine, that has been similarly associated with vision damage. *See* Ferguson  
TJ, et al. *Chronic use of pentosan polysulfate sodium associated with risk of vision-threatening disease.* Intl.  
Urogynecology J. (2019) 30:337-338.

1 80. In July 2020, researchers at Emory and other institutions published a retrospective  
2 case series to evaluate the disease course of retinal pigmentary changes/maculopathy associated  
3 with Elmiron use (referred to as “PPS-associated maculopathy”) after drug cessation. Of the 11  
4 patients included in the study with confirmed PPS-associated maculopathy, none of the patients  
5 exhibited demonstrable improvement after discontinuing Elmiron; in fact, nine of the patients  
6 reported worsening visual symptoms. Imaging confirmed expansion of the affected areas of the  
7 retina over time and even atrophy encroaching on the foveal center, which suggests that “PPS-  
8 associated maculopathy continues to evolve after drug cessation for at least 10 years . . . [and] may  
9 pose a long-term threat to central vision.”<sup>11</sup>

10 81. Despite this overwhelming body of research and literature, as well as evidence from  
11 AERs received since approval, it was not until June 16, 2020 that the Elmiron label was updated  
12 to include a warning regarding retinal pigmentary changes and to recommend initial and periodic  
13 retinal screening both during and following Elmiron use.

14 82. Notably, the Elmiron labels in Canada and Europe were updated in 2019 to include  
15 warnings regarding pigmentary maculopathy.

16 83. Despite Defendants’ knowledge of the increased risk of severe injury and retinal  
17 pigmentary changes among Elmiron users, Defendants did not warn patients until June 16, 2020,  
18 and instead continued to defend Elmiron, mislead physicians and the public, and minimize  
19 unfavorable findings.

20 84. Consumers, including Plaintiff Iris Smith, who have used Elmiron for the relief of  
21 bladder pain or discomfort associated with interstitial cystitis, have alternative safer treatments  
22 available to treat this condition.

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24  
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27 <sup>11</sup> Shah, R., et al. *Disease Course in Patients With Pentosan Polysulfate Sodium-Associated Maculopathy*  
28 *After Drug Cessation*. JAMA Ophthalmol. July 9, 2020.

1 85. Defendants knew of the significant risk of retinal pigmentary changes caused by  
2 ingestion of Elmiron.

3 86. However, Defendants did not adequately and sufficiently warn consumers until  
4 June 16, 2020, including Plaintiff, or the medical community of the severity of such risks.

5 87. To the contrary, Defendants conducted nationwide sales and marketing campaigns  
6 to promote the sale of Elmiron and willfully deceived Plaintiff Iris Smith, Plaintiff's health care  
7 professionals, the medical community, and the general public as to the health risks and  
8 consequences of the use of the Elmiron.

9 88. As a direct result, in or about 2000, Plaintiff Iris Smith was prescribed and began  
10 taking Elmiron, primarily for the relief of bladder pain or discomfort associated with interstitial  
11 cystitis.

12 89. Plaintiff Iris Smith ingested and used Elmiron as prescribed and in a foreseeable  
13 manner.

14 90. The Elmiron used by Plaintiff Iris Smith, was provided to her in a condition  
15 substantially the same as the condition in which it was manufactured and sold.

16 91. Plaintiff Iris Smith agreed to initiate treatment with Elmiron in an effort to relieve  
17 bladder pain or discomfort associated with interstitial cystitis.

18 92. In agreeing to initiate treatment with Elmiron, Plaintiff Iris Smith relied on claims  
19 made by Defendants that Elmiron was safe and effective for the relief of bladder pain or discomfort  
20 associated with interstitial cystitis.

21 93. Instead, Elmiron can cause severe injuries, including retinal pigmentary changes.

22 94. After beginning treatment with Elmiron, and as a direct and proximate result  
23 thereof, Plaintiff Iris Smith suffered from retinal pigmentary changes.

24 95. Defendants knew or should have known the risks associated with the use of  
25 Elmiron, including the risk of retinal pigmentary changes (among other injuries).

26 96. The development of Plaintiff Iris Smith's injuries was preventable and resulted  
27 directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly



1 assess and publicize safety signals, suppression of information revealing serious risks, willful and  
2 wanton failure to provide adequate instructions, and willful misrepresentations concerning the  
3 nature and safety of Elmiron. This conduct, as well as the product defects complained of herein,  
4 was a substantial factor in bringing about and exacerbating Plaintiff's injuries.

5 97. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants'  
6 conduct and Elmiron's defects.

7 98. At all times material hereto, Defendants, by and through their agents, servants and  
8 employees, negligently, recklessly and carelessly marketed, distributed and sold Elmiron without  
9 adequate instructions or warning of its serious side effects and unreasonably dangerous risks.

10 99. Plaintiff Iris Smith would not have used Elmiron had Defendants properly disclosed  
11 the risks associated with the drug. Thus, had Defendants properly disclosed the risks associated  
12 with Elmiron, Plaintiff Iris Smith would have avoided the risk of developing the injuries  
13 complained of herein by not ingesting Elmiron.

14 100. Defendants, through their affirmative misrepresentations and omissions, actively  
15 concealed from Plaintiff Iris Smith and her physicians the true and significant risks associated with  
16 taking Elmiron.

17 101. As a result of Defendants' actions, Plaintiff Iris Smith and her prescribing  
18 physicians were unaware, and could not reasonably have known or learned through reasonable  
19 diligence, that Plaintiff Iris Smith had been exposed to the risks identified herein, and that those  
20 risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

21 102. As a direct and proximate result of Defendants' negligence, wrongful conduct, and  
22 the unreasonably dangerous and defective characteristics of Elmiron, Plaintiff Iris Smith suffered  
23 severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering,  
24 emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for  
25 medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory,  
26 and punitive damages from Defendants.



- 1 (c) Not conducting sufficient testing programs to determine whether or not Elmiron  
2 was safe for use; in that Defendants herein knew or should have known that Elmiron  
3 was unsafe and unfit for use by reason of the dangers to its users;
- 4 (d) Selling Elmiron without making proper and sufficient tests to determine the dangers  
5 to its users;
- 6 (e) Negligently failing to adequately and correctly warn Plaintiff, the public, the  
7 medical and healthcare profession, and the FDA of the dangers of Elmiron;
- 8 (f) Failing to provide adequate instructions regarding safety precautions to be observed  
9 by users, handlers, and persons who would reasonably and foreseeably come into  
10 contact with, and more particularly, use, Elmiron;
- 11 (g) Failing to test Elmiron and/or failing to adequately, sufficiently and properly test  
12 Elmiron.
- 13 (h) Negligently advertising and recommending the use of Elmiron without sufficient  
14 knowledge as to its dangerous propensities;
- 15 (i) Negligently representing that Elmiron was safe for use for its intended purpose,  
16 when, in fact, it was unsafe;
- 17 (j) Negligently representing that Elmiron had equivalent safety and efficacy as other  
18 forms of treatment for the relief of bladder pain or discomfort associated with  
19 interstitial cystitis;
- 20 (k) Negligently designing Elmiron in a manner which was dangerous to its users;
- 21 (l) Negligently manufacturing Elmiron in a manner which was dangerous to its users;
- 22 (m) Negligently producing Elmiron in a manner which was dangerous to its users;
- 23 (n) Negligently assembling Elmiron in a manner which was dangerous to its users;
- 24 (o) Concealing information from the Plaintiff in knowing that Elmiron was unsafe,  
25 dangerous, and/or non-conforming with FDA regulations;
- 26 (p) Improperly concealing and/or misrepresenting information from the Plaintiff,  
27 healthcare professionals, and/or the FDA, concerning the severity of risks and  
28 dangers of Elmiron compared to other forms of treatment for the relief of bladder  
pain or discomfort associated with interstitial cystitis.

