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UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

IRIS SMITH Plaintiff, vs. JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN ORTHO LLC; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC; ORTHO-MCNEIL PHARMACEUTICALS, LLC; JOHNSON & JOHNSON COMPANY; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; AND TEVA PHARMACEUTICALS USA, INC. Defendants.	Case No.: 2:20-at-01181 **ORIGINAL COMPLAINT** **JURY TRIAL DEMANDED**

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

JURISDICTION AND VENUE

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

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

NATURE OF THE CASE

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

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

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

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

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

PLAINTIFF

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

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

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

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

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

DEFENDANTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

at 400 Interpace Parkway, Parsippany, NJ 07054.

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

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

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

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

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

FACTUAL BACKGROUND

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

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

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

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

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

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

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

60. On August 7, 1985, the United Sates Food and Drug Administration (hereinafter referred to as "FDA") designated Elmiron an orphan drug product due to the rarity of interstitial cystitis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[2] Pearce WA, et al. *Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium.* Ophthalmology. 2018 May 22.

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

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

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

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

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

[4] Hanif AM, et al. *Strength of Association between Pentosan Polysulfate and a Novel Maculopathy*. Ophthalmology. 2019 Oct;126(10):1464-1466.

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

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

77. Another presentation at the October 2019 AAO meeting was "the first study to

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[5] Hanif A, et al. *Phenotypic Spectrum of Pentosan Polysulfate Sodium-Associated Maculopathy: A Multicenter Study*. JAMA Ophthalmol. 2019;137(11):1275-1282.

[6] "More Evidence Linking Common Bladder Medication to a Vision-threatening Eye Condition." AAO Press Release. Oct. 12, 2019.

[7] Vora RA, et al. *Prevalence of Maculopathy Associated with Long-Term Pentosan Polysulfate Therapy*. Ophthalmology. 2020 June;127(6):835-836.

demonstrate a *dose-response correlation* between exposure to [Elmiron] and retinal toxicity."[8]

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

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

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[8] Schaal, S. and Hadad, A. "Qualitative and Quantitative Analysis of Pentosan Polysulfate Sodium Retinal Toxicity Demonstrates a Dose-Response Curve." AAO PA068 – 2.

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

[10] Huckfeldt R, et al. *Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium*. Ophthalmic Surgery, Lasers & Imaging Retina. 2019;50(10):656-659. Similar screening guidelines have been 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.

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

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

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

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

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

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[11] Shah, R., et al. *Disease Course in Patients With Pentosan Polysulfate Sodium-Associated Maculopathy After Drug Cessation*. JAMA Ophthalmol. July 9, 2020.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

103. Plaintiff Iris Smith has suffered from mental anguish from the knowledge that she may suffer life-long complications as a result of the injuries caused by Elmiron.

FIRST CAUSE OF ACTION

AS AGAINST THE DEFENDANTS

(NEGLIGENCE)

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

105. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, and/or distribution of Elmiron into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

106. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Elmiron into interstate commerce in that Defendants knew or should have known that using Elmiron created a high risk of unreasonable, dangerous side effects, including but not limited to retinal pigmentary changes, vision changes, and potentially irreversible vision damage, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

107. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Elmiron without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing Elmiron without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not Elmiron was safe for use; in that Defendants herein knew or should have known that Elmiron was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling Elmiron without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Elmiron;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Elmiron;

(g) Failing to test Elmiron and/or failing to adequately, sufficiently and properly test Elmiron.

(h) Negligently advertising and recommending the use of Elmiron without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that Elmiron was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that Elmiron had equivalent safety and efficacy as other forms of treatment for the relief of bladder pain or discomfort associated with interstitial cystitis;

(k) Negligently designing Elmiron in a manner which was dangerous to its users;

(l) Negligently manufacturing Elmiron in a manner which was dangerous to its users;

(m) Negligently producing Elmiron in a manner which was dangerous to its users;

(n) Negligently assembling Elmiron in a manner which was dangerous to its users;

(o) Concealing information from the Plaintiff in knowing that Elmiron was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Elmiron compared to other forms of treatment for the relief of bladder pain or discomfort associated with interstitial cystitis.

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

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

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

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

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

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

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

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

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

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

(h) Were otherwise careless and/or negligent.

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.

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

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

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

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

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

SECOND CAUSE OF ACTION

AS AGAINST THE DEFENDANTS

(STRICT PRODUCTS LIABILITY)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THIRD CAUSE OF ACTION

AS AGAINST THE DEFENDANTS

(BREACH OF EXPRESS WARRANTY)

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

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

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

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

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

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

(b) was of merchantable quality;

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

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

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

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

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

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

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

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

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

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

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

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

155. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and 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

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

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

FOURTH CAUSE OF ACTION

AS AGAINST THE DEFENDANTS

(BREACH OF IMPLIED WARRANTIES)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FIFTH CAUSE OF ACTION AS

AGAINST THE DEFENDANTS

(FRAUDULENT MISREPRESENTATION)

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

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

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Elmiron had been tested and found to be safe and effective for the relief of bladder pain or discomfort associated with interstitial cystitis; and

(b) Upon information and belief, Defendants represented that Elmiron was safer than other alternative medications.

