UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MARTHA TURNER, Plaintiff, v. TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., f/k/a Teva Global Respiratory Research, LLC.; TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD; JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.; ORTHO-MCNEIL PHARMACEUTICAL, LLC.; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a Johnson & Johnson Research & Development, L.L.C.; ALZA CORPORATION; JANSSEN ORTHO LLC; and JOHNSON & JOHNSON Defendants.	Case No.: **COMPLAINT** **JURY TRIAL DEMANDED**

MARTHA TURNER ("Plaintiff") hereby sues TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., f/k/a Teva Global Respiratory Research, LLC.; TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD; JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.; ORTHO-MCNEIL PHARMACEUTICAL, LLC.; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a Johnson & Johnson Research & Development, L.L.C.; ALZA CORPORATION; JANSSEN ORTHO LLC; and JOHNSON & JOHNSON;, (collectively, "Defendants") and alleges as follows:

INTRODUCTION

1. This is an action for damages related to Defendants' wrongful conduct in connection with the development, testing, clinical trials, manufacturing, packaging, labeling,

promoting, advertising, marketing, distribution and selling of pentosan polysulfate sodium (PPS) as Defendants' prescription drug Elmiron® (hereinafter "Elmiron").

2. Defendants manufacture, test, promote, advertise, market and sell Elmiron as a prescription drug to treat interstitial cystitis (also known as "IC" or "bladder pain syndrome"). Elmiron is manufactured as a capsule suitable for oral consumption.

3. Elmiron injured the Plaintiff by causing harmful, but latent, irreversible damage to the retina, including maculopathy and resulting in severely impaired vision.

4. Numerous patient reports, adverse events reports, scientific studies and even alerts by governmental agencies warned that Elmiron causes damage to the retina and maculopathy.

5. In addition to the serious safety risks associated with Elmiron, early clinical studies relied upon by Defendants to support the approval of the drug, failed to demonstrate Elmiron was an efficacious treatment for IC.

6. Additional studies have also been conducted that demonstrate Elmiron is no more effective than a placebo for the treatment of IC.

7. Nevertheless, at all times Plaintiff was prescribed, purchased, and ingested Elmiron, Defendants failed to warn, advise, educate or otherwise inform Elmiron users, prescribers or governmental regulators in the United States about the risk of damage to the patient's eyes, vision, retina, maculopathy, or the need for medical, ophthalmological testing and/or monitoring.

8. Indeed, at all times Plaintiff was prescribed, purchased, and ingested Elmiron, the U.S. label did not contain any warning regarding the risk to patients' eyes, vision, retina, maculopathy, or the need for medical, ophthalmological testing and/or monitoring, associated with the use of Elmiron, despite information regarding these risks being available to Defendants.

9. As a proximate result of Defendants' negligent, reckless, grossly negligent and wrongful actions, inactions and/or conduct, Plaintiff was injured and suffered damages from the use of Elmiron.

10. Plaintiff therefore demands judgment against Defendants and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, costs and all other available remedies and damages allowed by law.

PARTY PLAINTIFF

11. Plaintiff Martha Turner is, and at all relevant times described herein, was a resident and citizen of the State of Tennessee.

12. Plaintiff was diagnosed with interstitial cystitis.

13. Plaintiff took Elmiron as prescribed by her physician from approximately 2001 through 2020 while she was a resident of Tennessee.

14. Plaintiff was given no warning by Defendants of the serious risk of vision threatening retinal changes, including vision loss and maculopathy posed by Elmiron.

15. Plaintiff was given no warning by her physicians of the serious risk of vision threatening retinal changes, including vision loss and maculopathy posed by Elmiron.

16. Plaintiff had no knowledge of the serious risk of vision threatening retinal changes, including vision loss and maculopathy loss posed by Elmiron.

17. Plaintiff's prescribing physicians were given no warning by Defendants of the serious risk of vision threatening retinal changes, including vision loss and maculopathy posed by Elmiron.

18. Plaintiff was given no warning by Defendants of the need for ophthalmologic monitoring before taking, while taking, and after discontinuing Elmiron.

19. Plaintiff was given no warning by her physicians of the need for ophthalmologic monitoring before taking, while taking, and after discontinuing Elmiron.

20. Plaintiff had no knowledge of the need for ophthalmologic monitoring before taking, while taking, and after discontinuing Elmiron.

21. Plaintiff's prescribing physicians were given no warning by Defendants of the need for ophthalmologic monitoring before taking, while taking, and after discontinuing Elmiron.

22. As a result of her exposure to Elmiron, Plaintiff now suffers from severe maculopathy, in both eyes, that causes her to experience severe symptoms including but not limited to blurry vision, night blindness, difficulty adjusting to dim lighting, dark/blank spots in her field of vision, near vision problems, and straight lines appearing curved or squiggly.

23. Further, retinal and vision changes may continue to progress even though Plaintiff is no longer taking Elmiron.

PARTY DEFENDANTS

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.

24. TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., f/k/a Teva Global Respiratory Research, LLC, (hereinafter "TEVA") is a Delaware corporation with a principal place of business at 41 Moores Road, Malvern, Pennsylvania 19355.

25. Upon information and belief IVAX L.L.C. f/k/a IVAX Corporation (hereinafter "IVAX") and Baker Norton U.S., Inc. f/k/a Baker Norton Pharmaceuticals, Inc. f/k/a Baker Cummins Pharmaceuticals, Inc. (hereinafter "Baker Norton") are and have been wholly owned subsidiaries of TEVA.

26. Upon information and belief Baker Norton is and has been a wholly owned subsidiary of IVAX.

27. In June, 1991, Baker Norton submitted the NDA for Elmiron to the FDA and was the named sponsor on the approval of Elmiron by the FDA. In support of the NDA for Elmiron, Baker Norton conducted the clinical trials. The validity of two of these clinical trials was seriously questioned by the FDA.

28. Baker Norton held the NDA for Elmiron from the date of approval, September 26, 1996, until approximately September 1997.

29. In September 1997, IVAX licensed the rights to Elmiron in the United States and Canada to Alza Pharmaceuticals, a division of defendant ALZA CORPORATION, for $75 Million in up-front payments. At times hereinafter relevant, ALZA CORPORATION made the $75 Million up-front payment and additional payments required under the agreement to IVAX.

30. IVAX continues to receive milestone and royalty payments as a result of the sales of Elmiron.

31. Elmiron was and is a Registered Trademark of Defendant TEVA under license to Defendant JANSSEN PHARMA.

32. At all times relevant and material hereto, TEVA was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States.

TEVA PHARMACEUTICALS USA, INC.

33. Defendant TEVA PHARMACEUTICALS USA, INC. (hereinafter "TEVA PHARMACEUTICALS USA"), is a corporation organized under Delaware law with its principal place of business 400 Interpace Parkway, Parsippany, NJ 07054.

34. At all times relevant and material hereto, TEVA PHARMACEUTICALS USA was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States.

TEVA PHARMACEUTICAL INDUSTRIES LTD.

35. Defendants TEVA and TEVA PHARMACEUTICALS USA are subsidiaries of the parent company Defendant TEVA PHARMACEUTICAL INDUSTRIES LTD. (hereinafter "TEVA PHARMACEUTICAL INDUSTRIES"), a corporation with global headquarters at 5 Basel Street, Petach Tikva 49131, Israel, and U.S. Headquarters at 400 Interpace Parkway, #3, Parsippany, New Jersey 07054.

36. At all times relevant and material hereto, TEVA PHARMACEUTICAL INDUSTRIES was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States.

JANSSEN PHARMACEUTICALS, INC.

37. Defendant JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc., (hereinafter "JANSSEN PHARMA") is a corporation organized under Pennsylvania law with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

38. JANSSEN PHARMA has held the U.S. Food and Drug Administration (FDA) New Drug Application (NDA) for Elmiron since approximately August 2008.[1]

[1] The holder of the NDA is the party that controls the patents associated with a FDA approved drug, giving them the ability to, among other things, market and sell the subject drug. The NDA holder also has the ability and responsibility (footnote continued)

39. Elmiron is a Registered Trademark currently under license to JANSSEN PHARMA.

40. At all times relevant and material hereto, JANSSEN PHARMA was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States

OTHRO-MCNEIL PHARMACEUTICAL, L.L.C.

41. Defendant ORTHO-MCNEIL PHARMACEUTICAL, LLC. (hereinafter "ORTHO PHARMA") is a corporation organized under Delaware law with its principal place of business at 1000 US Highway 202, Raritan, New Jersey 08869.

42. ORTHO PHARMA held the NDA for Elmiron from approximately July 2004 until August 2008.

43. ORTHO PHARMA marketed, co-marketed, sold and distributed the defective product, Elmiron, through its division, Ortho Women's Health and Urology.

44. At all times relevant and material hereto, ORTHO PHARMA was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States.

JANSSEN RESEARCH & DEVELOPMENT LLC

45. Defendant JANSSEN RESEARCH & DEVELOPMENT LLC, f/k/a Johnson & Johnson Research & Development, L.L.C. (hereinafter "JANSSEN R&D") is a limited liability

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to update the product label, no matter where the update in the label is needed, to ensure that it warns of dangerous adverse events associated with its drug.

company organized under the laws of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

46. JANSSEN R&D's sole member is Centocor Research & Development, Inc. (hereinafter "Centocor"), a Pennsylvania corporation with its principal place of business at 800 Ridgeview Dr. Horsham, Pennsylvania 19044.