1 108. Defendants under-reported, underestimated and downplayed the serious dangers of  
2 Elmiron.

3 109. Defendants negligently compared the safety risk and/or dangers of Elmiron with  
4 other forms of treatment for the relief of bladder pain or discomfort associated with interstitial  
5 cystitis.

6 110. Defendants were negligent in the designing, researching, supplying, manufacturing,  
7 promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of Elmiron  
8 in that they:

9 (a) Failed to use due care in designing and manufacturing Elmiron so as to avoid the  
10 aforementioned risks to individuals when Elmiron was used for the relief of bladder  
11 pain or discomfort associated with interstitial cystitis;

12 (b) Failed to accompany their product with proper and/or accurate warnings regarding  
13 all possible adverse side effects associated with the use of Elmiron;

14 (c) Failed to accompany their product with proper warnings regarding all possible  
15 adverse side effects concerning the failure and/or malfunction of Elmiron;

16 (d) Failed to accompany their product with accurate warnings regarding the risks of all  
17 possible adverse side effects concerning Elmiron;

18 (e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the  
19 warnings given did not accurately reflect the symptoms, or severity of the side  
20 effects;

21 (f) Failed to conduct adequate testing, including pre-clinical and clinical testing and  
22 post-marketing surveillance to determine the safety of Elmiron;

23 (g) Failed to warn Plaintiff, prior to actively encouraging the sale of Elmiron, either  
24 directly or indirectly, orally or in writing, about the need for more comprehensive,  
25 more regular medical monitoring than usual to ensure early discovery of potentially  
26 serious side effects;

27 (h) Were otherwise careless and/or negligent.

28 111. Despite the fact that Defendants knew or should have known that Elmiron caused  
unreasonably dangerous side effects, Defendants continued and continue to market, manufacture,  
distribute and/or sell Elmiron to consumers, including the Plaintiff, Iris Smith.

1 112. Defendants knew or should have known that consumers such as the Plaintiff would  
2 foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth  
3 above.

4 113. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and  
5 economic loss that Plaintiff suffered and/or will continue to suffer.

6 114. As a result of the foregoing acts and omissions, the Plaintiff Iris Smith was caused  
7 to suffer serious and dangerous side effects including but not limited to retinal pigmentary changes,  
8 vision changes, and potentially irreversible vision damage, as well as other severe and personal  
9 injuries which are permanent and lasting in nature, physical pain and mental anguish, including  
10 diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or  
11 medications.

12 115. As a result of the foregoing acts and omissions the Plaintiff Iris Smith requires  
13 and/or will require more health care and services and did incur medical, health, incidental and  
14 related expenses. Plaintiff is informed and believes and further alleges that she will in the future  
15 be required to obtain further medical and/or hospital care, attention, and services.

16 116. By reason of the foregoing, Plaintiff has been damaged by the Defendants.

17 **SECOND CAUSE OF ACTION**

18 **AS AGAINST THE DEFENDANTS**

19 **(STRICT PRODUCTS LIABILITY)**

20 117. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
21 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
22 as if more fully set forth herein.

23 118. At all times herein mentioned, the Defendants designed, researched, manufactured,  
24 tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the  
25 Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed,  
26 sold and distributed Elmiron as hereinabove described that was used by the Plaintiff, Iris Smith.

27 119. That Elmiron was expected to and did reach the usual consumers, handlers, and

1 persons coming into contact with said product without substantial change in the condition in which  
2 it was produced, manufactured, sold, distributed, and marketed by the Defendants.

3 120. At those times, Elmiron was in an unsafe, defective, and inherently dangerous  
4 condition, which was dangerous to users, and in particular, the Plaintiff herein.

5 121. The Elmiron designed, researched, manufactured, tested, advertised, promoted,  
6 marketed, sold and distributed by Defendants was defective in design or formulation in that, when  
7 it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits  
8 associated with the design or formulation of Elmiron.

9 122. The Elmiron designed, researched, manufactured, tested, advertised, promoted,  
10 marketed, sold and distributed by Defendants was defective in design and/or formulation, in that,  
11 when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably  
12 dangerous, and it was more dangerous than an ordinary consumer would expect.

13 123. At all times herein mentioned, Elmiron was in a defective condition and unsafe,  
14 and Defendants knew or had reason to know that said product was defective and unsafe, especially  
15 when used in the form and manner as provided by the Defendants.

16 124. Defendants knew, or should have known, that at all times herein mentioned its  
17 Elmiron was in a defective condition, and was and is inherently dangerous and unsafe.

18 125. At the time of the Plaintiff's use of Elmiron, Elmiron was being used for the  
19 purposes and in a manner normally intended, namely for the relief of bladder pain or discomfort  
20 associated with interstitial cystitis.

21 126. Defendants with this knowledge voluntarily designed its Elmiron in a dangerous  
22 condition for use by the public, and in particular the Plaintiff Iris Smith.

23 127. Defendants had a duty to create a product that was not unreasonably dangerous for  
24 its normal, intended use.

25 128. Defendants created a product unreasonably dangerous for its normal, intended use.

26 129. The Elmiron designed, researched, manufactured, tested, advertised, promoted,  
27 marketed, sold and distributed by Defendants was manufactured defectively in that Elmiron left

1 the hands of Defendants in a defective condition and was unreasonably dangerous to its intended  
2 users.

3 130. The Elmiron designed, researched, manufactured, tested, advertised, promoted,  
4 marketed, sold and distributed by Defendants reached their intended users in the same defective  
5 and unreasonably dangerous condition in which the Defendants' Elmiron was manufactured.

6 131. Defendants designed, researched, manufactured, tested, advertised, promoted,  
7 marketed, sold and distributed a defective product which created an unreasonable risk to the health  
8 of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the  
9 injuries sustained by the Plaintiff.

10 132. The Plaintiff could not, by the exercise of reasonable care, have discovered  
11 Elmiron's defects herein mentioned and perceived its danger.

12 133. The Elmiron designed, researched, manufactured, tested, advertised, promoted,  
13 marketed, sold and distributed by Defendants was defective due to inadequate warnings or  
14 instructions as the Defendants knew or should have known that the product created a risk of serious  
15 and dangerous side effects including but not limited to retinal pigmentary changes, vision changes,  
16 and potentially irreversible vision damage, as well as other severe and personal injuries which are  
17 permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

18 134. The Elmiron designed, researched, manufactured, tested, advertised, promoted,  
19 marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or  
20 inadequate testing.

21 135. The Elmiron designed, researched, manufactured, tested, advertised, promoted,  
22 marketed, sold and distributed by Defendants was defective due to inadequate post-marketing  
23 surveillance and/or warnings because, after Defendants knew or should have known of the risks  
24 of serious side effects including but not limited to retinal pigmentary changes, vision changes, and  
25 potentially irreversible vision damage, as well as other severe and permanent health consequences  
26 from Elmiron, they failed to provide adequate warnings to users or consumers of the product, and  
27 continued to improperly advertise, market and/or promote their product, Elmiron.

1 136. By reason of the foregoing, the Defendants have become strictly liable in tort to  
2 Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective  
3 product, Elmiron.

4 137. Defendants' defective design, manufacturing defect, and inadequate warnings of  
5 Elmiron were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

6 138. That said defects in Defendants' drug Elmiron were a substantial factor in causing  
7 Plaintiff's injuries.

