**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

**IN RE: ELMIRON (PENTOSAN POLYSULFATE SODIUM) PRODUCTS LIABILITY LITIGATION**

RIVA ZRINSKI

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; JOHNSON & JOHNSON COMPANY; ORTHO-MCNEIL PHARMACEUTICALS, LLC; ALZA CORPORATION; and, TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. f/k/a TEVA GLOBAL RESPIRATORY RESEARCH, LLC, f/k/a IVAX RESEARCH LLC, f/k/a IVAX RESEARCH INC., f/k/a IVAX LABORATORIES INC., f/k/a BAKER NORTON PHARMACEUTICALS, INC., IVAX LLC f/k/a IVAX CORPORATION,

Defendants.

**MDL No. 2973**
**Case No. 2:20-md-02973(BRM)(ESK)**

**JUDGE BRIAN R. MARTINOTTI**
**JUDGE EDWARD S. KIEL**

DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 6

Civil Action No:_____

Plaintiff Riva Zrinski ("Plaintiff"), by her attorneys, **SEEGER WEISS LLP**, upon information and belief, at all times hereinafter mentioned, alleges 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 as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs,

and because Defendants are citizens of states other than the state in which Plaintiff resides, which is Alabama.

2. This Court has personal jurisdiction over Defendants consistent with the United States Constitution as Plaintiff's claims arise out of Defendants' transaction of business and the tortuous acts within the State of New Jersey, and by virtue of Defendants' substantial, continuous, and systematic contacts with the State of New Jersey 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; ALZA CORPORATION (hereinafter referred to as "ALZA"); and TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. f/k/a Teva Global Respiratory Research, LLC, f/k/a Ivax Research LLC, f/k/a Ivax Research Inc., f/k/a Ivax Laboratories Inc., f/k/a Baker Norton Pharmaceuticals, Inc., ("Baker Norton") (hereinafter "TEVA R&D"), IVAX LLC f/k/a IVAX Corporation (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, have suffered and may continue to suffer severe and permanent personal injuries, including but not limited to retinal pigmentary changes such as pigmentary maculopathy, 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 suffered retinal pigmentary changes including but not limited to retinal pigmentary changes due to ELMIRON use. Plaintiff's ingestion of the defective and unreasonably dangerous drug ELMIRON has caused and will continue to cause injury and damage to Plaintiff.

7. Plaintiff brings this action for personal injuries suffered as a proximate result of Plaintiff 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.

## PARTY PLAINTIFF

8. Plaintiff, Riva Zrinski, is a citizen and resident of the State of Alabama in Madison County.

9. Plaintiff was born on June 8th, 1992.

10. Plaintiff was prescribed and ingested ELMIRON from approximately 2018 through June 2021.

11. As a result of using Defendants' ELMIRON, Plaintiff was caused to suffer retinal pigmentary changes.

12. As a result of using Defendants' ELMIRON, Plaintiff was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

13. The injuries and damages sustained by Plaintiff were caused by Defendants' ELMIRON.

**PARTY DEFENDANTS**

14. 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.

15. 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.

16. Upon information and belief, Defendant JANSSEN PHARM has transacted and conducted business in the State of New Jersey and the State of Alabama.

17. Upon information and belief, Defendant JANSSEN PHARM, has derived substantial revenue from goods and products used in the State of New Jersey and the State of Alabama.

18. 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 New Jersey and the State of Alabama, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Alabama, more particularly.

19. 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.

20. 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 State Road 933 Km 0 1, Street State Ro, Gurabo, Puerto Rico 00778. Defendant JANSSEN ORTHO is a subsidiary of Johnson & Johnson.

21. 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.

22. Upon information and belief, Defendant JANSSEN ORTHO has transacted and conducted business in the State of New Jersey and the State of Alabama.

23. Upon information and belief, Defendant JANSSEN ORTHO has derived substantial revenue from goods and products used in the State of New Jersey and the State of Alabama.

24. Upon information and belief, Defendant JANSSEN ORTHO 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 Alabama, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Alabama, more particularly.

25. 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.

