UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MARIA WINDHAM Plaintiff, v. JANSSEN PHARMACEUTICALS, INC. f/k/a JANSSEN PHARMACEUTICA INC. f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; JANSSEN ORTHO LLC; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC; ORTHO-MCNEIL PHARMACEUTICALS, LLC; JOHNSON & JOHNSON COMPANY; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; and TEVA PHARMACEUTICALS USA, INC. Defendants.	)	Civil Action No. ***As relates to Case Nos.*** **3:20-cv-08074; 3:20-cv-12605; 3:20-cv-07758; 3:20-cv-07756; 3:20-cv-09530; 3:20-cv-10080; 3:20-cv-07753; 3:20-cv-12328; 3:20-cv-11913; 3:20-cv-11912; 3:20-cv-12608; 3:20-cv-07079; 3:20-cv-10341; 3:20-cv-11921; 3:20-cv-12421; 3:20-cv-13940; 3:20-cv-10342; 3:20-cv-07750; 3:20-cv-12547; 3:20-cv-10966; 3:20-cv-11919; 3:20-cv-10968; 3:20-cv-12264; 3:20-cv-13596; 3:20-cv-06070; 3:20-cv-10960** **JUDGE BRIAN R. MARTINOTTI** **COMPLAINT AND DEMAND FOR JURY TRIAL**

COMPLAINT

Maria Windham ("Plaintiff"), an individual, through her undersigned counsel, based on personal knowledge, investigation of counsel, and information and belief, alleges as follows.

NATURE OF THE ACTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of 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; ORTHO-MCNEIL

PHARMACEUTICALS, LLC; JOHNSON & JOHNSON COMPANY; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; and TEVA PHARMACEUTICALS USA, INC. (collectively "Defendants")'s 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.

2. 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, vision changes, and potentially irreversible vision damage.

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

4. Defendants concealed, and continue to conceal, their knowledge of ELMIRON's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

5. 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.

PARTIES

Plaintiff

6. Plaintiff Maria Windham is a citizen and a resident of Metairie, Louisiana.

7. Plaintiff was born on March 26, 1955.

8. Plaintiff began taking ELMIRON in or about 2012.

9. As result of using Defendants' ELMIRON, Plaintiff was caused to suffer retinal pigmentary changes, including macular degeneration, in or about September 2014.

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

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

12. Plaintiff has incurred and will continue to require and incur medical and related expenses in connection with these injuries, which were caused by Defendants' ELMIRON, and their unlawful conduct with respect to ELMIRON's design, manufacture, marketing, distribution, and sale.

13. Plaintiff has endured and will continue to endure pain, suffering, mental anguish, and loss of enjoyment of life as a result of her injuries, has suffered lost earnings and/or a loss of earning capacity, and other injuries and damages to be proven at trial.

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 Louisiana.

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 Louisiana.

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 Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Louisiana, 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 Stateroad 933 Km 0 1, Street Statero, 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 Louisiana.

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 Louisiana.

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 Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Louisiana.

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 PHARMACEUTICAL 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 Louisiana.

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

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 Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Louisiana, 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 Louisiana.

33. Upon information and belief, Defendant ORTHO PHARMA has derived

substantial revenue from goods and products used in the State of New Jersey and the State of Louisiana.

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 Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Louisiana, 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 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.

37. Upon information and belief, and at all relevant times, Defendants JANSSEN PHARM, ORTHO PHARMA, and JANSSEN R&D were wholly owned subsidiaries of Defendant J&J.

38. 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.

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

40. 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 Louisiana.

41. 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 Louisiana, and derived substantial revenue from interstate commerce within the United States and the State of New Jersey and the State of Louisiana.

42. 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.

43. Upon information and belief, Defendant TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. (hereinafter referred to as "TEVA R&D") is a corporation organized under the laws of Delaware, having a principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

44. 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.

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

46. 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 Louisiana.

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

48. 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.

49. Upon information and belief, Defendant TEVA PHARMACEUTICALS USA, INC. (hereinafter referred to as "TEVA USA") is a corporation organized under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054

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

51. Upon information and belief, Defendant TEVA USA has transacted and conducted business in the State of New Jersey and the State of Louisiana.