8 139. As a result of the foregoing acts and omissions, the Plaintiff Iris Smith was caused  
9 to suffer serious and dangerous side effects including retinal pigmentary changes, vision changes,  
10 and potentially irreversible vision damage, as well as other severe and personal injuries which are  
11 permanent and lasting in nature, physical pain and mental anguish, including diminished  
12 enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or  
13 medications.

14 140. As a result of the foregoing acts and omissions the Plaintiff Iris Smith requires  
15 and/or will require more health care and services and did incur medical, health, incidental and  
16 related expenses. Plaintiff is informed and believes and further alleges that she will in the future  
17 be required to obtain further medical and/or hospital care, attention, and services.

18 141. By reason of the foregoing, Plaintiff has been damaged by the Defendants.

19 **THIRD CAUSE OF ACTION**

20 **AS AGAINST THE DEFENDANTS**

21 **(BREACH OF EXPRESS WARRANTY)**

22 142. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
23 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
24 as if more fully set forth herein.

25 143. At all times material hereto, Defendants engaged in the business of testing,  
26 developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or  
27



1 distributing Elmiron, which is unreasonably dangerous and defective, thereby placing Elmiron into  
2 the stream of commerce.

3 144. Under Cal. Com. Code § 2313 any affirmation of fact or promise made by the seller  
4 to the buyer which relates to the goods and becomes part of the basis of the bargain creates an  
5 express warranty that the goods shall conform to the affirmation or promise.

6 145. Defendants expressly represented to Plaintiff, Iris Smith, other consumers,  
7 Plaintiff's physicians, and the medical community, by and through statements made and written  
8 materials disseminated by Defendants or their authorized agents or sales representatives, that  
9 Elmiron:

10 (a) was safe and fit for its intended purposes;

11 (b) was of merchantable quality;

12 (c) did not produce any dangerous side effects; and

13 (d) had been adequately tested and found to be safe and effective for the relief of  
14 bladder pain or discomfort associated with interstitial cystitis.

15 146. These express representations include incomplete prescribing information that  
16 purports, but fails, to include the true risks associated with use of Elmiron. In fact, Defendants  
17 knew or should have known that the risks identified in Elmiron's prescribing information and  
18 package inserts do not accurately or adequately set forth the drug's true risks. Despite this,  
19 Defendants expressly warranted Elmiron as safe and effective for use.

20 147. Defendants advertised, labeled, marketed, and promoted Elmiron, representing the  
21 quality to health care professionals, Plaintiff Iris Smith, and the public in such a way as to induce  
22 Elmiron's purchase or use, thereby making an express warranty that Elmiron would conform to  
23 the representations. More specifically, the prescribing information for Elmiron did not and does  
24 not contain adequate information about the true risks of developing the injuries complained of  
25 herein.

26 148. Despite this, Defendants expressly represented that Elmiron was safe and effective,  
27 that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and

1 effective for the relief of bladder pain or discomfort associated with interstitial cystitis. Portions  
2 of the prescribing information relied upon by Plaintiff and her health care professionals, including  
3 the “Warnings and Precautions” section, purport to expressly include the risks associated with the  
4 use of Elmiron, but those risks are neither accurately nor adequately set forth.

5 149. The representations about Elmiron contained or constituted affirmations of fact or  
6 promises made by the seller to the buyer which related to the goods and became part of the basis  
7 of the bargain creating an express warranty that the goods shall conform to the affirmations of fact  
8 or promises.

9 150. Elmiron does not conform to Defendants’ express representations because it is not  
10 safe, has numerous and serious side effects, and causes severe and permanent injuries. Therefore,  
11 Defendants breached the aforementioned warranties.

12 151. At all relevant times, Elmiron did not perform as safely as an ordinary consumer  
13 would expect when used as intended or in a reasonably foreseeable manner.

14 152. Neither Plaintiff nor her prescribing health care professionals had knowledge of the  
15 falsity or incompleteness of the Defendants’ statements and representations concerning Elmiron.

16 153. Plaintiff, other consumers, Plaintiff Iris Smith’s physicians, and the medical  
17 community justifiably and detrimentally relied upon Defendants’ express warranties when  
18 prescribing and ingesting Elmiron.

19 154. Had the prescribing information for Elmiron accurately and adequately set forth the  
20 true risks associated with the use of such product, including Plaintiff Iris Smith’s injuries, rather  
21 than expressly excluding such information and warranting that the product was safe for its intended  
22 use, Plaintiff Iris Smith could have avoided the injuries complained of herein.

23 155. As a foreseeable, direct, and proximate consequence of Defendants’ actions,  
24 omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and  
25 other related health complications. In addition, Plaintiff Iris Smith requires and will continue to  
26 require healthcare and services. Plaintiff has incurred and will continue to incur medical and  
27 related expenses. Plaintiff Iris Smith also has suffered and will continue to suffer diminished

1 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting  
2 conditions, activation of latent conditions, and other losses and damages. Plaintiff Iris Smith's  
3 direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has  
4 incurred and will continue to incur mental and physical pain and suffering.

5 156. By reason of the foregoing, Plaintiff has been damaged by the Defendants.

6 **FOURTH CAUSE OF ACTION**

7 **AS AGAINST THE DEFENDANTS**

8 **(BREACH OF IMPLIED WARRANTIES)**

9 157. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
10 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
11 as if more fully set forth herein.

12 158. Defendants manufactured, distributed, advertised, promoted, and sold Elmiron.

13 159. Under Cal. Com. Code § 2314 a warranty that the goods are merchantable is  
14 implied. In order for goods to be considered merchantable they must at least, among other things,  
15 be fit for the ordinary purpose for which such goods are used, be adequately contained packaged  
16 and labeled, and conform to the promises or affirmations of fact made on the container or label.

17 160. At all relevant times, Defendants knew of the use for which Elmiron was intended,  
18 and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

19 161. Defendants were aware that consumers, including Plaintiff Iris Smith, would use  
20 Elmiron for the relief of bladder pain or discomfort associated with interstitial cystitis.

21 162. Elmiron was neither safe for its intended use nor of merchantable quality, as  
22 impliedly warranted by Defendants, in that Elmiron has dangerous propensities when used as  
23 intended and can cause serious injuries, including but not limited to retinal pigmentary changes,  
24 vision changes, and potentially irreversible vision damage.

25 163. At all relevant times, Defendants intended that Elmiron be used in the manner used  
26 by Plaintiff, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for  
27 such use, despite the fact that Elmiron was not adequately tested.

1 164. Defendants were aware that consumers, including Plaintiff Iris Smith, would use  
2 Elmiron as marketed by Defendants. As such, Plaintiff Iris Smith was a foreseeable user of  
3 Elmiron.

4 165. Upon information and belief, Plaintiff Iris Smith and/or her health care  
5 professionals were at all relevant times in privity with Defendants.

6 166. Elmiron was dangerous and defective when Defendants placed it into the stream of  
7 commerce because of its propensity to cause Plaintiff Iris Smith's injuries.

8 167. Plaintiff and the medical community reasonably relied upon the judgment and  
9 sensibility of Defendants to sell Elmiron only if it was indeed of merchantable quality and safe  
10 and fit for its intended use.

11 168. Defendants breached their implied warranty to consumers, including Plaintiff.  
12 Elmiron was not of merchantable quality, nor was it safe and fit for its intended use.

13 169. Plaintiff Iris Smith and her physicians reasonably relied upon Defendants' implied  
14 warranty for Elmiron when prescribing and ingesting Elmiron.

15 170. Plaintiff Iris Smith's use of Elmiron was as prescribed and in a foreseeable manner  
16 as intended, recommended, promoted, and marketed by Defendants.

17 171. Elmiron was expected to reach and did in fact reach consumers, including Plaintiff  
18 Iris Smith, without substantial change in the condition in which it was manufactured and sold by  
19 Defendants.