26. 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 is Centocor Research & Development, Inc., which 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 determining diversity under 28 U.S.C. § 1332.

27. Upon information and belief, Defendant JANSSEN R&D has transacted and conducted business in the State of New Jersey and the State of Alabama.

28. Upon information and belief, Defendant JANSSEN R&D has derived substantial revenue from good and products used in the State of New Jersey and the State of Alabama.

29. Upon information and belief, Defendant JANSSEN R&D 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 Alabama, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Alabama, more particularly.

30. 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.

31. 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.

32. Upon information and belief, Defendant ORTHO PHARMA has transacted and conducted business in the State of New Jersey and the State of Alabama.

33. Upon information and belief, Defendant ORTHO PHARMA has derived substantial revenue from good and products used in the State of New Jersey and the State of Alabama.

34. Upon information and belief, Defendant ORTHO PHARMA 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 Alabama, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Alabama, more particularly.

35. 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.

36. Upon information and belief, Defendant ALZA is a corporation organized under Delaware law with its principal place of business in California. ALZA held the NDA for Elmiron.

37. As part of its business, ALZA is involved in the research, development, sales, and marketing of pharmaceutical products including Elmiron.

38. Upon information and belief, and at all relevant times, Defendant ALZA was in the business of and did advertise, promote, market, sell, and distribute the drug Elmiron.

39. Upon information and belief, Defendant JOHNSON & JOHNSON COMPANY (hereinafter referred to as "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.

40. Upon information and belief, and at all relevant times, Defendants JANSSEN PHARM, ORTHO PHARMA, JANSSEN R&D, ALZA, and JANSSEN ORTHO have been wholly owned subsidiaries of Defendant J&J with their profits inuring to Defendant J&J's benefit.

41. 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.

42. Upon information and belief, Defendant J&J has transacted and conducted business in the State of New Jersey and State of Alabama.

43. Upon information and belief, Defendant J&J has derived substantial revenue from goods and products used in the State of New Jersey and the State of Alabama.

44. Upon information and belief, Defendant J&J 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 Alabama, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Alabama, more particularly.

45. 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.

46. Upon information and belief, Defendant TEVA R&D is a corporation organized under the laws of Delaware, having a principal place of business in Pennsylvania.

47. 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.

48. Upon information and belief, Defendant TEVA R&D has transacted and conducted business in the State of New Jersey and the State of Alabama.

49. 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 Alabama.

50. Upon information and belief, Defendant TEVA R&D 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 Alabama, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Alabama, more particularly.

51. 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.

52. Defendant IVAX LLC f/k/a Ivax Corporation (hereinafter “IVAX” or “IVAX LLC”) is a Florida limited liability company.

53. Upon information and belief, IVAX and Baker Norton conducted clinical trials on Elmiron that were used to support FDA approval of the drug.

54. Upon information and belief, at all relevant times, Defendant IVAX was actively involved in Baker Norton's business operations, including the early testing, developing, manufacturing, marketing, distribution, and selling of Elmiron.

55. In approximately September 1997, IVAX transferred the NDA and licensed the rights to Elmiron in the United States and Canada to Defendant ALZA, for $75 million in up-front payments and additional consideration.

56. IVAX LLC continued to report royalty revenues derived from the sale and distribution of Elmiron in Securities and Exchange Commission filings through at least 2005.

57. At all relevant times TEVA R&D, IVAX, and ALZA were, and still are, pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale and release for use to the general public of Elmiron in Alabama and New Jersey and throughout the United States.

## FACTUAL BACKGROUND

58. 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.

59. 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 Alabama.

60. Upon information and belief, the original New Drug Application (hereinafter referred to as "NDA") for ELMIRON was submitted by Baker Norton Pharmaceuticals (hereinafter referred to as "the sponsor").

61. ELMIRON sales in the United States total more than $150 million each year.

62. ELMIRON is an oral medication approved for use to relieve bladder pain or discomfort associated with interstitial cystitis.

63. Interstitial cystitis is a bladder condition affecting, mainly women, in the United States that causes increased bladder pressure, bladder pain, and even pelvic pain that can often be severe.

64. 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).

65. 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.

66. 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.