47. JANSSEN R&D held the NDA for Elmiron from approximately August 2002 until August 2004.

48. At all times relevant and material hereto, JANSSEN R&D was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States.

ALZA CORPORATION

49. Defendant ALZA CORPORATION (hereinafter "ALZA") is a corporation organized under Delaware law with its principal place of business at 700 Eubanks Drive, Vacaville California.

50. In September 1997, IVAX licensed the rights to Elmiron in the United States and Canada to Defendant ALZA for $75 Million in up-front payments.

51. Upon information and belief, Defendant ALZA made the $75 Million up-front payment and additional payments required under the agreement.

52. Defendant ALZA held the NDA for Elmiron from approximately April 1998 until August 2002.

53. At all times relevant and material hereto, ALZA was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and

release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States.

JANSSEN ORTHO, LLC

54. Defendant JANSSEN ORTHO, LLC (hereinafter "JANSSEN ORTHO") is a limited liability company organized under Delaware law with its principal place of business at Gurabo 00777, Puerto Rico. JANSSEN ORTHO's sole member is OMJ PR Holdings, a corporation incorporated in Ireland with a principal place of business in Puerto Rico.

55. At all times relevant and material hereto, JANSSEN ORTHO was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States.

JOHNSON & JOHNSON

56. Defendant JOHNSON & JOHNSON is a corporation organized under New Jersey law with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

57. Upon information and belief, JANSSEN PHARMA, ORTHO PHARMA, JANSSEN R&D, JANSSEN ORTHO, and ALZA are and have been wholly owned subsidiaries of JOHNSON & JOHNSON.

58. Upon information and belief, JOHNSON & JOHNSON maintains a controlling interest in OMJ PR Holdings and Centocor.

59. On June 22, 2001, JOHNSON & JOHNSON acquired licensing rights to Elmiron when a wholly owned subsidiary of JOHNSON & JOHNSON merged with and into ALZA, in a $10.5 billion stock-for-stock transaction.

60. JOHNSON & JOHNSON and its "family of companies" do business in New Jersey and other states by, among other things, designing, developing, testing, manufacturing, labeling, packaging, distributing, marketing, selling and/or profiting from Elmiron in New Jersey and throughout the United States.

61. Defendants were jointly engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Elmiron, and controlling the Elmiron NDA.

JURISDICTION & VENUE

62. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different States and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

63. This Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

64. Venue is proper in this forum pursuant to 28 U.S.C. § 1391 because the Defendants transact business in this District and a substantial portion of the practices, events and omissions complained of herein occurred and/or had an effect in this judicial district.

FACTUAL ALLEGATIONS

A. Laws and Regulations Governing the Approval and Labeling of Prescription Drugs

65. The Federal Food, Drug and Cosmetic Act ("FDCA" or the "Act") requires manufacturers that develop a new drug product to file a New Drug Application ("NDA") in order to obtain approval from the Food and Drug Administration ("FDA") before selling the drug in interstate commerce. 21 U.S.C. § 355.

66. The NDA must include, among other things, all data regarding the safety and effectiveness of the drug, information on any patents that purportedly apply to the drug or a method of using the drug and the labeling proposed to be used for the drug. 21 U.S.C. § 355(b).

67. Manufacturers with an approved NDA must review all adverse drug experience information obtained by or otherwise received by them from any source, foreign or domestic, including but not limited to information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature and unpublished scientific papers. 21 C.F.R. § 314.80(b).

68. After FDA approval, manufacturers may only promote drugs in a manner consistent with the contents of the drug's FDA-approved label. 21 C.F.R. § 202.1.

69. Although the FDA eventually approves the label submitted to the FDA by the manufacturer, it is the duty of the drug manufacturer to warn of dangerous adverse reactions that may be associated with its drug.

70. It is the duty of the manufacturer to ensure the label is up to date and/or accurate. 21 CFR § 201, et. seq.

71. Further, when the risks of a particular drug use become apparent, the manufacturer has a duty to update the drug's labeling to add or strengthen a contraindication, warning, precaution, or adverse reaction that adequately describes that risk.[2]

72. Under what is known as the Changes Being Effected ("CBE") regulation, a manufacturer with an approved NDA can, among other things, to add or strengthen a

[2] See *In re Fosamax (Alendroate Sodium) Products Liability Litigation*, 852 F.3d 268, 283 (3rd Cir. 2017), vacated and remanded sub nom *Merck Sharp & Dohme v. Albrecht*, ___ U.S. ___, 139 S.Ct. 1668 (2019)

contraindication, warning, precaution, or adverse reaction in its label without prior FDA approval by simply sending the FDA a "supplemental submission." 21 C.F.R. § 314.70(c)(6)(iii).

73. Specifically, the manufacturer can "add or strengthen a contraindication, warning, precaution, or adverse reactions for which the evidence of causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter" and "to add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product." 21 C.F.R. § 314.70(c)(6)(iii)(A) and (C).

74. The Warnings and Precautions section of its label "must describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant therapy) and steps that should be taken if they occur (e.g., dosage modification). The frequency of all clinically significant adverse reactions and the approximate mortality and morbidity rates for patients experiencing the reaction, if known and necessary for the safe and effective use of the drug, must be expressed as provided under paragraph (c)(7) of this section." 21 C.F.R. § 201.57(c)(6)(i).

75. A manufacturer must also revise its label "to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established." 21 C.F.R. § 201.57(c)(6)(i).

76. The Warnings and Precautions "section must contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (e.g., precautions not required under any other specific section or subsection)." 21 C.F.R. § 201.57(c)(6)(ii).

77. The Warnings and Precautions section of the label "must identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during and after therapy." *Id.* § 201.57(c)(6)(iii). According to an FDA Guidance for Industry on the Warnings and Precautions section of the labeling, "[i]nformation about the frequency of testing and expected ranges of normal and abnormal values should also be provided if available."[3]

78. Adverse reactions must be added to the label in the "Adverse Reactions" section where, there "is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." Where frequency data is available "adverse reactions must be listed in decreasing order of frequency." Where it is not available "adverse reaction must be listed in decreasing order of severity." *Id.* § 201.57(c)(7).

79. An August 22, 2008 amendment to these regulations provides that a CBE supplement to amend the labeling for an approved product must reflect "newly acquired information." Fed. Reg. 49609 *see also* 21 CFR 314.70. "Newly acquired information" is not limited to new data but also includes "new analysis of previously submitted data." *Id.* at 49606. "[I]f a sponsor submits adverse event information to FDA and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports

[3] FDA Guidance Document, Warnings and, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format, October 2011, https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf (last visited, June 5, 2020).

previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'" *Id*. at 49607.

B. History of Elmiron

80. Elmiron, also known as Pentosan Polysulfate Sodium (PPS), is an oral heparinoid derived from beech tree bark. It is a macromolecule resembling glycosaminoglycans (GAGs) and was initially used in the 1950's as a blood thinner – similar to Heparin.

81. Elmiron was the first – and remains the only – oral drug approved by the FDA specifically for the treatment of patients with interstitial cystitis.

82. However, Elmiron is not the only treatment for Interstitial cystitis that is available to physicians and patients.

83. IC is a diagnosis that applies to patients with chronic bladder pain in the absence of other explanatory etiologies (or causes). The symptoms associated with IC range from discomfort to debilitating pain.

84. Under the IC treatment guidelines established by the American Urological Association (AUA), Elmiron is not a first-line treatment. Rather, Elmiron is one of ten suggested second-line treatments, including three other oral medications: amitriptyline, cimetidine and hydroxyzine. The guidelines further include numerous third, fourth, fifth and sixth-line treatments. According to the AUA, "first-line treatments" should be suggested to all patients and "sixth-line treatments" should be reserved for the most severe cases, with the remaining treatment options falling in-between.

85. Defendants market Elmiron as "The Only Oral Medication Approved to Treat the Bladder Pain or Discomfort of Interstitial Cystitis (IC)."[4] However, while Elmiron is the only oral medication approved by the FDA specifically for the purpose of treating IC, as set forth above, it is not the only oral medication approved by the FDA which can be used to treat IC and it is not the only IC treatment.

86. On August 7, 1985, Elmiron was designated an orphan drug by the FDA. At that time, non-party Medical Marketing Specialists, located in Boonton, New Jersey, was the owner of Elmiron. The orphan drug designation is a special status granted under the Orphan Drug Act ("ODA") to a drug used to treat a rare disease or condition upon request of a sponsor. For a drug to qualify for orphan designation, both the drug and the disease or condition must meet certain criteria specified in the ODA and FDA's implementing regulations (21 CFR Part 316). Orphan designation qualifies the sponsor of the drug for various development incentives provided by the ODA, including tax credits for qualified clinical testing. However, the granting of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and effectiveness of a drug must be established through adequate and well-controlled studies.

87. In 1986, Elmiron was made available for compassionate use. Compassionate use is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, medical device, or combination product) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

[4] https://www.orthoelmiron.com/patient/about-elmiron.

88. The original NDA for Elmiron was submitted on June 11, 1991, five (5) years after it was made available for compassionate use by Baker Cummins Pharmaceuticals, Inc., now Baker Norton, which at the time was a subsidiary of IVAX.

89. On February 18, 1992, FDA Division Director Wiley A. Chambers, MD issued his review of the Elmiron NDA. In his review, Dr. Chambers indicated the NDA was not recommended for approval, citing several very serious flaws with the clinical trials purported to support approval of the drug. Specifically, Dr. Chambers stated:

> The application as submitted lacks substantial evidence consisting of adequate and well-controlled investigations, as defined in 21 CFR 314.126 that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling. Specifically, the analysis of the results of the submitted studies are not adequate to assess the effects of the drug.