20 172. Defendants breached the warranties of merchantability and fitness for its particular  
21 purpose because Elmiron was unduly dangerous and caused undue injuries, including Plaintiff Iris  
22 Smith.

23 173. The harm caused by Elmiron far outweighed its alleged benefit, rendering Elmiron  
24 more dangerous than an ordinary consumer or health care professional would expect and more  
25 dangerous than alternative products.

26 174. Neither Plaintiff Iris Smith nor her health care professionals reasonably could have  
27 discovered or known of the risk of serious injury associated with Elmiron.

1 175. Defendants' breach of these implied warranties caused Plaintiff's injuries.

2 176. As a foreseeable, direct, and proximate consequence of Defendants' actions,  
3 omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and  
4 other related health complications. In addition, Plaintiff Iris Smith requires and will continue to  
5 require healthcare and services. Plaintiff have incurred and will continue to incur medical and  
6 related expenses. Plaintiff Iris Smith also has suffered and will continue to suffer diminished  
7 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting  
8 conditions, activation of latent conditions, and other losses and damages. Plaintiff Iris Smith's  
9 direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has  
10 incurred and will continue to incur mental and physical pain and suffering.

11 177. By reason of the foregoing, Plaintiff has been damaged by the Defendants.

12 **FIFTH CAUSE OF ACTION AS**  
13 **AGAINST THE DEFENDANTS**  
14 **(FRAUDULENT MISREPRESENTATION)**

15 178. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
16 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
17 as if more fully set forth herein.

18 179. Defendants made fraudulent misrepresentations with respect to Elmiron in the  
19 following particulars:

- 20 (a) Defendants represented through their labeling, advertising, marketing materials,  
21 detail persons, seminar presentations, publications, notice letters, and regulatory  
22 submissions that Elmiron had been tested and found to be safe and effective for the  
23 relief of bladder pain or discomfort associated with interstitial cystitis; and  
24 (b) Upon information and belief, Defendants represented that Elmiron was safer than  
25 other alternative medications.  
26 (c) Defendants knew that their representations were false, yet they willfully, wantonly,  
27 and recklessly disregarded their obligation to provide truthful representations  
regarding the safety and risk of Elmiron to Plaintiff Iris Smith, other consumers,  
Plaintiff Iris Smith's physicians, and the medical community.

1 180. The representations were made by the Defendants with the intent that doctors and  
2 patients, including Plaintiff Iris Smith and her physicians, rely upon them.

3 181. Defendants' representations were made with the intent of defrauding and deceiving  
4 Plaintiff, other consumers, Plaintiff Iris Smith's physicians, and the medical community to induce  
5 and encourage the sale of Elmiron.

6 182. Plaintiff Iris Smith, her doctors, and others relied upon these representations.

7 183. As a foreseeable, direct, and proximate consequence of Defendants' actions,  
8 omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and  
9 other related health complications. In addition, Plaintiff Iris Smith requires and will continue to  
10 require healthcare and services. Plaintiff has incurred and will continue to incur medical and  
11 related expenses. Plaintiff Iris Smith also has suffered and will continue to suffer diminished  
12 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting  
13 conditions, activation of latent conditions, and other losses and damages. Plaintiff Iris Smith's  
14 direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff Iris  
15 Smith has incurred and will continue to incur mental and physical pain and suffering.

16 184. By reason of the foregoing, Plaintiff has been damaged by the Defendants.

17 **SIXTH CAUSE OF ACTION AS**  
18 **AGAINST THE DEFENDANTS**  
19 **(FRAUDULENT CONCEALMENT)**

20 185. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
21 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
22 as if more fully set forth herein.

23 186. Throughout the relevant time period, Defendants knew that Elmiron was defective  
24 and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose  
25 and/or suppressed information regarding the true nature of the risks of use of Elmiron.

26 187. Defendants fraudulently concealed information with respect to Elmiron in the  
27 following particulars:

- 1 (a) Defendants represented through their labeling, advertising, marketing materials,  
2 detail persons, seminar presentations, publications, notice letters, and regulatory  
3 submissions that Elmiron was safe and fraudulently withheld and concealed  
4 information about the severity of the substantial risks of using Elmiron; and
- 5 (b) Upon information and belief, Defendants represented that Elmiron was safer than  
6 other alternative medications and/or treatments and fraudulently concealed  
7 information which demonstrated that Elmiron was not safer than alternatives  
8 available on the market.
- 9 (c) Defendants were under a duty to Plaintiff Iris Smith to disclose and warn of the  
10 defective and dangerous nature of Elmiron because:
- 11 (d) Defendants had sole access to material facts concerning, and unique and special  
12 expertise regarding, the dangers and unreasonable risks of Elmiron;
- 13 (e) Defendants knowingly made false claims and omitted important information about  
14 the safety and quality of Elmiron in the documents and marketing materials  
15 Defendants provided to physicians and the general public; and
- 16 (f) Defendants fraudulently and affirmatively concealed the defective and dangerous  
17 nature of Elmiron from Plaintiff.

18 188. As the designers, manufacturers, sellers, promoters, and/or distributors of Elmiron,  
19 Defendants had unique knowledge and special expertise regarding Elmiron. This placed them in a  
20 position of superiority and influence over Plaintiff Iris Smith and her healthcare providers. As  
21 such, Plaintiff Iris Smith and her healthcare providers reasonably placed their trust and confidence  
22 in Defendants and in the information disseminated by Defendants.

23 189. The facts concealed or not disclosed by Defendants to Plaintiff Iris Smith were  
24 material facts that a reasonable person would have considered to be important in deciding whether  
25 or not to purchase or use Elmiron.

26 190. The concealment and/or non-disclosure of information by Defendants about the  
27 severity of the risks caused by Elmiron was intentional, and the representations made by  
28 Defendants were known by them to be false.

191. The concealment of information and the misrepresentations about Elmiron were  
made by Defendants with the intent that doctors and patients, including Plaintiff Iris Smith rely

1 upon them so that Plaintiff Iris Smith would request and purchase Elmiron and her health care  
2 providers would prescribe and recommend Elmiron.

3 192. Plaintiff Iris Smith, her doctors, and others reasonably relied on Defendants'  
4 representations and were unaware of the substantial risk posed by Elmiron.

5 193. Had Defendants not concealed or suppressed information regarding the severity of  
6 the risks of Elmiron, Plaintiff Iris Smith and her physicians would not have prescribed or ingested  
7 the drug.

8 194. Defendants, by concealment or other action, intentionally prevented Plaintiff Iris  
9 Smith and her health care professionals from acquiring material information regarding the lack of  
10 safety of Elmiron, thereby preventing Plaintiff from discovering the truth. As such, Defendants are  
11 liable for fraudulent concealment.

12 195. As a foreseeable, direct, and proximate consequence of Defendants' actions,  
13 omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and  
14 other related health complications. In addition, Plaintiff Iris Smith requires and will continue to  
15 require healthcare and services. Plaintiff has incurred and will continue to incur medical and  
16 related expenses. Plaintiff Iris Smith also has suffered and will continue to suffer diminished  
17 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting  
18 conditions, activation of latent conditions, and other losses and damages. Plaintiff Iris Smith's  
19 direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff Iris  
20 Smith has incurred and will continue to incur mental and physical pain and suffering.

21 196. By reason of the foregoing, Plaintiff has been damaged by the Defendants.

22 **SEVENTH CAUSE OF ACTION AS**

23 **AGAINST THE DEFENDANTS**

24 **(NEGLIGENT MISREPRESENTATION)**

25 197. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
26 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
27 as if more fully set forth herein.