52. Upon information and belief, Defendant TEVA USA has derived substantial revenue from goods and products used in the State of New Jersey and the State of Louisiana.

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

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

JURISDICTION AND VENUE

55. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a)(1) because this case is a civil action where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different States.

56. 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.

57. Venue is properly set in this District pursuant to 28 U.S.C. § 1391(b) and (c), since Defendants transact business within, is found in, and/or has agents in this judicial district.

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 Louisiana.

60. Upon information and belief, the original New Drug Application (hereinafter referred to as "NDA") for ELMIRON was submitted by Baker Norton Pharmaceuticals, Inc. (hereinafter referred to as "the sponsor"), which was owned by Ivax Corporation. Ivax Corporation licensed ELMIRON to Ortho-McNeil Pharmaceutical, Inc. n/k/a Defendant JANSSEN PHARM. Defendant TEVA R&D then purchased Ivax Corporation and continued to license ELMIRON to Defendant JANSSEN PHARM.

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

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

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

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

65. 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).

66. On January 27, 1993, the FDA issued its first non-approval letter due to numerous problems with the clinical trial analyses and results, as well as interaction between the clinical trial investigators. Specifically, the FDA stated that the NDA lacked the requisite two (2) adequate and well-controlled studies for determining the effects of ELMIRON. The 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 pivotal studies already submitted.

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

69. 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 the FDA on August 31, 1995.

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

71. The second clinical trial was an unblinded retrospective analysis of 2,499 patients, mostly women, in the ELMIRON Compassionate Use program. After three (3) months, over half of the patients dropped out or were deemed ineligible for the trial; importantly, 31% of those patients reported lack of efficacy and 17% reported an adverse event. The percentage 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.

72. In reviewing the NDA for a third time, the FDA accepted the Compassionate Use data in lieu of a randomized controlled clinical trial, the typical gold standard. However, the 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.

73. In reviewing the clinical trial data overall, the 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.

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

75. 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.

76. Then, in the Spring of 2018, a team at Emory Eye Center submitted a letter to the editor of the Journal of Urology reporting findings of unusual retinal pigmentary changes or maculopathy (i.e., any condition affecting the macula at the center of the retina) in six (6) female patients on long-term ELMIRON treatment (median use of 15.5 years) *that did not resemble any other type of retinal disease*.[1] That case series was published online at the end of April 2018.[2] None of the patients had family history of retinal disease or any pathogenic process that would predispose them to such a disease. Of the six (6), five (5) had received 400mg daily of ELMIRON (but two reduced their dose to 200mg 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.

77. 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:

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

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

> 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]

78. 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]

79. 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

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

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

imaging) and presentation of this specific form of maculopathy, which proved distinctive from other retinal diseases and conditions.[5]

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

81. 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]

82. 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

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

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

[7] Vora RA, et al. *Prevalence of Maculopathy Associated with Long-Term Pentosan Polysulfate Therapy*. Ophthalmology, June 2020; 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.

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]

83. 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 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]

84. 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

[9] Jain N, et al. *Association of macular disease with long-term use of pentosan polysulfate sodium: findings from a US cohort*. British Journal of Ophthalmology, November 6, 2019.

[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*. International Urogynecology Journal, 2019, 30:337-338.

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]

85. 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.

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

87. 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.

88. 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.

89. Defendants knew of the significant risk of retinal pigmentary changes caused by ingestion of ELMIRON.

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

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

91. 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.

92. As a direct result, in or about [March] 2012, Plaintiff was prescribed and began taking ELMIRON, primarily for the relief of bladder pain or discomfort associated with interstitial cystitis.

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

94. 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.

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

96. 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.

97. Instead, ELMIRON can cause severe injuries, including retinal pigmentary changes.

98. After beginning treatment with ELMIRON, and as a direct and proximate result thereof, Plaintiff suffered from retinal pigmentary changes, including macular degeneration.