He further stated:

> The purpose of conducting clinical investigations of a drug is to distinguish the effect of a drug from other influences. Based on the analyses submitted to date for studies E-001 and E-002, there appears to be significant investigator interaction. The results obtained by the first investigator listed in each study are significantly different than the results obtained by each of the other investigators in the studies. In the absence of an adequate explanation for these differences, studies E-001 and E-002 cannot be considered to be adequate and well-controlled. It is recommended that an additional clinical investigation utilizing investigators not included in previous studies be conducted and submitted as part of any resubmission of this application.

90. The investigators referenced in Dr. Chambers' review as having "significantly different" results compared to all of the other investigators were Dr. Philip Hanno and Dr. C. Lowell Parsons.

91. Dr. Parsons' results in study E-002 were particularly concerning to the FDA reviewers. Specifically, Dr. Parson's found that 10/15 or 66.7% of his patients treated with Elmiron described their bladder pain as "better." Interestingly, no other investigator in that study had more than 40% of patients fit into this category and collectively, the other six investigators

combined reported that only 23% of patients described their bladder pain as "better." As noted by FDA reviewer Dr. John Kenealy:

> [I]n each of the studies herein presented, elimination of the results from one of the centers all but destroys the statistical significance of the results of that study. The medical reviewer has indicated that one of the two investigators is known to have a financial interest in this drug. Because of the strong influence of these centers on the outcome, Scientific Investigations has been requested to audit the records of these centers for these studies.

FDA reviewer Dr. Paul Waymack also stated:

> [I]t should be noted that when reviewing the data, it was determined that if the data from a single investigator (the champion of this therapy) was removed from the study, not only was statistical significance lost, but even the trend towards benefit was lost.

92. Both reviewers were referring to Dr. Parsons, who had both a financial interest in Elmiron, as well as connections with the sponsor at the time, Baker Norton.

93. Indeed, after Elmiron was approved, Dr. Parsons gave numerous lectures and presentations touting Elmiron as "an amazing breakthrough" to treat interstitial cystitis.

94. Upon information and belief, Dr. Parsons received and continues to receive from the Defendants, royalty payments from the sale of Elmiron.

95. Due in part to the serious flaws in the clinical studies performed by Dr. Parsons and other concerns expressed by the FDA, on January 27, 1993, the FDA sent a letter to Baker Norton indicating the NDA for Elmiron was not approvable. The letter included the following statement as one of the reasons the NDA was denied:

> One purpose of conducting clinical investigations of a drug is to distinguish the effect of a drug from other influences. Based on the analyses submitted for studies E-001 and E-002, there appears to be significant investigator interaction. The results obtained by the first investigator listed in each study are significantly different than the results obtained by each of the other investigators in the studies. In the absence of an adequate explanation for these differences, studies E-001 and E-002 cannot be considered to be adequate and well-controlled. We recommend that an additional clinical investigation utilizing investigators not included in previous studies be conducted and submitted as part of any amending of this application.

> We recommend that you consider carrying out an additional study to demonstrate effectiveness of the drug.

96. On March 19, 1993, a meeting was held between the FDA and Baker Norton, during which the FDA again requested Baker Norton perform an additional clinical study to support the efficacy of Elmiron. During the meeting, the parameters of the recommended study were discussed in detail. However, during this meeting, FDA also agreed that Baker Norton could submit additional analyses to support their position that the existing data was adequate. This included further analysis of clinical trials E-001 and E-002, along with an analysis of the compassionate use experience. The re-analysis of the clinical trials was submitted to FDA on July 7, 1993.

97. After receipt of the new analysis submitted by Baker Norton, FDA issued a memo again declaring the NDA for Elmiron remained not approvable, citing a lack of independence by a clinical investigator, failure to meet the level of statistical significance required and a failure of the case report forms to support the scale used for analysis. FDA again requested that a new clinical trial be conducted. At this time, the compassionate use data had not yet been provided to FDA.

98. On July 20, 1993, Baker Norton submitted a brief study protocol for a proposed urinary concentration-controlled trial of Elmiron. Upon information and belief this study was not conducted prior to approval.

99. On August 29, 1994, Dr. Waymack sent a correspondence to Division Director Patricia Love expressing further serious concerns about studies E-001 and E-002, stating:

> They have reanalyzed the data from the E-002 trial, after excluding all the data from Dr. Parsons. When this was done, the lowest p value obtained was only .107, which was for the Overall Improvement (Investigator Impression). This raises a number of possible explanations for the significant p values obtained from the studies, other than the drug having an effect. These would include a different patient population at the site of Dr. Parsons investigations, a loss of blinding, some other form of bias, or a random statistical event.

100. On October 28, 1994, FDA issued a second letter declining to approve Baker Norton's NDA for Elmiron. The letter indicated that study E-001 did not provide adequate evidence of effectiveness and that study E-002 provided only "some" evidence of effectiveness (as indicated above, the results of study E-002 were disproportionately affected by Dr. Parson's data). Thus, FDA requested that Baker Norton perform an additional adequate and well-controlled clinical study designed to show effectiveness and safety. FDA suggested that if the study was clearly positive and otherwise acceptable it, along with study E-002, would provide sufficient evidence for approval.

101. On February 16, 1995, a meeting was held between FDA and Baker Norton. During this meeting, FDA again reiterated the need for an additional clinical trial and Baker Norton continued to resist, arguing for the validity of the two trials already conducted. FDA was not convinced, stating:

> We indicated that we need replication of an adequate study. This is in part needed in order to show that other physicians can safely use the product. So far, their data shows that one physician can use Elmiron; the results from the other physicians do not show improvement. The sponsor showed a slice with pooled data from all investigators in order to support their position. This slide confirmed our point that the data is driven by one physician (Parsons).

102. Baker Norton continued to push back against conducting an additional trial and instead suggested that the compassionate use data would be sufficient to show the product worked. FDA noted that such an analysis would be the "third reassessment of old data that was twice deemed inadequate."

103. On August 31, 1995, Baker Norton submitted its analysis of the compassionate use experience.

104. On March 1, 1996, despite Baker Norton's refusal to conduct an additional clinical trial to demonstrate the effectiveness of Elmiron, for some yet unknown reason, FDA approved

the NDA, giving Baker Norton the right to market Elmiron in the United States. This approval was based on study E-002, previously deemed inadequate and a compassionate use experience analysis, also previously deemed inadequate.

105. In September 1997, Alza Corporation acquired all rights to Elmiron from Baker Norton, which at this point in time was still owned by IVAX. Baker Norton/IVAX sold the rights to Elmiron to ALZA for $75 million up front and continued to receive milestone and royalty payments thereafter.

C. The Dangers of Elmiron

106. Despite numerous studies and other information in the possession of the Defendants providing clear evidence of the dangers of Elmiron, Defendants have failed to adequately investigate the threat that Elmiron poses to patients' vision.

107. Despite numerous studies and other information in the possession of the Defendant providing clear evidence of the dangers of Elmiron, Defendants failed to warn physicians in any way of the risk that their patients could suffer retinal injury and vision impairment prior to on or about June 16, 2020.

108. As more fully stated herein, the updated Warnings section and labeling published on or about June 16, 2020 were inadequate.

109. Despite numerous studies and other information in the possession of the Defendant providing clear evidence of the dangers of Elmiron, Defendants failed to warn patients in any way of the risk that they could suffer retinal injury and vision impairment prior to or on about June 16, 2020.

110. Clear evidence that Elmiron use is associated with ocular damage, including maculopathy, dates back to the initial evaluations of compassionate use experience conducted in

the late 1980s and early 1990s, and submitted in support of the NDA. Indeed, during this analysis, the following adverse reactions were noted: atrophic macular degeneration, retinal disorder, retinal artery occlusion, optic atrophy, optic neuritis, eye hemorrhage and eye disorder. Defendants relied upon this study when seeking FDA approval and therefore had direct knowledge of the adverse effects.[5]

111. The reported adverse effects included the following descriptions:[6]

> a.) Blurred Vision. Left Central Optic Vein Occlusion: A 32 year old white female without a prior history of eye trauma, hypertension, diabetes or previous significant ophthalmologic history complained of experiencing blurred vision.
>
> b.) "Filmy Sensation Over Left Eye" Possible Left Optic Neuritis: A 21 year old white female without any history of ophthalmological problems, head trauma, diabetes, or any previous neurological symptoms experienced a "filmy sensation over the left eye."

112. Available medical research also identified as early as 1991, that PPS inhibits regrowth and proliferation of retinal pigment epithelial (RPE) cells,[7] and could thereby impair an important physiological pathway for retinal health.

113. In fact, by 1992 PPS was also in Phase I trials for certain cancer treatments because of its "potent inhibition of cell motility," which further corroborates the role of PPS inhibiting cell regrowth and proliferation.

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[5] A Statistical and Medical Review of an Amendment to the New Drug Application for Elmiron® (Pentosan Polysulfate), NDA #20193, Appendix D (January 1996) (attached hereto as Exhibit "A").

[6] *Id.*

[7] Katrinka H. Leschey, John Hines, Jeff H. Singer, Sean F. Hackett, and Peter A. Campochiaro, *Inhibition of Growth Factor Effects in Retinal Pigment Epithelial Cells*, 32 INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 1770–1778 (1991) (attached hereto as Exhibit "B").