1 198. Defendants owed a duty in all of their undertakings, including the dissemination of  
2 information concerning Elmiron, to exercise reasonable care to ensure they did not create  
3 unreasonable risks of personal injury to others.

4 199. Defendants disseminated to health care professionals and consumers—through  
5 published labels, marketing materials, and otherwise—information that misrepresented the  
6 properties and effects of Elmiron with the intention that health care professionals and consumers  
7 would rely upon that information in their decisions concerning whether to prescribe or ingest  
8 Elmiron.

9 200. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors  
10 of Elmiron, knew or reasonably should have known that health care professionals and consumers  
11 of Elmiron rely on information disseminated and marketed to them regarding the product when  
12 weighing the potential benefits and potential risks of prescribing or ingesting Elmiron.

13 201. Defendants failed to exercise reasonable care to ensure that the information they  
14 disseminated to health care professionals and consumers concerning the properties and effects of  
15 Elmiron were accurate, complete, and not misleading. As a result, Defendants disseminated  
16 information to health care professionals and consumers that was negligently and materially  
17 inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff Iris  
18 Smith.

19 202. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of  
20 Elmiron, knew or reasonably should have known that health care professionals would write  
21 prescriptions for Elmiron in reliance on the information disseminated by Defendants, and that the  
22 patients receiving prescriptions for Elmiron would be placed in peril of developing serious injuries  
23 if the information disseminated by Defendants and relied upon was materially inaccurate,  
24 misleading, or otherwise false.

25 203. From the time Elmiron was first tested, studied, researched, evaluated, endorsed,  
26 manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose  
27 material facts regarding the safety of Elmiron. Defendants made material misrepresentations to

1 Plaintiff Iris Smith, her health care professionals, the healthcare community, and the general  
2 public, including:

- 3 (a) stating that Elmiron had been tested and found to be safe and effective for the relief  
4 of bladder pain or discomfort associated with interstitial cystitis;
- 5 (b) concealing, misrepresenting, and actively downplaying the severe risks of harm to  
6 users of Elmiron, when compared to comparable or superior alternative drug  
7 therapies; and
- 8 (c) misrepresenting Elmiron's risk of unreasonable, dangerous, adverse side effects.

9 204. Defendants made the foregoing representations without any reasonable ground for  
10 believing them to be true.

11 205. These representations were made directly by Defendants, their sales representative,  
12 and other authorized agents, and in publications and other written materials directed to health care  
13 professionals, medical patients, and the public.

14 206. Defendants made these representations with the intent to induce reliance thereon,  
15 and to encourage the prescription, purchase, and use of Elmiron.

16 207. Defendants had a duty to accurately and truthfully represent to medical  
17 professionals and consumers, including Plaintiff Iris Smith, the truth regarding Defendants' claims  
18 that Elmiron had been tested and found to be safe and effective for the relief of bladder pain or  
19 discomfort associated with interstitial cystitis.

20 208. The misrepresentations made by Defendants, in fact, were false and known by  
21 Defendants to be false at the time the misrepresentations were made.

22 209. Defendants failed to exercise ordinary care in making their representations  
23 concerning Elmiron and in the manufacture, sale, testing, quality assurance, quality control, and  
24 distribution in interstate commerce of Elmiron.

25 210. Defendants engaged in a nationwide marketing campaign, over-promoting Elmiron  
26 in written marketing literature, in written product packaging, and in direct-to-consumer advertising  
27 via written and internet advertisements and television commercial advertisements. Defendants'

1 over-promotion was undertaken by touting the safety and efficacy of Elmiron while concealing,  
2 misrepresenting, and actively downplaying the serious and severe risks of harm to users of  
3 Elmiron, when compared to comparable or superior alternative drug therapies. Defendants  
4 negligently misrepresented Elmiron's risk of unreasonable and dangerous adverse side effects.

5 211. Defendants' conduct, as described above, was reckless. Defendants risked the lives  
6 of consumers and users of Elmiron, including Plaintiff Iris Smith. Defendants had knowledge of  
7 the safety problems and suppressed this knowledge from the general public. Defendants made  
8 conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public.  
9 Defendants' reckless conduct warrants an award of punitive damages.

10 212. As a foreseeable, direct, and proximate consequence of Defendants' actions,  
11 omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and  
12 other related health complications. In addition, Plaintiff Iris Smith requires and will continue to  
13 require healthcare and services. Plaintiff has incurred and will continue to incur medical and  
14 related expenses. Plaintiff Iris Smith also has suffered and will continue to suffer diminished  
15 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting  
16 conditions, activation of latent conditions, and other losses and damages. Plaintiff Iris Smith's  
17 direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff Iris  
18 Smith has incurred and will continue to incur mental and physical pain and suffering.

19 213. By reason of the foregoing, Plaintiff has been damaged as against the Defendants.

20 **EIGHTH CAUSE OF ACTION AS**  
21 **AGAINST THE DEFENDANTS**  
22 **(FRAUD AND DECEIT)**

23 214. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
24 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
25 as if more fully set forth herein.

26 215. Defendants conducted research and used Elmiron as part of their research.  
27

1           216. As a result of Defendants' research and testing, or lack thereof, Defendants  
2 blatantly and intentionally distributed false information, including but not limited to assuring the  
3 public, Plaintiff Iris Smith, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA  
4 that Elmiron was safe and effective for the relief of bladder pain or discomfort associated with  
5 interstitial cystitis.

6           217. As a result of Defendants' research and testing, or lack thereof, Defendants  
7 intentionally omitted certain results of testing and research to the public, healthcare professionals,  
8 and/or the FDA, including the Plaintiff Iris Smith.

9           218. Defendants had a duty when disseminating information to the public to disseminate  
10 truthful information and a parallel duty not to deceive the public and Plaintiff, as well as Plaintiff  
11 Iris Smith's respective healthcare providers and/or the FDA.

12           219. The information distributed to the public, the FDA, and Plaintiff by Defendants,  
13 including but not limited to reports, press releases, advertising campaigns, television commercials,  
14 print advertisements, magazine advertisements, billboards, and all other commercial media  
15 contained material representations of fact and/or omissions.

16           220. The information distributed to the public, the FDA, and Plaintiff by Defendants  
17 intentionally included representations that Defendants' drug Elmiron was safe and effective for  
18 the relief of bladder pain or discomfort associated with interstitial cystitis.

19           221. The information distributed to the public, the FDA, and Plaintiff by Defendants  
20 intentionally included representations that Defendants' drug Elmiron carried the same risks,  
21 hazards, and/or dangers as other forms of treatment for the relief of bladder pain or discomfort  
22 associated with interstitial cystitis.

23           222. The information distributed to the public, the FDA, and Plaintiff by Defendants  
24 intentionally included false representations that Elmiron was not injurious to the health and/or  
25 safety of its intended users.

26           223. The information distributed to the public, the FDA, and Plaintiff by Defendants  
27 intentionally included false representations that Elmiron was as potentially injurious to the health

1 and/or safety of its intended as other forms of treatment for the relief of bladder pain or discomfort  
2 associated with interstitial cystitis.

3 224. These representations were all false and misleading.

4 225. Upon information and belief, Defendants intentionally suppressed, ignored and  
5 disregarded test results not favorable to the Defendants, and results that demonstrated that Elmiron  
6 was not safe as a means of treatment for the relief of bladder pain or discomfort associated with  
7 interstitial cystitis.

8 226. Defendants intentionally made material representations to the FDA and the public,  
9 including the medical profession, and Plaintiff, regarding the safety of Elmiron, specifically but  
10 not limited to Elmiron not having dangerous and serious health and/or safety concerns.