99. Defendants knew or should have known the risks associated with the use of ELMIRON, including the risk of retinal pigmentary changes and macular degeneration (among other injuries).

100. The development of Plaintiff's injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize safety signals, suppression of information revealing serious risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of ELMIRON. This conduct, as well as the product defects complained of herein, was a substantial factor in bringing about and exacerbating Plaintiff's injuries.

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

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

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

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

105. 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.

106. 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.

107. 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.

FIRST CAUSE OF ACTION
NEGLIGENCE

108. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

109. 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 ensure that the product would not cause users to suffer unreasonable, dangerous side effects.

110. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of ELMIRON into interstate commerce in that Defendants

knew or should have known that using ELMIRON created a high risk of unreasonable, dangerous side effects, including but not limited to retinal pigmentary changes, vision changes, and potentially irreversible vision damage, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

a. Manufacturing, producing, promoting, formulating, creating, and/or designing ELMIRON without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing ELMIRON without adequately testing it;

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

d. Selling ELMIRON without making proper and sufficient tests to determine the dangers to its users;

e. Failing to adequately and correctly warn Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of ELMIRON;

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

g. Failing to test ELMIRON and/or failing to adequately, sufficiently and properly test ELMIRON;

h. Advertising and recommending the use of ELMIRON without sufficient knowledge as to its dangerous propensities;

i. Representing that ELMIRON was safe for use for its intended purpose, when it was, in fact, unsafe;

j. 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. Designing ELMIRON in a manner which was dangerous to its users;

l. Manufacturing ELMIRON in a manner which was dangerous to its users;

m. Producing ELMIRON in a manner which was dangerous to its users;

n. Assembling ELMIRON in a manner which was dangerous to its users;

o. Concealing information from Plaintiff in knowing that ELMIRON was unsafe, dangerous, and/or non-conforming with FDA regulations;

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

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

113. 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.

114. 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.

115. 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 Plaintiff.

116. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care.

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

118. 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, vision changes, and potentially irreversible vision damage, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

119. As a result of the foregoing acts and omissions, 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.

120. Plaintiff suffered damages in an amount to be determined at trial.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY

121. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

122. 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 Plaintiff.

123. That ELMIRON was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

124. At those times, ELMIRON was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff.

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

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

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

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

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

130. Defendants with this knowledge voluntarily designed its ELMIRON in a dangerous condition for use by the public, and in particular Plaintiff.

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

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

133. The ELMIRON designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that ELMIRON left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

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

135. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health

of consumers and to Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

136. Plaintiff could not, by the exercise of reasonable care, have discovered ELMIRON's defects herein mentioned or perceived its danger.

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

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

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

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

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

142. Said defects in Defendants' drug ELMIRON were a substantial factor in causing Plaintiff's injuries.

143. As a result of the foregoing acts and omissions, 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 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.

144. As a result of the foregoing acts and omissions 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.

145. Plaintiff suffered damages in an amount to be determined at trial.

THIRD CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

146. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

147. 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.

148. 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.

149. 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 that ELMIRON was safe and effective for use.

150. 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.

151. 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.

152. 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.

153. 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.

154. 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.

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

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

157. 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.

158. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes, including macular degeneration, and other related health complications. 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.

159. Plaintiff suffered damages in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

160. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

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

162. 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.

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

164. 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.

165. 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.

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

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

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

169. 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.

170. 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.

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

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

173. 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.

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

175. 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.

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

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

178. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes, including macular degeneration, and other related health complications. 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 has also 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.

179. Plaintiff suffered damages in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

180. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

181. Defendants made fraudulent 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, notice letters, and regulatory submissions that ELMIRON had been tested and found to be safe and effective for the relief of bladder pain or discomfort associated with interstitial cystitis; and

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

c. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of ELMIRON to Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

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

183. 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.

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

185. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes, including macular degeneration, and other related health complications. 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 has also 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.

186. Plaintiff suffered damages in an amount to be determined at trial.

SIXTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

187. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

188. 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.