114. There is no indication that any of the Defendants ever advised the FDA that available medical research from as early as 1991, identified that PPS effects on the fibroblast growth factors (FGF) as well as other growth factors, inhibits regrowth and proliferation of retinal pigment epithelial (RPE) cells and could thereby impair an important physiological pathway for retinal health.

115. There is no indication that any of the Defendants ever advised the FDA that the medical research continued to build since 1991, as to the effects of Elmiron on the fibroblast growth factors (FGF) as well as other growth factors, that inhibits regrowth and proliferation of retinal pigment epithelial (RPE) cells and could thereby impair an important physiological pathway for retinal health.

116. Almost immediately after the FDA approved Elmiron, patients and doctors began reporting serious complications relating to eye and vision problems in patients taking Elmiron.[8]

117. Nearly 150 cases of eye disorders were reported to the FDA as adverse effects of Elmiron, ranging from blurred vision to maculopathy and blindness. Other reported symptoms include visual impairment, halo vision and reduced visual acuity.[9]

[8] According to the FDA Adverse Events Reporting System (FAERS) Public Dashboard, eight patients taking Elmiron reported serious adverse effects to their vision in the 1997 calendar year. https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/59a37af8-d2bb-4dee-90bf-6620b1d5542f/state/analysis.

[9] To date, at least 164 patients have reported "serious" adverse effects to their vision. https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/59a37af8-d2bb-4dee-90bf 6620b1d5542f/state/analysis

118. In 2018, researchers from the Emory Eye Center published their concerns about the presentation of a unique eye disease they were seeing in patients taking Elmiron in the Journal of Ophthalmology.[10]

119. The researchers also summarized their findings in a letter to the editor of the Journal of Urology:

> We wish to alert readers to a concerning new observation of vision threatening retinal changes associated with long-term exposure to [Elmiron]. We recently reported our findings of retinal pigmentary changes in six patients undergoing long-term therapy with [Elmiron]. These patients primarily described difficulty reading and/or trouble adjusting to dim lighting. Each patient had received a standard dosage of [Elmiron], ranging from 200 to 400 mg daily, for a median duration of 15.5 years. . . . Examination findings in patients with this condition are suggestive of injury to the retina and the underlying retinal pigment epithelium. . . . After extensive investigations, which included molecular testing for hereditary retinal disease, we found these cases to resemble no other retinal disease.[11]

120. The study, "Pigmentary Maculopathy Associated with Chronic Exposure to [Elmiron]," focused on six women with IC who presented to the Emory clinic between May 2015 and October 2017 with pigmentary maculopathy.[12] Maculopathy is a general term referring to any pathological condition that affects the macula, the central portion of the retina upon which visual acuity and sensitivity depend.

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[10] William A. Pearce, Rui Chen, and Nieraj Jain, *Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium*, 125 OPHTHALMOLOGY 1793–1802 (2018), https://www.ncbi.nlm.nih.gov/pubmed/29801663 (attached hereto as Exhibit "C").

[11] William A. Pearce, Adam M. Hanif, and Nieraj Jain, Letter to the Editor Re: *FDA BRUDAC 2018 Criteria for Interstitial Cystitis/Bladder Pain Syndrome Clinical Trials*, 200 UROLOGY 1122 (2018) (attached hereto as Exhibit "D")

[12] William A. Pearce, Rui Chen, and Nieraj Jain, *Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium*, 125 OPHTHALMOLOGY 1793–1802 (2018), https://www.ncbi.nlm.nih.gov/pubmed/29801663 (Exhibit "C")

121. Most of these patients had difficulty reading and difficulty seeing in darkness. Two patients experienced a generalized dimming of their vision as the first symptom. Two others had difficulty with near vision: one had paracentral scotomas (vision loss) in part of her eye, while the other had metamorphopsia (distorted vision where straight lines become wavy).

122. All six patients underwent rigorous diagnostic imaging and DNA testing to determine if they had any genes associated with hereditary retinal loss. None had a family history of retinal disease or the discovery of any pathogenic process.

123. What they had in common was a use of Elmiron.

124. Examinations of their eyes showed clear changes: "Nearly all eyes (10 eyes of 5 patients) showed subtle parafoveal pigmented deposits at the level of the retinal pigment epithelium (RPE)."[13] All eyes "showed subtle vitelliform deposits that increased in number and extended beyond the major arcade of vessels in cases judged to be more severe. Four eyes of 2 patients showed RPE atrophy that was noted to increase in area and encroach on the central fovea over time."[14] Retinal imaging also found clear diseased regions, atrophy, or both.[15]

125. The youngest patient in the study was 37 years old. Diagnosed with IC at the age of 23 and on a steady dosage of Elmiron, she began showing visual symptoms (difficulty with near vision and difficulty reading) at the age of 30 — just six years after she was diagnosed. She had the most severe damage in the study with deep scotomas of both eyes.[16]

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[13] *Id*. at 1798.

[14] *Id.*

[15] *Id.*

[16] *Id*. at 1795, Table 2.

126. The authors expressed concern that "the region of affected tissue may expand centrifugally over time."[17]

127. They concluded that "[c]linicians should be aware of this condition because it can be mistaken for other well-known macular disorders such as pattern dystrophy and age-related macular degeneration."[18]

128. They also encouraged "drug cessation in affected patients," and "recommend that any patient with suggestive visual symptoms undergo a comprehensive ophthalmic examination."[19]

129. IC experts Robert Moldwin and Curtis Nickel responded to the Emory findings with extreme concern: "It is quite unlikely that urologists treating patients with [IC] ever would have made this association . . . yet the implications are either frightening if our treatment is causing this condition or instructive if this condition is a previously unknown manifestation of [IC]."[20]

130. In a letter published online on April 24, 2019, five doctors from the Cleveland Clinic Cole Eye Institute responded to Pearce et al.: *Pigmentary maculopathy associated with chronic exposure to pentosan polysulfate sodium* 125 OPHTHALMOLOGY 1793–1802 (2018). The doctors suggested "…that long-term antagonism of FGF signaling in human retinas by PPS has the potential to be an underlying mechanism of toxicity." They further indicated that "[o]ne

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[17] *Id*. at 1800.

[18] *Id*. at 1801.

[19] William A. Pearce, Adam M. Hanif, and Nieraj Jain, Letter to the Editor Re: *FDA BRUDAC 2018 Criteria for Interstitial Cystitis/Bladder Pain Syndrome Clinical Trials*, 200 UROLOGY 1122 (2018) (Exhibit "D").

[20] J.C. Nickel and R. Moldwin, Reply to Letter to the Editor Re: *FDA BRUDAC 2018 Criteria for Interstitial Cystitis/Bladder Pain Syndrome Clinical Trials*, 200 UROLOGY 1122, 1123 (2018) (Exhibit "D").

could surmise that, without the appropriate FGF signaling, and thereby activity of support cells such as Muller glia, long-term accumulation of damage without repair could be the culprit."[21]

131. At the American Urology Association 2019 Annual Meeting in May 2019, the Emory team submitted another study of ten IC patients who had taken Elmiron and experienced macular disease.[22]

132. The patients had a median age of 59 years (range 38–68) and median time since IC diagnosis of 19 years (range 4–40). The most commonly reported symptoms were difficulty reading and difficulty adapting to dim lighting.

133. Eye examinations showed symmetric pigmentary changes in the retina. Retinal imaging demonstrated that the abnormalities were primarily in the retinal pigment epithelium. They note that their clinic has seen 156 patients with IC who did not have any Elmiron exposure—and these patients showed no pigmentary maculopathy.

134. The Emory team concluded that structural changes of the retina are occurring in patients taking Elmiron and they are unclear if stopping the medication will alter the course of the damage. They encouraged affected patients to discontinue the use of medications and to undergo comprehensive ophthalmic examinations.

135. On June 27, 2019, The European Medicines Agency (EMA), a decentralized agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU, through its Committee for Medicinal Products for

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[21] Tyler Greenlee, Grant Hom, Thais Conti, Amy S. Babiuch, and Rishi Singh, Letter to the Editor Re: Pearce et al.: *Pigmentary maculopathy associated with chronic exposure to pentosan polysulfate sodium* (Ophthalmology. 2018; 125:1793-1802) (Published online April 24, 2019) (attached hereto as Exhibit "E").

[22] Jenelle Foote, Adam Hanif, and Nieraj Jain, *Chronic Exposure to Pentosan Polysulfate Sodium is Associated with Retinal Pigmentary Changes and Vision Loss*, 201 UROLOGY e688 (2019), https://www.auajournals.org/doi/10.1097/01.JU.0000556315.46806.ca (attached hereto as Exhibit "F").