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

68. On October 28, 1994, FDA issued a second non-approval letter due to insufficient clinical trial evidence to establish efficacy.

69. Once again, the FDA emphasized that the studies could not be considered independent due to issues with the investigators.

70. In removing the data generated by those investigators, neither study was powered to show statistical significance for any of the primary efficacy endpoints.

71. While FDA did find that study 002 provided 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.

72. 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.

73. Ultimately, for its third resubmission of the NDA, the sponsor relied on two clinical studies.

74. The first study (study 002) was a blinded, randomized, placebo-controlled trial that evaluated only 151 patients for three (3) months.

75. Of the patients receiving ELMIRON, 38% reported greater than 50% improvement in bladder pain compared to 18% of the placebo patients.

76. 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.

77. Further, FDA also noted that one investigator in particular influenced the results.

78. When the data from that investigator were removed, the results still favored ELMIRON over placebo but were no longer statistically significant.

79. The second clinical trial was an unblinded retrospective analysis of 2,499 patients, mostly women, in the ELMIRON Compassionate Use program.

80. 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.

81. 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.

82. 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.

83. 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.

84. On September 26, 1996, FDA ultimately approved the NDA for ELMIRON based on these two studies despite the significant concerns.

85. The FDA reviewers noted that, while the studies had 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.

86. In approximately September 1997, IVAX transferred the NDA and licensed the rights to Elmiron in the United States and Canada to Defendant ALZA for $75 million in up-front payments and additional consideration.

87. IVAX continued to report royalty revenues derived from the sale and distribution of Elmiron in S.E.C. filings through at least 2005.

88. BAKER NORTON has owned the U.S. Trademark for "Elmiron" since 1992 through the present, and continues to be listed on the package insert as the licensee of the trademark.

89. At all times relevant and material hereto, BAKER NORTON, IVAX, and ALZA were, and still are, pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey, Alabama, and throughout the United States.

90. 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.

91. Upon information and belief, from approximately 2005 through 2017 vision injury from use of the drug continued to be an issue that was discussed by employees responsible for the drug and the drug's safety at one or more of the Defendants.

92. 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]

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

94. 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]

[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.
[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.

95. 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]

96. 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]

97. 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

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

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

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]

98. Another presentation at the October 2019 AAO meeting was "the first study to demonstrate a *dose-response correlation* between exposure to [ELMIRON] and retinal toxicity."[8]

99. 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 (5) and seven (7) years of use. At the seven (7) 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]

100. Also, in November 2019, a researcher at Harvard published a case study of ELMIRON-associated maculopathy that progressed over six (6) 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 (6) years and was determined

[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.
[8] Schaal, S. and Hadad, A. "Qualitative and Quantitative Analysis of Pentosan Polysulfate Sodium Retinal Toxicity Demonstrates a Dose-Response Curve." AAO PA068 – 2019.
[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.

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]

101. 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 (9) 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]

102. 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.

[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.

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

103. 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.

104. Consumers, including Plaintiff, 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.

105. Defendants knew or should have known of the significant risk of retinal pigmentary changes caused by ingestion of ELMIRON.

106. 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.

107. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of ELMIRON and willfully deceived Plaintiff, 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.

108. As a direct result, in or about 2018, Plaintiff was prescribed and began taking ELMIRON, primarily for the relief of bladder pain or discomfort associated with interstitial cystitis.

109. Plaintiff ingested and used ELMIRON as prescribed and in a foreseeable manner.

110. The ELMIRON used by Plaintiff, was provided to her in a condition substantially the same as the condition in which it was manufactured and sold.

111. Plaintiff agreed to initiate treatment with ELMIRON in an effort to relieve bladder pain or discomfort associated with interstitial cystitis.

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

113. Instead, ELMIRON can cause severe injuries, including retinal pigmentary changes such as pigmentary maculopathy.

114. After beginning treatment with ELMIRON, and as a direct and proximate result thereof, Plaintiff suffered retinal pigmentary changes due to ELMIRON use.

115. Defendants knew or should have known the risks associated with the use of ELMIRON, including the risk of retinal pigmentary changes such as pigmentary maculopathy (among other injuries).