189. Defendants fraudulently concealed information 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, notice letters, and regulatory

submissions that ELMIRON was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using ELMIRON; and

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

190. Defendants were under a duty to Plaintiff to disclose and warn of the defective and dangerous nature of ELMIRON because:

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

b. 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

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

191. 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.

192. 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.

193. 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.

194. 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 patients, including Plaintiff, would request and purchase ELMIRON and her health care providers would prescribe and recommend ELMIRON.

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

196. 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.

197. 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.

198. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes, including macular degeneration, and other related health complications. 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 has also 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.

199. Plaintiff suffered damages in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

200. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

201. 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.

202. 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.

203. 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.

204. 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.

205. 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.

206. 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.

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

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

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

210. 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.

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

212. 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.

213. 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.

214. 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.

215. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes, including macular degeneration, and other related health complications. 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 has also 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.

216. Plaintiff suffered damages in an amount to be determined at trial.

EIGHTH CAUSE OF ACTION
FRAUD AND DECEIT

217. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

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

219. 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, healthcare professionals, and/or the FDA that

ELMIRON was safe and effective for the relief of bladder pain or discomfort associated with interstitial cystitis.

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

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

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

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

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

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

226. The information distributed to the public, the FDA, and Plaintiff by Defendants intentionally included false representations that ELMIRON was as potentially injurious to the health and/or safety of its intended as other forms of treatment for the relief of bladder pain or discomfort associated with interstitial cystitis.

227. These representations were all false and misleading.

228. 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.

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

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

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

232. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or Plaintiff that

ELMIRON was fit and safe for the relief of bladder pain or discomfort associated with interstitial cystitis.

233. Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and Plaintiff that ELMIRON did not present serious health and/or safety risks.

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

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

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

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

238. 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.

239. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling 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.

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

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

242. 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.

243. At the time the representations were made, 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.

244. 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 Plaintiff with reasonable diligence have discovered the true facts.

245. Had 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.

246. The Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the public, including Plaintiff, as well as Plaintiff's respective healthcare professionals and the medical community.

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

248. As a result of the foregoing acts and omissions Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

249. Plaintiff suffered damages in an amount to be determined at trial.

NINTH CAUSE OF ACTION
VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT

250. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

251. At all times relevant, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et. seq., prohibits "[the] act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise…" and declares such acts or practices as unlawful.

252. Defendants violated the New Jersey Consumer Fraud Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of ELMIRON. 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.

253. As a result of violating the New Jersey Consumer Fraud Act, Defendants caused Plaintiff to be prescribed and to use ELMIRON, causing severe injuries and damages as previously described herein.

TENTH CAUSE OF ACTION
PRODUCT LIABILITY – DESIGN DEFECT— (N.J.S.A. 2A:58C-1 *et seq*)

254. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

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

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

257. 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.

258. 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;

b. When placed in the stream of commerce, ELMIRON was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with treatment for the relief of bladder pain or discomfort associated with interstitial cystitis;

c. ELMIRON was insufficiently tested;

d. ELMIRON caused harmful side effects that outweighed any potential utility;

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

f. ELMIRON was subject to inadequate post-marketing surveillance; and/or

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

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

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

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

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

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

264. When Defendants placed ELMIRON into the stream of commerce, they knew it would be prescribed for the relief of bladder pain or discomfort associated with interstitial cystitis, and they marketed and promoted ELMIRON as safe for the relief of bladder pain or discomfort associated with interstitial cystitis.

265. Plaintiff was prescribed, purchased, and used ELMIRON. Plaintiff used ELMIRON for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

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

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

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

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

270. 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.

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

272. 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.

273. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes, including macular degeneration, and other related health complications. 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 has also 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.

ELEVENTH CAUSE OF ACTION
PRODUCTS LIABILITY – FAILURE TO WARN (N.J.S.A. 2A:58C-1 *et seq.*)

274. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

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

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

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

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

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

280. This defect caused serious injury to Plaintiff who used ELMIRON for its intended purpose and in a reasonably anticipated manner.