Human Use (CHMP), published a report entitled, "Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)", apparently reviewing data from the period June 02, 2018 through December 01, 2018 stating in relevant part:

> Taking into account the PRAC Assessment Report on the PSUR(s) for pentosan polysulfate sodium (for centrally authorised product), the scientific conclusions of CHMP are as follows:
>
> In literature, pigmentary maculopathy has been reported rarely, with pentosan polysulfate sodium, especially after long-term use. Visual symptoms might include complaints of reading difficulty and prolonged adjustment to low or reduced light environments. After extensive investigations, which included molecular testing for hereditary retinal disease, the authors of the study found these cases to resemble no other known retinal disease. Additionally, from the EudraVigilance database, at least one case describes similar findings on macula. There are a further 10 cases under SOC "eye disorders", including visual impairment, blindness, retinopathy or optic neuritis.
>
> Pending further investigation, it remains unclear whether drug cessation will halt or alter the course of the retinal disease.
>
> Although majority of the reports available in literature describe a minimum exposure to PPS of 12 years and a higher dosage than recommended in the SmPC, 1 case occurred with the recommended daily dose of 300 mg (Pierce et al). Moreover, 3 cases retrieved from Vigilyse included also the recommended dosage of 300 mg/day. Regarding the time of exposure to PPS, Foote et al article includes 1 patient exposed during 27 months and a case from Vigilyse describes an exposure of less than 2 years. Therefore, based on the available data it cannot be concluded that the pathophysiologic changes cannot be detected earlier (perhaps in an asymptomatic, reversible stage), even with the recommended daily dosage of 300 mg.
>
> In the light of this information, the PRAC recommended an update of the product information to warn about this risk and recommend regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly in patients taking pentosan polysulfate sodium long-term.
>
> Additionally, the PRAC recommended the distribution of a DHPC, since even if rare, it is a potentially irreversible, serious condition, which might not be easily recognized by the urology community. [23]

[23] https://www.ema.europa.eu/documents/scientific-conclusion/elmiron-h-c-psusa-00010614-201812-epar-scientific-conclusions-grounds-variation-terms-marketing_en.pdf (last visited, June 17, 2020)

136. The CHMP also recommended a Direct Healthcare Professional Communication, the equivalent of what is often referred to as a "Dear Doctor Letter" in the U.S., due to the fact that the condition at issue is "a potentially irreversible, serious condition, which might not be easily recognized by the urology community."[24]

137. Shortly after the recommendation by the CHMP was issued, the product labeling in the EU for Elmiron was updated to specifically warn that "[a]ll patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly those with long term use of PPS. In such situations, treatment cessation should be considered."[25]

138. In July 2019, the Emory team published a study in the Review of Ophthalmology.[26]

139. "Our subsequent investigations," the team wrote, "demonstrated that this unique maculopathy is strongly associated with chronic [Elmiron] exposure, not IC itself or its other therapies. In fact, this characteristic maculopathy has, to date, been exclusively diagnosed in patients reporting prior [Elmiron] exposure."[27]

140. The team further observed that claims data from a nationally-present U.S. insurance company suggested that hundreds of thousands of individuals have likely been exposed

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[24] *Id.*

[25] https://www.ema.europa.eu/en/documents/product-information/elmiron-epar-product-information_en.pdf

[26] Adam M. Hanif and Nieraj Jain, *Clinical Pearls for a New Condition. Pentosan Polysulfate Therapy, a Common Treatment for Interstitial Cystitis, Has Been Associated with a Maculopathy*, REVIEW OF OPHTHALMOLOGY July 10, 2019, https://www.reviewofophthalmology.com/article/clinical-pearls-for-a-new-condition (attached hereto as Exhibit "G").

[27] *Id.*

to Elmiron in the US and recognized a study finding that Elmiron-exposed patients were found to have a significantly increased risk of being diagnosed with a new macular disease after seven years.

141. In September 2019, the Emory team published further research in the Journal of American Medical Association Ophthalmology ("JAMA Ophthalmology"), concluding that Elmiron-associated macular degeneration "is a vision-threatening condition that can manifest in the setting of long-term exposure to the drug."[28]

142. Further, on September 23, 2019, the Canadian Product Monograph for Elmiron was updated to include the following in the "Warnings and Precautions" section:

> **Ophthalmologic**
>
> Post-market cases of pigmentary maculopathy have been reported with chronic use of pentosan polysulfate sodium (PPS). Visual symptoms in these cases included difficulty reading and prolonged dark adaptation. All patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly those with long-term use of PPS. If pigmentary maculopathy is confirmed, treatment discontinuation should be considered.[29]

143. Shortly thereafter, Health Canada issued a Health Product Advisory informing the Canadian public of the new warnings added to the Elmiron Product Monograph, but only in Canada.[30]

144. On October 1, 2019, two physicians from Harvard Medical School published a case study that observed a very concerning serious medical issue – they noted that damage caused

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[28] Adam Hanif et al., *Phenotypic Spectrum of Pentosan Polysulfate Sodium-Associated Maculopathy: A multicenter Study*, 137 JAMA OPHTHALMOLOGY 1275, 1282 (Sep. 5, 2019), https://jamanetwork.com/journals/jamaophthalmology/article-abstract/2749093 (attached hereto as Exhibit "H").

[29] https://pdf.hres.ca/dpd_pm/00053268.PDF

[30]https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch/health-product-infowatch-october-2019.html#elmiron

by Elmiron continues to progress long after cessation of the drug.[31] In their study, a patient continued to exhibit worsening symptoms of PPS-associated retinal maculopathy for at least 6 years after she stopped taking Elmiron.

145. In November of 2019, a team from Emory and the University of Pennsylvania published an epidemiological study in the British Journal of Ophthalmology which concluded that "PPS users had significantly increased odds of having atypical maculopathy."[32]

146. Also, in 2019, a team from Kaiser Permanente Northern California treated a patient who was previously misdiagnosed with Stargardt disease, but was actually suffering from Elmiron-related maculopathy.[33] In their case report, the ophthalmologists stressed that "failure to diagnose a medication toxicity in a timely fashion may lead to preventable irreversible vision loss."[34]

147. The doctors noted "the present case adds a new layer of concern by demonstrating progressive maculopathy continuing for up to 6 years after cessation of PPS . . . this case

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[31] Rachel M. Huckfeldt and Demetrios G Vavvas, *Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium*, 50 OPHTHALMIC SURGERY, LASERS AND IMAGING RETINA 656–59 (2019), ncbi.nlm.nih.gov/pubmed/31671200 (attached hereto as Exhibit "I").

[32] Nieraj Jain et al., *Association of Macular Disease with Long-Term Use of Pentosan Polysulfate Sodium: Findings from a U.S. Cohort*, BRITISH JOURNAL OF OPHTHALMOLOGY (published online first, November 6, 2019), https://bjo.bmj.com/content/early/2019/11/06/bjophthalmol-2019-314765 (attached hereto as Exhibit "J").

[33] Robin A. Vora et al., *A Case of Pentosan Polysulfate Maculopathy Originally Diagnosed as Stargardt Disease*, 17 AMERICAN JOURNAL OF OPHTHALMOLOGY CASE REPORTS 100604 (published online first, January 2020), http://www.sciencedirect.com/science/article/pii/S2451993620300086?via%3Dihub (attached hereto as Exhibit "K").

[34] *Id.*

emphasizes the need for a screening regimen that balances the demands on patients and physicians with the importance of prompt identification of early toxicity."[35]

148. On January 20, 2020, another team of researchers published a paper in which they found a 20% prevalence of a unique PPS- associated maculopathy among a cohort of patients being treated at the University of California, Los Angeles.[36] Their study suggests "a significant risk of macular toxicity for PPS-treated patients," and that "more significant PPS exposure was associated with more severe atrophy."

149. The Interstitial Cystitis Network, a health publishing company dedicated to IC, launched its own patient survey on the heels of the Emory Eye Center findings. As of April 2019, the IC Network had almost 1,000 participants, of which 53% reported eye disease.

150. Patient reports on the IC Network Support Forum include:[37]

a. June 23, 2019: "I have been diagnosed with macular degeneration and no one in my family has it. I have been on elmiron for 15 years. I decided even though the correlation is not extremely strong to go off it for the sake of my eyes . . . am hoping the degeneration will slow if not stop. Am not looking for it reverse course. Am also hoping that I do not go back to the pain . . . all I can do is try. I feel to be between a rock and a hard place. I am an artist so my eyes are truly needed to continue my work."

b. February 3, 2019: "I saw the article too and took it to my ophthalmologist. She was very excited to see the research. She said that my macular degeneration that had occurred after 18 years of taking Elmiron was an unusual shape that they had not seen before. She said that while it won't heal me, they hoped that they could stop this from happening to other patients."

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[35] *Id*. at 658.

[36] Derrick Wang et al., *Pentosan-Associated Maculopathy: Prevalence, Screening Guidelines, and Spectrum of Findings Based on Prospective Multimodal Analysis*, CANADIAN JOURNAL OF OPHTHALMOLOGY (in press, published online January 2020), http://www.canadianjournalofophthalmology.ca/article/S00008-4182(19)31272-4/fulltext. (attached hereto as Exhibit "L")

[37] Interstitial Cystitis Network Patient Support Forum. https://forum.ic-network.com/.

c. March 25, 2019: "After 4 excruciating years, I was diagnosed with IC in 2003. I started on Elmiron and have taken it since then. I was diagnosed with macular degeneration in 2014. My severity is mild to moderate. The left eye is definitely worse. I can no longer drive at night. I'm pretty comfortable driving to places I am familiar with during the day. I am only 58. I dread the day I will not be able to drive."

151. In July of 2020, a team from Emory, the University of Michigan and the Oregon Health and Science University published the results of a retrospective study in JAMA Ophthalmology which concluded that "[t]hese retrospective data among 11 patients suggest PPS-associated maculopathy continues to evolve after drug cessation for at least 10 years. In some cases, progressive retinal pigment epithelium atrophy encroaches on the foveal center and thus may pose a long-term threat to central vision".[38]

152. In total, there are about two dozen articles published in professional medical and scientific journals detailing the serious adverse events caused by Elmiron.