116. The development of Plaintiff's injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies and testing, 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.

117. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and ELMIRON's defects.

118. At all times material hereto, Defendants, by and through their agents 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.

119. Plaintiff 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 would have avoided the risk of developing the injuries complained of herein by not ingesting ELMIRON.

120. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking ELMIRON.

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

122. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of ELMIRON, Plaintiff 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.

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

**DELAYED DISCOVERY**

124. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians and healthcare providers the true and significant risks associated with ELMIRON.

125. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians and healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

**FIRST CAUSE OF ACTION**
**AS AGAINST THE DEFENDANTS**
**(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)**

126. 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.

127. 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.

128. 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.

129. At those times, ELMIRON was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein. And Defendants knew or had reason to know that the product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

130. 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:

(a) the foreseeable risks exceeded the benefits associated with the design or formulation of ELMIRON;

(b) it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect;

(c) it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and injuries associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, macular degeneration and maculopathy;

(d) it contained inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury; and

(e) the Defendants knew or should have known that it 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 and continued to improperly advertise, market and/or promote their product, ELMIRON.

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

132. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

133. Defendants, as manufacturers and/or distributors of the subject prescription product, and as the Reference Listed Drug Company and the New Drug Application Holder, are held to the level of knowledge of an expert in the field.

134. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

135. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

136. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the subject product.

137. Had Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

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

139. Defendants' inadequate warnings of ELMIRON were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

140. As a result of the foregoing acts and omissions, the Plaintiff 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 due to ELMIRON use 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.

141. As a result of the foregoing acts and omissions, the Plaintiff requires and 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 Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

**SECOND CAUSE OF ACTION AS AGAINST THE DEFENDANTS (STRICT PRODUCTS LIABILITY – DESIGN DEFECT)**

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

144. Defendants expected ELMIRON to reach, and it did in fact reach consumers in the state of Alabama and throughout the United States, including Plaintiff without, substantial change in the condition in which it was manufactured and sold by the Defendants.

145. 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.

146. 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 to risks that exceeded the benefits of the drug, including permanent personal injuries including, but not limited to, developing Elmiron-associated maculopathy.

(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) The design defects of ELMIRON existed before it left the control of Defendants;

(d) ELMIRON was insufficiently tested;

(e) ELMIRON caused harmful side effects that outweighed any potential utility;

(f) ELMIRON was not accompanied by adequate instructions or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

(g) 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;

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

(i) At the time the product left the control of Defendants, there were practical and feasible safer alternative designs and formulations that would have prevented or significantly reduced the risk of Plaintiffs' injuries without substantially impairing the product's utility. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

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

148. Due to the unreasonably dangerous condition of ELMIRON, Defendants are liable to Plaintiff.

149. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of ELMIRON, including Plaintiff, 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.

150. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes and other related health complications due to ELMIRON use. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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 has incurred and will continue to incur mental and physical pain and suffering.

151. Defendants' defective design of ELMIRON amounts to willful, wanton, and/or reckless conduct by Defendants.

152. Defects in Defendants' drug ELMIRON were a substantial factor in causing Plaintiff's injuries.

153. As a result of the foregoing acts and omissions, the Plaintiff 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 due to ELMIRON use 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.

154. As a result of the foregoing acts and omissions the Plaintiff requires and 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 Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

**THIRD CAUSE OF ACTION AS AGAINST THE DEFENDANTS (MANUFACTURING DEFECT)**

155. 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.

156. 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.

157. At all times material to this action, ELMIRON was expected to reach, and did reach, consumers, including Plaintiff, in the State of Alabama and throughout the United States without substantial change in the condition in which it was sold.

158. 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.

159. The subject product manufactured and/or supplied by Defendants was not reasonably fit, suitable or safe for its intended purpose because when it left Defendants' hands, it deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or

formulae. In particular, the product is not safe, has numerous and serious side effects, and causes severe and permanent injuries including, but not limited to, developing Elmiron related maculopathy.