11 227. Defendants intentionally made material representations to the FDA and the public  
12 in general, including the medical profession, and Plaintiff, regarding the safety of Elmiron,  
13 specifically but not limited to Elmiron being a safe means of treatment for the relief of bladder  
14 pain or discomfort associated with interstitial cystitis.

15 228. That it was the purpose of Defendants in making these representations to deceive  
16 and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public,  
17 healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for  
18 use of Elmiron and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe,  
19 recommend, and/or continue to use Elmiron.

20 229. Defendants made the aforementioned false claims and false representations with  
21 the intent of convincing the public, healthcare professionals, the FDA, and/or Plaintiff that Elmiron  
22 was fit and safe for the relief of bladder pain or discomfort associated with interstitial cystitis.

23 230. Defendants made the aforementioned false claims and false representations with  
24 the intent of convincing the public, healthcare professionals, the FDA, and/or Plaintiff that Elmiron  
25 was fit and safe for the relief of bladder pain or discomfort associated with interstitial cystitis.

26 231. Defendants made claims and representations in its documents submitted to the  
27 FDA, to the public, to healthcare professionals, and Plaintiff that Elmiron did not present serious

1 health and/or safety risks.

2 232. Defendants made claims and representations in its documents submitted to the  
3 FDA, to the public, to healthcare professionals, and Plaintiff that Elmiron did not present health  
4 and/or safety risks greater than other forms of treatment for the relief of bladder pain or discomfort  
5 associated with interstitial cystitis.

6 233. These representations and others made Defendants were false when made, and/or  
7 were made with a pretense of actual knowledge when knowledge did not actually exist, and/or  
8 were made recklessly and without regard to the actual facts.

9 234. These representations and others, made by Defendants, were made with the  
10 intention of deceiving and defrauding the Plaintiff Iris Smith, including her respective healthcare  
11 professionals and/or the FDA, and were made in order to induce the Plaintiff Iris Smith and/or her  
12 respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff Iris  
13 Smith to purchase, use, rely on, request, dispense, recommend, and/or prescribe Elmiron.

14 235. Defendants, recklessly and intentionally, falsely represented the dangerous and  
15 serious health and/or safety concerns of Elmiron to the public at large, the Plaintiff Iris Smith in  
16 particular, for the purpose of influencing the marketing of a product known to be dangerous and  
17 defective and/or not as safe as other alternatives, including other forms of treatment for the relief  
18 of bladder pain or discomfort associated with interstitial cystitis.

19 236. That Defendants willfully and intentionally failed to disclose the material facts  
20 regarding the dangerous and serious safety concerns of Elmiron by concealing and suppressing  
21 material facts regarding the dangerous and serious health and/or safety concerns of Elmiron.

22 237. That Defendants willfully and intentionally failed to disclose the truth, failed to  
23 disclose material facts and made false representations with the purpose and design of deceiving  
24 and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security  
25 so that Plaintiff Iris Smith would rely on the representations and purchase, use and rely on Elmiron  
26 and/or that Plaintiff Iris Smith's respective healthcare providers would dispense, prescribe, and/or  
27 recommend the same.

1 238. Defendants, through their public relations efforts, which included but were not  
2 limited to public statements and press releases, knew or should have known that the public,  
3 including the Plaintiff Iris Smith, as well as Plaintiff Iris Smith's respective healthcare  
4 professionals would rely upon the information being disseminated.

5 239. Defendants utilized direct to consumer advertising to market, promote, and/or  
6 advertise Elmiron.

7 240. That the Plaintiff Iris Smith and/or her respective healthcare professionals did in  
8 fact rely on and believe the Defendants' representations to be true at the time they were made and  
9 relied upon the representations as well as the superior knowledge of treatment for the relief of  
10 bladder pain or discomfort associated with interstitial cystitis.

11 241. That at the time the representations were made, the Plaintiff Iris Smith and/or her  
12 respective healthcare providers did not know the truth with regard to the dangerous and serious  
13 health and/or safety concerns of Elmiron.

14 242. That the Plaintiff did not discover the true facts with respect to the dangerous and  
15 serious health and/or safety concerns, and the false representations of Defendants, nor could the  
16 Plaintiff Iris Smith with reasonable diligence have discovered the true facts.

17 243. That had the Plaintiff Iris Smith known the true facts with respect to the dangerous  
18 and serious health and/or safety concerns of Elmiron, Plaintiff would not have purchased, used  
19 and/or relied on Defendants' drug Elmiron.

20 244. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was  
21 committed and/or perpetrated willfully, wantonly and/or purposefully on Plaintiff.

22 245. As a result of the foregoing acts and omissions, the Plaintiff Iris Smith was caused  
23 to suffer serious and dangerous side effects including retinal pigmentary changes, as well as other  
24 severe and personal injuries which are permanent and lasting in nature, physical pain and mental  
25 anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment,  
26 monitoring and/or medications.

27 246. As a result of the foregoing acts and omissions the Plaintiff Iris Smith requires

1 and/or will require more health care and services and did incur medical, health, incidental and  
2 related expenses. Plaintiff is informed and believes and further alleges that she will in the future  
3 be required to obtain further medical and/or hospital care, attention, and services.

4 247. By reason of the foregoing, Plaintiff has been damaged by the Defendants.

5 **NINTH CAUSE OF ACTION AS**

6 **AGAINST THE DEFENDANTS**

7 **(PRODUCT LIABILITY – DESIGN DEFECT)**

8 248. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
9 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
10 as if more fully set forth herein.

11 249. Defendants designed, developed, researched, tested, licensed, manufactured,  
12 packaged, labeled, promoted, marketed, sold, and/or distributed Elmiron, including the Elmiron  
13 used by Plaintiff, Iris Smith, was in a defective and unreasonably dangerous condition.

14 250. Defendants expected Elmiron to reach, and it did in fact reach, Iris Smith without  
15 substantial change in the condition in which it was manufactured and sold by the Defendants.

16 251. At all times relevant hereto, Defendants' Elmiron was manufactured, designed, and  
17 labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by  
18 the public and in particular by Plaintiff Iris Smith.

19 252. At all times relevant to this action, Elmiron, as designed, developed, researched,  
20 tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by  
21 the Defendants, was defective in design and formulation in one or more of the following  
22 particulars:

23 (a) When placed in the stream of commerce, Elmiron contained unreasonably  
24 dangerous design defects and was not reasonably safe as intended to be used,  
subjecting Plaintiff Iris Smith to risks that exceeded the benefits of the drug;

25 (b) When placed in the stream of commerce, Elmiron was defective in design and  
26 formulation, making use of the drug more dangerous than an ordinary consumer  
27 would expect and more dangerous than other risks associated with treatment for the



- 1 relief of bladder pain or discomfort associated with interstitial cystitis;  
2 (c) Elmiron was insufficiently tested;  
3 (d) Elmiron caused harmful side effects that outweighed any potential utility;  
4 (e) Defendants were aware at the time Elmiron was marketed that ingestion of Elmiron  
5 would result in an increased risk of retinal pigmentary changes and other injuries;  
6 (f) Inadequate post-marketing surveillance; and/or  
7 (g) There were safer alternative designs and formulations that were not utilized.

8 253. Elmiron was defective, failed to perform safely, and was unreasonably dangerous  
9 when used by ordinary consumers, including Plaintiff Iris Smith, as intended and in a reasonably  
10 foreseeable manner.

11 254. Elmiron, as designed, developed, researched, tested, licensed, manufactured,  
12 packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in  
13 its design or formulation, in that it was unreasonably dangerous and its foreseeable risks exceeded  
14 the alleged benefits associated with Elmiron's design or formulation.