153. All of this information was known by and available to Defendants.

154. Despite numerous signs of the potential for severe retinal side effects, multiple studies conducted at top institutes, research published in major peer-reviewed journals, public warnings from prominent EU health agencies and Health Canada, and a warning placed in the European and Canadian Elmiron labeling, at all times Plaintiff was prescribed, purchased, and ingested Elmiron, Defendants were silent in the United States as to the harm.

155. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, Defendants failed to warn patients, including the Plaintiff, of:

a. the risks of vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron;

[38] Rachel Shah et al., *Disease Course in Patients With Pentosan Plolysulfate Sodium-Associated Maculopathy After Drug Cessation*, JAMA OPHTHALMOLOGY (Published online July 9, 2020).

b. the need for an ophthalmologic history prior to starting treatment with Elmiron;

c. the need for genetic testing if a family history of maculopathy or pattern dystrophy exists;

d. the need for a comprehensive baseline retinal examination for patients with pre-existing ophthalmologic conditions prior to starting Elmiron;

e. the need for ophthalmological monitoring commencing shortly after starting to take Elmiron, including but not limited to:

i. a baseline retinal examination within six months of starting treatment and periodically while continuing and after ceasing treatment;

ii. the need to re-evaluate the risks and benefits of continuing treatment if pigmentary changes in the retina develop, as they may be irreversible;

f. the need for ophthalmological monitoring after discontinuing Elmiron;

g. the ophthalmological imaging, testing, treatment, and/or monitoring required for patients already taking Elmiron;

h. the increased risks associated with higher doses of Elmiron; and

i. the increased risks associated with longer duration of use of Elmiron.

156. Similarly, at all times Plaintiff was prescribed, purchased, and ingested Elmiron, Defendants failed to warn physicians, including Plaintiffs prescribing physicians, of:

a. the risks of vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron;

b. the need for an ophthalmologic history prior to starting treatment with Elmiron;

c. the need for genetic testing if a family history of maculopathy or pattern dystrophy exists;

d. the need for a comprehensive baseline retinal examination for patients with pre-existing ophthalmologic conditions prior to starting Elmiron;

e. the need for ophthalmological monitoring commencing shortly after starting to take Elmiron, including but not limited to:

i. a baseline retinal examination within six months of starting treatment and periodically while continuing and after ceasing treatment;

ii. the need to re-evaluate the risks and benefits of continuing treatment if pigmentary changes in the retina develop, as they may be irreversible;

f. the need for ophthalmological monitoring after discontinuing Elmiron;

g. the ophthalmological imaging, testing, treatment, and/or monitoring required for patients already taking Elmiron;

h. the increased risks associated with higher doses of Elmiron; and

i. the increased risks associated with longer duration of use of Elmiron.

157. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, the labeling for Elmiron did not contain any information regarding:

a. the risks of vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron;

b. the need for an ophthalmologic history prior to starting treatment with Elmiron;

c. the need for genetic testing if a family history of maculopathy or pattern dystrophy exists;

d. the need for a comprehensive baseline retinal examination for patients with pre-existing ophthalmologic conditions prior to starting Elmiron;

e. the need for ophthalmological monitoring commencing shortly after starting to take Elmiron, including but not limited to:

i. a baseline retinal examination within six months of starting treatment and periodically while continuing and after ceasing treatment;

ii. the need to re-evaluate the risks and benefits of continuing treatment if pigmentary changes in the retina develop, as they may be irreversible;

f. the need for ophthalmological monitoring after discontinuing Elmiron;

g. the ophthalmological imaging, testing, treatment, and/or monitoring required for patients already taking Elmiron;

h. the increased risks associated with higher doses of Elmiron; and

i. the increased risks associated with longer duration of use of Elmiron.

158. Indeed, the Warnings section in the Elmiron label in the United States, during the relevant time period, read as follows:

WARNINGS

None.

159. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, the labeling for Elmiron did not list vision threatening retinal changes, vision loss, or maculopathy, despite the fact that it did list other serious side effects reported with the use of Elmiron.

160. At all times Plaintiff was prescribed, purchased, and ingested Elmiron the labeling for Elmiron did not list vision threatening retinal changes, vision loss, or maculopathy in the Adverse Reactions section.

161. In addition to the labeling that accompanied Elmiron, Defendants also prepared and distributed Elmiron marketing materials in the United States that was designed and distributed to patients, including their Elmiron "Patient Education Flyer", "Elmiron Patient Brochure", or "Patient Leaflet". Pursuant to the Defendants' marketing scheme, in conjunction with their design and distribution methods, these patient-facing materials constituted the sources of information most likely to be viewed by patients.

162. The Elmiron "Patient Education Flyer", "Elmiron Patient Brochure" and "Patient Leaflet" were documents created by Defendants and distributed to patients purporting to advise

patients, of the benefits, risks, "Important Safety Information" and the direction to "Please read the ELMIRON® Patient leaflet…" associated with the use of Elmiron.

163. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, Defendants did not make any mention of the need for ophthalmological monitoring in any of their U.S. patient materials —including their Elmiron "Patient Education Flyer", "Elmiron Patient Brochure" or "Patient Leaflet".

164. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, Defendants did not make any mention of the increased risks associated with higher doses of Elmiron in any of their U.S. patient materials —including their Elmiron "Patient Education Flyer", "Elmiron Patient Brochure" or "Patient Leaflet".

165. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, Defendants did not make any mention of the increased risks associated with longer duration of use of Elmiron in any of their U.S. patient materials —including their Elmiron "Patient Education Flyer", "Elmiron Patient Brochure" or "Patient Leaflet".

166. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, Defendants did not have any information in their U.S. patient materials – including their Elmiron "Patient Education Flyer", "Elmiron Patient Brochure", or "Patient Leaflet" that indicated Elmiron may cause, is linked to and/or is associated with vision threatening retinal changes, including vision loss and maculopathy.

167. The "Elmiron Patient Brochure" in particular, contained sections entitled, "Important Safety Information", "What is the most important information I should know about ELMIRON® (pentosan polysulfate sodium) Capsules?" and "What does your doctor need to know?".

168. The "Elmiron Patient Brochure" also recommended patients to "Please read the ELMIRON® Patient leaflet and discuss it with your doctor".

169. Over the years that Elmiron was marketed and sold to patients in United States, including the Plaintiff, Defendants made revisions and updates to the Elmiron "Patient Education Flyer", "Elmiron Patient Brochure" and/or "Patient leaflet".

170. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, the Elmiron "Patient Education Flyer", "Elmiron Patient Brochure" and/or "Patient leaflet" did not make any mention, or provide any warning to consumers, of the potential for vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron use.[39]

171. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, the Elmiron "Patient Education Flyer", "Elmiron Patient Brochure" and/or "Patient leaflet" did not make any mention, or provide any recommendation to consumers, of the need for ophthalmological monitoring while taking Elmiron or how to properly evaluate and screen Elmiron patients.

172. JANSSEN PHARMA maintains a website promoting Elmiron, www.orthoelmiron.com. The website includes, among things, "About Elmiron," "How Elmiron Works," "Important Safety Information," and "Patient Information."

173. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, the above-mentioned website did not make any mention, or provide any warning to consumers, of the potential for vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron use.[40]

[39] Last visited April 19, 2020.

[40] Last visited April 19, 2020.

174. At all times Plaintiff was prescribed, purchased, and ingested Elmiron, the above-mentioned website did not make any mention, or provide any recommendation to consumers, of the need for ophthalmological monitoring while taking, and after discontinuing, Elmiron or how to properly evaluate and screen Elmiron patients.

175. By creating the "Elmiron Patient Brochure", Elmiron "Patient Education Flyer", "Patient Leaflet", all of which included important safety information which the Defendants intended to provide to the users and potential users of Elmiron, Defendants assumed a duty to fully, completely and/or adequately warn of all the risks, adverse events and proper usage of Elmiron that were known or should have been known by Defendants.

176. However, at all times Plaintiff was prescribed, purchased, and ingested Elmiron, none of these patient/user materials ("Elmiron Patient Brochure", Elmiron "Patient Education Flyer", "Patient Leaflet") contained any warning or adverse event information regarding vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron, the need for ophthalmological monitoring, while taking, and after discontinuing, Elmiron, or how to properly evaluate and screen Elmiron patients.

177. By creating the website www.orthoelmiron.com website which included important safety information which the Defendants intended to provide to the users and potential users of Elmiron, Defendants assumed a duty to fully, completely and/or adequately warn of all the risks, adverse events and proper usage of Elmiron that were known or should have been known by Defendants. However, at all times Plaintiff was prescribed, purchased, and ingested Elmiron, the website contained any warning or adverse event information regarding vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron, the need for

ophthalmological monitoring while taking, and after discontinuing, Elmiron, or how to properly evaluate and screen Elmiron patients.

D. Defendants Could Have Unilaterally Strengthened the Elmiron Drug Label After FDA Approval in the United States under the CBE Regulation without Prior FDA Approval

178. Defendants could have strengthened the Elmiron label at any time under the CBE regulation without prior FDA approval. The CBE regulation permits manufacturers to strengthen drug labels based on "newly acquired information" – that is, information that was not previously presented to the FDA.

179. As described above, Defendants received significant "newly acquired information" on many occasions after the launch of Elmiron that should have resulted in a label change warning, through the CBE regulation, of the risks of vision threatening retinal changes, vision loss, and/or maculopathy associated with Elmiron. The then newly acquired information came in the forms including but not limited to post-market adverse events, newly published peer reviewed studies and government announcements and updated labeling.