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

282. Defendants negligently and recklessly labeled, distributed, and promoted ELMIRON.

283. Defendants had a continuing duty to warn Plaintiff of the dangers associated with ELMIRON.

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

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

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

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

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

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

a. Disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of ELMIRON;

b. Continued to aggressively promote ELMIRON even after they knew or should have known of the unreasonable risks from use;

c. Failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of ELMIRON and the comparative severity of such adverse effects;

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

e. Failed to adequately warn users, consumers, and physicians about the need to perform initial and periodic retinal examinations; and

f. Overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of ELMIRON.

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

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

292. Had Defendants properly disclosed and disseminated the risks associated with ELMIRON, Plaintiff would have avoided the risk of developing injuries as alleged herein.

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

294. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered retinal pigmentary changes, including macular degeneration, and other related health complications. 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 has also 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
PRODUCT LIABILITY – MANUFACTURING DEFECT
(N.J.S.A. 2A:58C-1 *et seq.*))

295. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

296. 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.

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

298. 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.

299. 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.

THIRTEENTH CAUSE OF ACTION PUNITIVE DAMAGES UNDER COMMON LAW, THE PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15 *et seq.*) AND THE PRODUCTS LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq.*))

300. Plaintiff repeats, reiterates and incorporates by reference each and every allegation of this Complaint contained in each of the foregoing paragraphs.

301. Defendants' conduct as alleged in this Complaint shows that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

302. As a direct and proximate result of Defendants' malicious, fraudulent, and/or intentional disregard of Plaintiff's rights, Plaintiff is entitled to punitive damages to punish Defendants and deter similar wrongdoing by others in the future.

303. Plaintiff is entitled to punitive damages because Defendants misrepresented and/or withheld information and materials from the FDA, the medical community and the public at large,

including Plaintiff, concerning the safety profile, and, more specifically, the serious side effects and/or complications associated with ELMIRON.

304. With respect to the FDA, physicians, and consumers, Defendants 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.

305. With respect to the FDA, physicians, and consumers, Defendants 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.

306. Defendants' failure to provide the necessary materials and information to the FDA, as well as their 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.

307. 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.

308. Defendants failed to provide the FDA, physicians and consumers with available materials, information and warnings that would have ultimately dissuaded physicians from prescribing ELMIRON to consumers and would have dissuaded 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:

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests judgment against all Defendants as follows:

1. For economic and non-economic damages, special damages, and general damages, including pain and suffering, in an amount to be supported by the evidence at trial;
2. For actual or compensatory damages for the acts complained of herein in an amount to be determined by a jury and as provided by applicable law;
3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;
4. For exemplary and punitive damages sufficient to punish Defendants for the acts complained of herein and to deter Defendants and others from future wrongful practices, in an amount to be determined by a jury;
5. For an award of reasonable attorneys' fees, court costs, and other litigation expenses;
6. For prejudgment interest;
7. For post-judgment interest; and
8. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: October 19, 2020

Respectfully submitted,

By: /s/ Christopher A. Seeger
Christopher A. Seeger
David R. Buchanan
Caleb Seeley
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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Maria Windham

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Seeger Weiss LLP
55 Challenger Road, 6th Floor, Ridgefield Park, NJ 07660
(973) 639-9100

DEFENDANTS

Janssen Pharmaceuticals, Inc., et al

County of Residence of First Listed Defendant Mercer County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	☒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	❒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	❒ 710 Fair Labor Standards Act	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 720 Labor/Management Relations	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 740 Railway Labor Act	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 751 Family and Medical Leave Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 790 Other Labor Litigation	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 791 Employee Retirement Income Security Act	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise				❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
				❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
					❒ 893 Environmental Matters
					❒ 895 Freedom of Information Act
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	❒ 896 Arbitration
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 950 Constitutionality of State Statutes
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence			
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332(a)(1)

Brief description of cause:
Lawsuit alleging: negligence, strict liability, failure to warn, unjust enrichment, breach of implied warranty etc.

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Brian R. Martinotti DOCKET NUMBER 3:20-cv-07750

DATE 10/19/2020

SIGNATURE OF ATTORNEY OF RECORD /s/ Christopher A. Seeger

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.