160. Defendants' manufacturing defect of ELMIRON amounts to willful, wanton, and/or reckless conduct by Defendants.

161. As a direct and proximate result of the design defect and Defendants' misconduct set forth herein, Plaintiff 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.

**FOURTH CAUSE OF ACTION**
**AS AGAINST THE DEFENDANTS**
**(NEGLIGENCE)**

162. 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.

163. 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.

164. 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 due to ELMIRON use 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.

165. The negligence of the Defendants, their agents 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 the Plaintiff, the public, and the medical and healthcare profession 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 and dangerous;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, 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.

166. Defendants under-reported, underestimated and downplayed the serious dangers of ELMIRON.

167. 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.

168. 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.

169. 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.

170. 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.

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

172. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to retinal pigmentary changes such as pigmentary maculopathy, vision changes, and potentially irreversible vision damage, as well as other severe and personal injuries due to ELMIRON use 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.

173. As a result of the foregoing acts and omissions the Plaintiff 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 Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

**FIFTH CAUSE OF ACTION**
**AS AGAINST THE DEFENDANTS**
**(BREACH OF EXPRESS WARRANTY)**

174. 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.

175. 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.

176. Defendants expressly represented to Plaintiff, 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.

177. 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.

178. Defendants advertised, labeled, marketed, and promoted ELMIRON, representing the quality to health care professionals, Plaintiff, 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.

179. 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.

180. 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.

181. 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.

182. 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.

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

184. Plaintiff, other consumers, Plaintiff's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when prescribing and ingesting ELMIRON.

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

186. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes and other related health complications due to ELMIRON use. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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 has incurred and will continue to incur mental and physical pain and suffering.

**SIXTH CAUSE OF ACTION**
**AS AGAINST THE DEFENDANTS**
**(BREACH OF IMPLIED WARRANTIES)**

187. 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.

188. Defendants manufactured, distributed, advertised, promoted, and sold ELMIRON.

189. 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.

190. Defendants were aware that consumers, including Plaintiff, would use ELMIRON for the relief of bladder pain or discomfort associated with interstitial cystitis.

191. 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.

192. 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.

193. Defendants were aware that consumers, including Plaintiff, would use ELMIRON as marketed by Defendants. As such, Plaintiff was a foreseeable user of ELMIRON.

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

195. ELMIRON was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

196. 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.

197. 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.

198. Plaintiff and her physicians reasonably relied upon Defendants' implied warranty for ELMIRON when prescribing and ingesting ELMIRON.

199. Plaintiff's use of ELMIRON was as prescribed and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

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

201. Defendants breached the warranties of merchantability and fitness for its particular purpose because ELMIRON was unduly dangerous and caused undue injuries to consumers, including Plaintiff.

202. 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.

203. Neither Plaintiff nor her health care professionals reasonably could have discovered or known of the risk of serious injury associated with ELMIRON.

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

205. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes and other related health complications due to ELMIRON use. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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 has incurred and will continue to incur mental and physical pain and suffering.

**SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (CONSUMER FRAUD)**

206. 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.

207. Defendants marketed, promoted and sold Elmiron through false and misleading misrepresentations or omissions of material fact. Defendants communicated the purported benefits of ELMIRON while failing to disclose the serious and dangerous side effects related to the use of ELMIRON with the intent that consumers, including Plaintiff, and her healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe ELMIRON, respectively.

208. Defendants made false and misleading misrepresentations with respect to ELMIRON, including but not limited to the following acts and/or omissions:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, and notice letters

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

209. As a result of this conduct, Defendants caused Plaintiff to be prescribed and to use ELMIRON, causing severe injuries and damages as previously described herein.

**EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD)**

210. 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.

211. Defendants conducted research and used ELMIRON as part of their research.

212. 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, Plaintiff's doctors, hospitals, and healthcare professionals, that ELMIRON was safe and effective for the relief of bladder pain or discomfort associated with interstitial cystitis.

213. 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 Plaintiff.

214. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers.

215. The information distributed to the public and the 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.

216. The information distributed to the public and the 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.

217. The information distributed to the public and the 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.

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

219. The information distributed to the public and the 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.

220. These representations were all false and misleading.

221. 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.