180. Due to the nature of the serious and irreversible injuries, as well as the need for ophthalmological monitoring while taking Elmiron and after discontinuing Elmiron, the method used to update the label with this new warning should have been the method that would have updated the label in the quickest period of time.

181. The CBE regulation provides for the fastest method to update prescription drug labeling.

182. While Defendants had ample opportunity to strengthen their label to add a warning regarding PPS Associated Maculopathy, prior to June 16, 2020, they declined to do so.

183. In fact, though Defendants have made at least five (5) changes to the label throughout the time that Plaintiff was prescribed, purchased, and ingested Elmiron, including some

changes using the CBE regulation, none of those changes included a warning that Elmiron could cause PPS Associated Maculopathy.

184. There is no clear evidence that the FDA would not have approved a label change adding a warning regarding vision threatening retinal changes, including vision loss and maculopathy at any time from the date of approval (September 26, 1996) to the present.

185. There is no clear evidence that the FDA would not have approved a warning regarding vision threatening retinal changes, including vision loss and maculopathy to be included in the original label at the time of approval.

186. By failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians of the risk of vision threatening retinal changes associated with using Elmiron, Defendants acted in a gross and flagrant character, evincing reckless disregard for human life, and of the safety of persons exposed to its dangerous drug.

187. Additionally, by failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians, of the risk of vision threatening retinal changes associated with using Elmiron, Defendants showed wantonness, recklessness, or grossly careless disregard for the public's safety and welfare.

E. June 16, 2020 Label Change

188. On June 24, 2019, Defendants submitted a Supplemental New Drug Application ("sNDA") seeking to revise the Warnings and Post-Marketing Experience sections of the label and to update the Patient labeling for Elmiron to include warnings relating to vision threatening retinal changes and maculopathy.

189. Defendants' NDA was not approved until June 16, 2020.

190. On that date, the label was amended to include the following in the "Warnings" section:

> **Retinal Pigmentary Changes**
>
> Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON® (see ADVERSE REACTIONS). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor.
>
> Visual symptoms in the reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. The visual consequences of these pigmentary changes are not fully characterized. Caution should be used in patients with retinal pigment changes from other causes in which examination findings may confound the appropriate diagnosis, follow-up, and treatment. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®. If there is a family history of hereditary pattern dystrophy, genetic testing should be considered. For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, ocular coherence tomography (OCT), and auto-fluorescence imaging) is recommended prior to starting therapy. A baseline retinal examination (including OCT and auto-fluorescence imaging) is suggested for all patients within six months of initiating treatment and periodically while continuing treatment. If pigmentary changes in the retina develop, then risks and benefits of continuing treatment should be re-evaluated, since these changes may be irreversible. Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.

191. The "Post-Marketing Experience" section was also amended to include the following:

> **Post-Marketing Experience**
> The following adverse reactions have been identified during post approval use of pentosan polysulfate sodium; because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:
>
> • pigmentary changes in the retina (see WARNINGS).

192. While Defendants had the opportunity to immediately update the label for Elmiron under the CBE regulation by simply sending the FDA a "supplemental submission." (see 21 C.F.R. § 314.70(c)(6)(iii)), Defendants instead chose to submit a sNDA which is a much lengthier and time-consuming process, thereby delaying the dissemination of this important safety information to physicians and patients.

193. Defendants' failure to amend the Elmiron label under the CBE regulations resulted in unnecessary further delay in disseminating important safety information to physicians and patients. This additional, needless delay prevented physicians and patients from obtaining this critical information in the timeliest manner possible, which could have guided their care and treatment and allowed for an earlier diagnosis of the relevant condition.

194. The recently added warnings in the US label remain inadequate, however, as they fail to warn, instruct and advise current or past patients who are or were taking Elmiron, as to what they should do and what procedures they should follow, in order to properly screen, test and monitor for vision and/or retinal damage as a result of their use of Elmiron.

F. Elmiron is no Better than Placebo in Treating IC

195. As described above, Elmiron was eventually approved by the FDA based on two seriously flawed clinical trials that were determined not to be adequate and well controlled, in part due to a lack of independence, as well as compassionate use data that the FDA had twice previously determined to be inadequate.

196. Prior to approval, one of the top concerns expressed by the FDA was that when the data from a single investigator (Dr. Parsons) was removed, there was no proof that Elmiron was an effective treatment IC/Bladder Pain Syndrome.

197. Since the initial approval, additional data has been published that serves as further evidence of Elmiron's lack of efficacy.

198. In a March 2012 Citizen's Petition to the FDA requesting a bioequivalence study for any new generics coming to market – in an effort to maintain its market position and block generics from coming to market – Defendant JANSSEN PHARMA admitted that "the drug has

low bioavailability, is poorly absorbed from the gastrointestinal tract, and cannot be reliably assayed by determining serum levels."[41]

199. JANSSEN PHARMA further elaborated:

> ***ELMIRON has not yet been fully characterized***. ELMIRON contains a mix of many components, which vary in chain length (molecular weight), number and location of glucuronic acid sidechains, and number of location of sodium sulfate groups. ***Moreover, no definitive information exists to identify which of the components are active (i.e., responsible for the safety and efficacy of ELMIRON)*** . . . The information presented above demonstrates that due to the ***unknown etiology of IC, the inability to characterize ELMIRON and understand how it works in the body, the difficulty of measuring PPS in plasma, blood, or urine, and the lack of a reliable bioassay to measure the product's effects***, conventional methods of determining bioequivalence are inadequate.[42]

200. In 2015, an article was published in the Journal of Urology comparing the efficacy and safety of the recommended dose of Elmiron with a third of the daily dose of Elmiron and with placebo. This study involved 368 patients with IC/bladder pain syndrome and took place over the course of 24 weeks. The study found that "[t]here was no statistically significant difference between the pentosan polysulfate sodium group and the placebo group or between the 2 pentosan polysulfate sodium groups for the primary end point, defined as responder achieving a 30% or greater reduction from the baseline ICSI total score at study end." The authors concluded "[r]esults of this study in a broad population of patients with symptoms consistent with interstitial cystitis revealed no treatment effect vs placebo for pentosan polysulfate sodium at the currently established dose or at a third of the daily dose."[43]

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[41] March 26, 2012 Janssen Citizen Petition requesting FDA adoption of appropriate bioequivalence requirements to govern approval of any abbreviated new drug application ("ANDA") relying on ELMIRON (pentosan polysulfate sodium) as its reference product (hereinafter "Janssen Citizen Petition") (emphasis added).

[42] *Id.* (emphasis added).

[43] J Curtis Nickel et al. *Pentosan Polysulfate Sodium for Treatment of Interstitial Cystitis/Bladder Pain Syndrome: Insights From a Randomized, Double-Blind, Placebo Controlled Study*, JOURNAL OF UROLOGY (published online first September 20, 2014) (attached hereto as Exhibit "M").

201. The low efficacy and bioavailability of Elmiron are even more troubling in light of the significant risks of permanent vision loss and retinal issues caused by the drug. These design defects render Elmiron more dangerous than other drugs and treatment options designed to treat IC and cause an unreasonable increased risk of injury, including but not limited to permanent vision and retinal injuries.

G. Defendant's Failure to Test Elmiron

202. Defendants admit that "the mechanism of action of pentosan polysulfate sodium in interstitial cystitis is not known," and Defendants have failed to conduct tests to determine the mechanism of action of the drug.

203. In the Elmiron NDA file, the FDA noted that: "Elmiron works by binding to exposed epithelium," which may explain its apparent effect on the urinary bladder epithelium.

204. Defendants knew or should have known of the potential impact of the drug on other epithelial cells – particularly the retinal epithelial cells of the eye – but failed to adequately test for these adverse events.

205. Defendants acknowledged that their Phase III testing of Elmiron was "subjective" and that "an objective measure" may be more appropriate. JANSSEN PHARMA stated:

> The Phase III studies on which the ELMIRON approval was initially based assessed the effect of the drug on subjects' pain and discomfort levels, as measured by the subjects' individual assessments. Pain and discomfort, while key symptoms of the IC diagnosis, are inherently subjective elements. Therefore, while patients' individual assessments based on these subjective impressions were useful in the Phase III ELMIRON trials to demonstrate a clinical benefit as compared to placebo, ***an objective measure is more appropriate*** for studies with clinical endpoints to assess bioequivalence.[44]

[44]Janssen Citizen Petition (emphasis added)

206. Furthermore, JANSSEN PHARMA not only failed to conduct pharmacokinetic ("PK") and pharmacodynamic ("PD") testing on the drug, but in fact advocated against such testing, stating:

> ***A PK study, while generally appropriate for drugs that are systemically absorbed, is inappropriate*** for determining bioequivalence of an oral dosage form of PPS. Although PPS is systemically absorbed and distributed to the bladder, it has extremely low bioavailability; even with the use of radioactive drug, PPS is difficult to detect in blood or plasma. Due to low serum concentration and the inherent complexity of the product, attempts by the manufacturer of the product, bene, to develop a sensitive and reliable bioassay have been futile. ***Indeed, Janssen is not aware of any analytical techniques presently available to predict or measure systemic concentration of PPS*** . . . Finally, because the mechanism of action of PPS and the pathophysiology of IC is unknown, ***there is no known pharmacodynamic marker other than clinical effect measured as reduction of pain***.[45]

207. To be clear, PK and PD testing is not "inappropriate". To the contrary, an understanding of pharmacokinetics of a drug – including absorption, distribution, metabolism, and excretion – is a critical aspect of drug design and is crucial to understanding how the drug interacts with the human body and evaluate potential risks associated with the drug.