15 255. Elmiron, as designed, developed, researched, tested, licensed, manufactured,  
16 packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in  
17 design or formulation in that it posed a greater likelihood of injury than other treatments for the  
18 relief of bladder pain or discomfort associated with interstitial cystitis and was more dangerous  
19 than an ordinary consumer could reasonably foresee or anticipate.

20 256. At all times relevant to this action, Defendants knew or had reason to know that  
21 Elmiron was in a defective condition and was inherently dangerous and unsafe when used in the  
22 manner instructed, provided, and/or promoted by Defendants.

23 257. Defendants had a duty to properly test, develop, design, manufacture, inspect,  
24 package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and  
25 otherwise ensure that Elmiron was not unreasonably dangerous for its normal, common, intended  
26 use, or for use in a form and manner instructed and provided by Defendants.

27 258. When Defendants placed Elmiron into the stream of commerce, they knew it would

1 be prescribed for the relief of bladder pain or discomfort associated with interstitial cystitis, and  
2 they marketed and promoted Elmiron as safe for the relief of bladder pain or discomfort associated  
3 with interstitial cystitis.

4 259. Plaintiff Iris Smith was prescribed, purchased, and used Elmiron. Plaintiff Iris  
5 Smith used Elmiron for its intended purpose and in the manner recommended, promoted,  
6 marketed, and reasonably anticipated by Defendants.

7 260. Neither Plaintiff Iris Smith nor her health care professionals, by the exercise of  
8 reasonable care, could have discovered the defects and risks associated with Elmiron before  
9 Plaintiff Iris Smith's ingestion of Elmiron.

10 261. The harm caused by Elmiron far outweighed its benefit, rendering Elmiron more  
11 dangerous than an ordinary consumer or health care professional would expect and more  
12 dangerous than alternative products. Defendants could have designed Elmiron to make it less  
13 dangerous. When Defendants designed Elmiron, the state of the industry's scientific knowledge  
14 was such that a less risky design was attainable.

15 262. At the time Elmiron left Defendants' control, there was a practical, technically  
16 feasible and safer alternative design that would have prevented the harm Plaintiff Iris Smith  
17 suffered without substantially impairing the reasonably anticipated or intended function of  
18 Elmiron. This was demonstrated by the existence of other treatments for the relief of bladder pain  
19 or discomfort associated with interstitial cystitis that had a more established safety profile and a  
20 considerably lower risk profile.

21 263. Defendants' defective design of Elmiron was willful, wanton, fraudulent,  
22 malicious, and done with reckless disregard for the health and safety of users of Elmiron.  
23 Defendants' conduct was motivated by greed and the intentional decision to value profits over the  
24 safety and well-being of the consumers of Elmiron.

25 264. The defects in Elmiron were substantial and contributing factors in causing Plaintiff  
26 Iris Smith's injuries. But for Defendants' acts and omissions, Plaintiff Iris Smith would not have  
27 suffered the injuries complained of herein.

1 265. Due to the unreasonably dangerous condition of Elmiron, Defendants are liable to  
2 Plaintiff.

3 266. Defendants' conduct, as described above, was reckless. Defendants risked the lives  
4 of consumers and users of Elmiron, including Plaintiff Iris Smith, with knowledge of the safety  
5 problems associated with Elmiron, and suppressed this knowledge from the general public.  
6 Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting  
7 public. Defendants' reckless conduct warrants an award of punitive damages.

8 267. As a foreseeable, direct, and proximate consequence of Defendants' actions,  
9 omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and  
10 other related health complications. In addition, Plaintiff Iris Smith requires and will continue to  
11 require healthcare and services. Plaintiff has incurred and will continue to incur medical and  
12 related expenses. Plaintiff Iris Smith also has suffered and will continue to suffer diminished  
13 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting  
14 conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical  
15 losses and costs include physician care, monitoring, and treatment. Plaintiff Iris Smith has incurred  
16 and will continue to incur mental and physical pain and suffering.

17 **TENTH CAUSE OF ACTION AS**

18 **AGAINST THE DEFENDANTS**

19 **(PRODUCTS LIABILITY – FAILURE TO WARN)**

20 268. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
21 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
22 as if more fully set forth herein.

23 269. Defendants have engaged in the business of designing, developing, researching,  
24 testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or  
25 distributing Elmiron. Through that conduct, Defendants knowingly and intentionally placed  
26 Elmiron into the stream of commerce with full knowledge that it reaches consumers, such as  
27 Plaintiff Iris Smith, who ingested it.

1 270. Defendants researched, developed, designed, tested, manufactured, inspected,  
2 labeled, distributed, marketed, promoted, sold, and otherwise released Elmiron into the stream of  
3 commerce. In the course of same, Defendants directly advertised, marketed, and promoted Elmiron  
4 to the FDA, health care professionals, Plaintiff, and other consumers, and therefore had a duty to  
5 warn of the risks associated with the use of Elmiron.

6 271. Defendants expected Elmiron to reach, and it did in fact reach, prescribing health  
7 care professionals and consumers, including Plaintiff Iris Smith and her prescribing health care  
8 professionals, without any substantial change in the condition of the product from when it was  
9 initially distributed by Defendants.

10 272. Elmiron, as manufactured and/or supplied by Defendants, was defective due to  
11 inadequate warnings or instructions. Defendants knew or should have known that the product  
12 created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to  
13 adequately warn consumers and/or their health care professionals of such risks.

14 273. Elmiron was defective and unsafe such that it was unreasonably dangerous when it  
15 left Defendants' possession and/or control, was distributed by Defendants, and ingested by  
16 Plaintiff Iris Smith. Elmiron contained warnings insufficient to alert consumers, including Plaintiff  
17 Iris Smith, to the dangerous risks and reactions associated with Elmiron, including the  
18 development of Plaintiff Iris Smith's injuries.

19 274. This defect caused serious injury to Plaintiff Iris Smith who used Elmiron for its  
20 intended purpose and in a reasonably anticipated manner.

21 275. At all times herein mentioned, Defendants had a duty to properly test, develop,  
22 design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and  
23 take such other steps as are necessary to ensure Elmiron did not cause users to suffer from  
24 unreasonable and dangerous risks.

25 276. Defendants negligently and recklessly labeled, distributed, and promoted Elmiron.

26 277. Defendants had a continuing duty to warn Plaintiff of the dangers associated with  
27 Elmiron.

1 278. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held  
2 to the knowledge of an expert in the field.

3 279. Plaintiff could not have discovered any defects in Elmiron through the exercise of  
4 reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

5 280. Defendants were aware of the probable consequences of the aforesaid conduct.  
6 Despite the facts that Defendants knew or should have known that Elmiron caused serious injuries,  
7 they failed to exercise reasonable care to warn of the severity of the dangerous risks associated  
8 with its use. The dangerous propensities of Elmiron, as referenced above, were known to the  
9 Defendants, or scientifically knowable to them, through appropriate research and testing by known  
10 methods, at the time they distributed, supplied, or sold the product. Such information was not  
11 known to ordinary physicians who would be expected to prescribe the drug for their patients.

12 281. Elmiron, as manufactured and/or supplied by Defendants, was unreasonably  
13 dangerous when used by consumers, including Plaintiff Iris Smith, in a reasonably and intended  
14 manner without knowledge of this risk of serious bodily harm.

15 282. Each of the Defendants knew or should have known that the limited warnings  
16 disseminated with Elmiron were inadequate, but they failed to communicate adequate information  
17 on the dangers and safe use of its product, taking into account the characteristics of and the ordinary  
18 knowledge common to physicians who would be expected to prescribe the drug. In particular,  
19 Defendants failed to communicate warnings and instructions to doctors that were appropriate and  
20 adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses,  
21 including the common, foreseeable, and intended use of the product for the relief of bladder pain  
22 or discomfort associated with interstitial cystitis.