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

223. Defendants intentionally made material representations to the public in general, including the medical profession, and the 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.

224. That it was the purpose of Defendants in making these representations to deceive and defraud the public, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals 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.

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

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

227. That Defendants made claims and representations in its documents provided to the public, to healthcare professionals, and the 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.

228. That these representations and others Defendants made 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.

229. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe ELMIRON.

230. That Defendants recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of ELMIRON to the public at large, the Plaintiff 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.

231. 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.

232. 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 luring the Plaintiff, as well as her respective healthcare professionals into a sense of security

so that Plaintiff would rely on the representations and purchase, use and rely on ELMIRON and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

233. 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 as well as Plaintiff's respective healthcare professionals, would rely upon the information being disseminated.

234. Defendants utilized direct to consumer advertising to market, promote, and/or advertise ELMIRON.

235. That the Plaintiff 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.

236. That at the time the representations were made, the Plaintiff 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.

237. 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 with reasonable diligence have discovered the true facts.

238. That had the Plaintiff 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.

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

240. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including retinal pigmentary changes and other related health complications due to ELMIRON use 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.

241. As a result of the foregoing acts and omissions the Plaintiff 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 Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

**NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT MISREPRESENTATION)**

242. 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.

243. 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.

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

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

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

246. Plaintiff, her doctors, and others relied upon these representations.

247. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes and other related health complications due to ELMIRON use. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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 has incurred and will continue to incur mental and physical pain and suffering.

248. The accrual and running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent misrepresentations.

249. Each Defendant is equitably estopped from asserting any limitations defense by virtue of its fraudulent misrepresentations and other misconduct as described in this Complaint.

**TENTH CAUSE OF ACTION**
**AS AGAINST THE DEFENDANTS**
**(FRAUDULENT CONCEALMENT)**

250. 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.

251. 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.

252. 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;

(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 to disclose and warn of the defective and dangerous nature of ELMIRON because:

i. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of ELMIRON;

ii. 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

iii. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of ELMIRON from Plaintiff.

253. 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 and her healthcare providers. As such, Plaintiff and her healthcare providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

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

255. 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.

256. The concealment of information and the misrepresentations about ELMIRON were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them

so that Plaintiff would request and purchase ELMIRON and her health care providers would prescribe and recommend ELMIRON.

257. Plaintiff, her doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by ELMIRON.

258. Had Defendants not concealed or suppressed information regarding the severity of the risks of ELMIRON, Plaintiff and her physicians would not have prescribed or ingested the drug.

259. Defendants, by concealment or other action, intentionally prevented Plaintiff 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.

260. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes and other related health complications due to ELMIRON use. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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 has incurred and will continue to incur mental and physical pain and suffering.

261. The accrual and running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

262. Each Defendant is equitably estopped from asserting any limitations defense by virtue of its fraudulent concealment and other misconduct as described in this Complaint.

**ELEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)**

263. 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.

264. 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.

265. 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.

266. 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.

267. 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.

268. 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.

269. 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, 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.

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

271. 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.

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

273. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, 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.

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

275. 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.

276. 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.

277. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of ELMIRON, including Plaintiff. 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.

278. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes and other related health complications due to ELMIRON use. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff 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 has incurred and will continue to incur mental and physical pain and suffering.

## TWELFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (PUNITIVE DAMAGES)

279. 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.

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

281. In respect to 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.

282. In respect to the 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.

283. Defendants' failure to warn physicians and consumers of the serious side effects and/or complications, was reckless and without regard for the public's safety and welfare.

284. 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.

285. Defendants failed to provide physicians and consumers, including Plaintiff, 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, 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**

Plaintiff hereby demands a trial by jury as to all claims in this action.

Date: June 7, 2022

RESPECTFULLY SUBMITTED,

*/s/ Parvin K. Aminolroaya*
SEEGER WEISS LLP
Christopher A. Seeger
Parvin K. Aminolroaya
55 Challenger Road, Suite 600
Ridgefield Park, NJ 07660
Telephone: (212) 584-0700
cseeger@seegerweiss.com
paminolroaya@seegerweiss.com