(c) Defendants knew that their representations were false, yet they willfully, wantonly, 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.

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

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

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

183. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and 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 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff Iris Smith's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff Iris Smith has incurred and will continue to incur mental and physical pain and suffering.

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

SIXTH CAUSE OF ACTION AS

AGAINST THE DEFENDANTS

(FRAUDULENT CONCEALMENT)

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

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

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

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Elmiron was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using Elmiron; and

(b) Upon information and belief, Defendants represented that Elmiron was safer than other alternative medications and/or treatments and fraudulently concealed information which demonstrated that Elmiron was not safer than alternatives available on the market.

(c) Defendants were under a duty to Plaintiff Iris Smith to disclose and warn of the defective and dangerous nature of Elmiron because:

(d) Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of Elmiron;

(e) Defendants knowingly made false claims and omitted important information about the safety and quality of Elmiron in the documents and marketing materials Defendants provided to physicians and the general public; and

(f) Defendants fraudulently and affirmatively concealed the defective and dangerous nature of Elmiron from Plaintiff.

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

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

190. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by Elmiron was intentional, and the representations made by 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

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

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

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

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

195. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and 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 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff Iris Smith's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff Iris Smith has incurred and will continue to incur mental and physical pain and suffering.

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

SEVENTH CAUSE OF ACTION AS

AGAINST THE DEFENDANTS

(NEGLIGENT MISREPRESENTATION)

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

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

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

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

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

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

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

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

(a) stating that Elmiron had been tested and found to be safe and effective for the relief of bladder pain or discomfort associated with interstitial cystitis;

(b) concealing, misrepresenting, and actively downplaying the severe risks of harm to users of Elmiron, when compared to comparable or superior alternative drug therapies; and

(c) misrepresenting Elmiron's risk of unreasonable, dangerous, adverse side effects.

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

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

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

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

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

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

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

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

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

212. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and 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 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff Iris Smith's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff Iris Smith has incurred and will continue to incur mental and physical pain and suffering.

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

EIGHTH CAUSE OF ACTION AS

AGAINST THE DEFENDANTS

(FRAUD AND DECEIT)

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

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

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

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

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

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

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

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

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

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

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

224. These representations were all false and misleading.

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

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

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

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

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

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

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

health and/or safety risks.

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

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

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

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

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

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

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

239. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Elmiron.

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

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

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

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

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

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

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

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

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

NINTH CAUSE OF ACTION AS

AGAINST THE DEFENDANTS

(PRODUCT LIABILITY – DESIGN DEFECT)

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

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

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

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

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

(a) When placed in the stream of commerce, Elmiron contained unreasonably 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;

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

relief of bladder pain or discomfort associated with interstitial cystitis;

(c) Elmiron was insufficiently tested;

(d) Elmiron caused harmful side effects that outweighed any potential utility;

(e) Defendants were aware at the time Elmiron was marketed that ingestion of Elmiron would result in an increased risk of retinal pigmentary changes and other injuries;

(f) Inadequate post-marketing surveillance; and/or

(g) There were safer alternative designs and formulations that were not utilized.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

267. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and 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 capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff Iris Smith has incurred and will continue to incur mental and physical pain and suffering.

TENTH CAUSE OF ACTION AS

AGAINST THE DEFENDANTS

(PRODUCTS LIABILITY – FAILURE TO WARN)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

288. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff Iris Smith suffered retinal pigmentary changes and 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

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

ELEVENTH CAUSE OF ACTION AS

AGAINST THE DEFENDANTS

(PRODUCT LIABILITY – MANUFACTURING DEFECT)

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

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

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

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

(a) When placed in the stream of commerce, Elmiron contained manufacturing defects which rendered the product unreasonably dangerous;

(b) The subject product's manufacturing defects occurred while the product was in the possession and control of Defendants;

(c) The subject product was not made in accordance with Defendants' specifications or performance standards; and/or

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

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

TWELVTH CAUSE OF ACTION AS

AGAINST THE DEFENDANTS

(PUNITIVE DAMAGES)

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

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

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

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

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

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

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

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

PRAYER FOR RELIEF

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

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

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

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

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

DEMAND FOR JURY TRIAL

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

Dated: November 30, 2020

Respectfully submitted,
FEARS NACHAWATI, PLLC

/s/ Arati C. Furness

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