23 283. Defendants communicated to health care professionals information that failed to  
24 contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that  
25 would enable health care professionals to prescribe the drug safely for use by patients for the  
26 purposes for which it is intended. In particular, Defendants:

27 (a) disseminated information that was inaccurate, false, and misleading, and which

1 failed to communicate accurately or adequately the comparative severity, duration,  
2 and extent of the risk of injuries with use of Elmiron;

3 (b) continued to aggressively promote Elmiron even after Defendants knew or should  
4 have known of the unreasonable risks from use;

5 (c) failed to accompany their product with proper or adequate warnings or labeling  
6 regarding adverse side effects and health risks associated with the use of Elmiron  
7 and the comparative severity of such adverse effects;

8 (d) failed to provide warnings, instructions or other information that accurately  
9 reflected the symptoms, scope, and severity of the side effects and health risks,  
10 including but not limited to those associated with Elmiron's capacity to cause its  
11 users to suffer retinal pigmentary changes;

12 (e) failed to adequately warn users, consumers, and physicians about the need to  
13 perform initial and periodic retinal examinations; and

14 (f) overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing  
15 and promotion, the risks associated with the use of Elmiron.

16 284. To this day, Defendants have failed to adequately and accurately warn of the true  
17 risks of injuries associated with the use of Elmiron.

18 285. Due to these deficiencies and inadequacies, Elmiron was unreasonably dangerous  
19 and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by  
20 the Defendants.

21 286. Had Defendants properly disclosed and disseminated the risks associated with  
22 Elmiron, Plaintiff Iris Smith would have avoided the risk of developing injuries as alleged herein.

23 287. The Defendants are liable to Plaintiff for injuries caused by their negligent or willful  
24 failure to provide adequate warnings or other clinically relevant information and data regarding  
25 the appropriate use of Elmiron and the risks associated with its use.

26 288. As a foreseeable, direct, and proximate consequence of Defendants' actions,  
27 omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and  
28 other related health complications. In addition, Plaintiff Iris Smith requires and will continue to  
require healthcare and services. Plaintiff has incurred and will continue to incur medical and  
related expenses. Plaintiff Iris Smith also has suffered and will continue to suffer diminished

1 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting  
2 conditions, activation of latent conditions, and other losses and damages. Plaintiff Iris Smith's  
3 direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff Iris  
4 Smith has incurred and will continue to incur mental and physical pain and suffering.

5 **ELEVENTH CAUSE OF ACTION AS**

6 **AGAINST THE DEFENDANTS**

7 **(PRODUCT LIABILITY – MANUFACTURING DEFECT)**

8 289. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
9 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
10 as if more fully set forth herein.

11 290. At all times material to this action, Defendants were engaged in the business of  
12 designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing,  
13 labeling, and/or selling Elmiron.

14 291. At all times material to this action, Elmiron was expected to reach, and did reach,  
15 consumers in the State of California and throughout the United States, including Plaintiff, Iris  
16 Smith, without substantial change in the condition in which it was sold.

17 292. At all times material to this action, Elmiron was designed, developed,  
18 manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by  
19 Defendants in a defective and unreasonably dangerous condition at the time it was placed in the  
20 stream of commerce in ways which include, but are not limited to, one or more of the following  
21 particulars:

- 22 (a) When placed in the stream of commerce, Elmiron contained manufacturing defects  
23 which rendered the product unreasonably dangerous;
- 24 (b) The subject product's manufacturing defects occurred while the product was in the  
25 possession and control of Defendants;
- 26 (c) The subject product was not made in accordance with Defendants' specifications  
27 or performance standards; and/or

1 (d) The subject product's manufacturing defects existed before it left the control of  
2 Defendants.

3 293. As a direct and proximate result of the design defect and Defendants' misconduct  
4 set forth herein, Plaintiff Iris Smith has suffered and will continue to suffer serious and permanent  
5 physical and emotional injuries, has expended and will continue to expend large sums of money  
6 for medical care and treatment, has suffered and will continue to suffer economic loss, and has  
7 otherwise been physically, emotionally and economically injured.

8 **TWELVTH CAUSE OF ACTION AS**  
9 **AGAINST THE DEFENDANTS**  
10 **(PUNITIVE DAMAGES)**

11 294. Plaintiff repeats, reiterates, and realleges each and every allegation of this  
12 Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect  
13 as if more fully set forth herein.

14 295. Plaintiff is entitled to punitive damages because Defendants misrepresented and/or  
15 withheld information and materials from the FDA, the medical community and the public at large,  
16 including the Plaintiff Iris Smith, concerning the safety profile, and, more specifically the serious  
17 side effects and/or complications associated with Elmiron.

18 296. In respect to the FDA, physicians, and consumers, Defendant downplayed,  
19 understated or disregarded knowledge of the serious and permanent side effects and risks  
20 associated with the use of Elmiron, despite available information that Elmiron was likely to cause  
21 serious side effects and/or complications.

22 297. In respect to the FDA, physicians, and consumers, Defendant downplayed,  
23 understated or disregarded knowledge of the serious and permanent side effects and risks  
24 associated with the use of Elmiron, despite available information that Elmiron was likely to cause  
25 serious side effects and/or complications.

26 298. Defendants' failure to provide the necessary materials and information to the FDA,  
27 as well as their failure warn physicians and consumers of the serious side effects and/or



1 complications, was reckless and without regard for the public's safety and welfare.

2 299. Defendants were or should have been in possession of evidence demonstrating that  
3 Elmiron causes serious side effects. Nevertheless, Defendant continued to market Elmiron by  
4 providing false and misleading information with regard to safety and efficacy.

5 300. Defendants failed to provide the FDA, physicians and consumers with available  
6 materials, information and warnings that would have ultimately dissuaded physicians from  
7 prescribing Elmiron to consumers, from purchasing and consuming Elmiron, thus depriving  
8 physicians and consumers from weighing the true risks against the benefits of prescribing and/or  
9 purchasing and consuming Elmiron.

10 **PRAYER FOR RELIEF**

11 **WHEREFORE**, Plaintiff demands judgment against the Defendants on each of the above-  
12 referenced claims and Causes of Action and as follows:

13 1. Awarding compensatory damages to Plaintiff for past and future damages,  
14 including but not limited to pain and suffering for severe and permanent personal injuries sustained  
15 by the Plaintiff Iris Smith, health care costs, medical monitoring, together with interest and costs  
16 as provided by law;

17 2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless  
18 acts of the Defendants who demonstrated a complete disregard and reckless indifference for the  
19 safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish  
20 Defendants and deter future similar conduct;

21 3. Awarding Plaintiff reasonable attorneys' fees;

22 4. Awarding Plaintiff the costs of these proceedings; and

23 5. Such other and further relief as this Court deems just and proper.

24 **DEMAND FOR JURY TRIAL**

25 Pursuant to FED. R. CIV. P. 38(b), Plaintiff demands a jury trial for any and all issues triable  
26 by a jury.

1 Dated: November 30, 2020

Respectfully submitted,  
FEARS NACHAWATI, PLLC

3 /s/ Arati C. Furness  
4 ARATI C. FURNESS (CA SBN: 225435)  
5 afurness@fnlawfirm.com  
6 PATRICK A. LUFF (TX SBN: 24092728)  
7 *Application for Admission Pro Hac Vice*  
8 *Anticipated*  
9 pluff@fnlawfirm.com  
5473 Blair Road  
Dallas, Texas 75231  
Telephone: (214) 890-0711  
Facsimile: (214) 890-0712

*Attorneys for Plaintiff*