H. Exemplary/Punitive Damages

208. Defendants' conduct as alleged herein was grossly negligent and done with reckless disregard for human life.

209. Defendants' conduct as alleged herein was done with malice.

210. Defendants acted with oppression, fraud or malice and their actions were carried on with a willful and conscious disregard of the safety of others, including the Plaintiff.

[45] *Id.* (emphasis added)

211. Defendants were fully aware of the safety risks of Elmiron dating back to their clinical trials. Nonetheless, Defendants deliberately crafted their label, marketing and promotion to mislead consumers and their physicians on these serious and permanent life-altering injuries.

212. This conduct by the Defendants was not done by accident. Rather, Defendants knew that they could turn a profit by convincing physicians and consumers that Elmiron came without any serious harmful risks. Defendants further knew that full disclosure of the true risks of Elmiron would limit the amount of money it would make selling the drug. Defendants' object was accomplished not only through inadequate warnings in their label, but through a comprehensive scheme of misleading marketing and deceptive omissions more fully alleged throughout this pleading. Plaintiff's physician and Plaintiff were denied the opportunity and the right to have a discussion in order to make an informed decision about whether to prescribe and take Elmiron. Defendants accomplished this by failing to provide the serious risks, and specifically those affecting vision and the fact that the damage may be irreversible, and/or Elmiron's lack of efficacy. Such conduct was done with conscious disregard of Plaintiff's rights.

213. Accordingly, Plaintiff requests punitive damages against Defendants for the harms caused to Plaintiff.

TOLLING OF THE STATUTE OF LIMITATIONS

A. Discovery Rule Tolling

214. As a result of the acts and omissions of Defendants, neither the Plaintiff, nor their physicians could have discovered, through the exercise of reasonable due diligence, that exposure to Elmiron was associated with increased exposure to vision threatening retinal changes, including vision loss and maculopathy as set forth above. Thus, the applicable limitations periods did not

begin to accrue until Plaintiff discovered, or through the exercise of reasonable diligence should have discovered, Defendants' wrongful acts and omissions.

B. Fraudulent Concealment Tolling

215. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron throughout the time period relevant to this action.

216. Defendants are under a continuing duty to disclose the true character, quality, safety issues and safety concerns of Elmiron to its users and Plaintiff specifically. To date, Defendants have nevertheless failed to adequately and fully inform patients and doctors about the vision threatening retinal changes, including vision loss and maculopathy and its potential irreversibility, associated with Elmiron, as discussed above.

217. Plaintiff reasonably relied upon Defendants' knowing, affirmative or active concealment when she continued to use Elmiron as prescribed.

218. Because Defendants actively concealed the true risk of vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron, they are estopped from relying on any statutes of limitations defense.

C. Estoppel

219. Defendants were and are, under a continuous duty to disclose to Plaintiff the vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron. Instead, at all relevant times, they actively concealed the true character, quality and nature of Elmiron and knowingly made misrepresentations and/or omissions about the safety of Elmiron

and the vision threatening retinal changes, including vision loss and maculopathy associated with it.

220. Plaintiff reasonably relied upon Defendants' knowing and affirmative misrepresentations and active concealment of material facts and safety issues with Elmiron. Therefore, Defendants are estopped from relying on any defense based on statutes of limitations in this action.

221. As a result of the Defendants conduct as set forth above, the Defendants have waived and/or lost whatever right they may claim to the "learned intermediary defense".

COUNT I
Strict Liability – Failure to Warn

222. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

223. As more fully alleged above and incorporated herein by reference, Defendants failed to warn Plaintiff and her physicians of the unavoidable risks and side effects associated with Elmiron that Defendants knew or should have known. Specifically, the risk of vision threatening retinal changes, including vision loss and maculopathy. Defendants therefore failed to provide Plaintiff with the option to make an informed choice whether to use the product or refrain.

224. Had Plaintiff been provided with a warning regarding the risk of vision threatening retinal changes, including vision loss and maculopathy she would not have chosen to take Elmiron.

225. As more fully alleged above and incorporated herein by reference, Defendants failed to adequately instruct Plaintiff, as to how Elmiron should be used, including how to properly evaluate Elmiron patients, in order to eliminate or reduce the risk of harm. Defendants therefore failed to provide information that could have allowed Plaintiff to use the product in a way that would minimize the degree of danger.

226. Had Plaintiff been adequately instructed on how Elmiron should be used in order to eliminate or reduce the risk of harm, her injuries could have been avoided or prevented from developing into the severe maculopathy and vision loss that she suffers today.

227. As more fully alleged above and incorporated herein by reference, at the time Plaintiff was prescribed, purchased and ingested Elmiron, no section of the label, including the "Warnings and Precautions" and the "Adverse Reactions" sections, contained any warnings regarding the risk of vision threatening retinal changes, including vision loss and maculopathy.

228. As more fully alleged above and incorporated herein by reference, at the time Plaintiff was prescribed, purchased and ingested Elmiron, no section of the label, including the "Warnings and Precautions" and the "Adverse Reactions" sections, contained any instructions regarding how Elmiron should be used, including how to properly evaluate Elmiron patients, in order to eliminate or reduce the risk of harm.

229. As more fully alleged above and incorporated herein by reference, at the time Plaintiff was prescribed, purchased, and ingested Elmiron the "Elmiron Patient Brochure", Elmiron "Patient Education Flyer", "Patient Leaflet", and www.orthoelmiron.com website, which included important safety information regarding Elmiron, did not contain a warning regarding vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron

230. As more fully alleged above and incorporated herein by reference, at the time Plaintiff was prescribed, purchased, and ingested Elmiron the "Elmiron Patient Brochure", Elmiron "Patient Education Flyer", "Patient Leaflet", and www.orthoelmiron.com website, which included important safety information regarding Elmiron, did not contain instructions regarding how Elmiron should be used, including how to properly evaluate Elmiron patients, in order to eliminate or reduce the risk of harm.

231. By publishing direct to patient information in the "Elmiron Patient Brochure", Elmiron "Patient Education Flyer", "Patient Leaflet", and on the www.orthoelmiron.com website, including important safety information, Defendants assumed the duty to directly warn patients of all the risks associated with Elmiron that were known or should have been known by Defendants.

232. Defendants knew or should have known through testing, scientific knowledge, advances in the field, adverse events, communications with patients, communications with physicians and otherwise, that Elmiron created a risk of serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy, and was unsafe and dangerous to Plaintiff and other consumers, all about which Defendants failed to warn.

233. The Elmiron supplied to Plaintiff by Defendants was unsafe, dangerous, and had inadequate warnings and/or instructions at the time it was sold to Plaintiff

234. The dangerous propensities associated with Elmiron were either known by Defendants, or reasonably scientifically knowable, at the time Plaintiff was prescribed, purchased, and ingested Elmiron.

235. At times after Elmiron was supplied to Plaintiff Defendants acquired additional knowledge and information confirming the dangerous nature of Elmiron.

236. Despite having this knowledge and information, Defendants failed to issue adequate warnings and/or post-sale warnings or notifications to physicians that Elmiron causes serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy.

237. Despite having this knowledge and information, as more fully alleged above and incorporated herein by reference, Defendants failed to issue adequate warnings and/or post-sale warnings or notifications to patients and specifically Plaintiff herein that Elmiron causes serious

and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy.

238. Despite having this knowledge and information, as more fully alleged above and incorporated herein by reference, Defendants failed to issue adequate warnings and/or post-sale warnings or notifications to physicians regarding how Elmiron should be used, including how to properly evaluate Elmiron patients, in order to eliminate or reduce the risk of harm.

239. Defendants failed to provide adequate warnings to users, purchasers, or prescribers of Elmiron, including Plaintiff and prescribing physicians and instead continued to sell Elmiron in an unreasonably dangerous form without adequate warnings or instructions.

240. By failing to adequately test and research harms associated with Elmiron use patients and the medical community, including prescribing doctors, were inadequately informed about the true risk-benefit profile of Elmiron and were not sufficiently aware that serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy might be associated with Elmiron use.

241. By failing to provide appropriate precautions about Elmiron use, patients and the medical community, including prescribing doctors, were inadequately informed about the true risk-benefit profile of Elmiron and were not sufficiently aware that serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy might be associated with Elmiron use.

242. Nor were the medical community, patients, patients' families or regulators, including Plaintiff's physicians and Plaintiff herein, appropriately informed and/ or warned by Defendants that serious and potentially irreversible vision threatening retinal changes, including

vision loss and maculopathy might be a side effect of Elmiron use and should or could be reported as an adverse event.

243. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research and the dangerous nature of Elmiron, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses and aggravation of previously existing conditions. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT II
Strict Liability – Defective Design

244. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

245. At all relevant times, Defendants engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Elmiron and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

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

247. Defendants breached that duty when they created a product unreasonably dangerous for its intended and foreseeable use.

248. 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 Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

249. The Elmiron supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and a defective condition because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants, posing a risk of serious and potentially irreversible vision issues and retinal harm to Plaintiff and other consumers.

250. Elmiron is a medication prescribed primarily for IC, a bladder condition. Elmiron in fact causes serious and potentially irreversible vision issues, retinal harm, PPS toxicity, PPS Maculopathy, and/or could interfere with the normal health, healing, proliferation, migration, and/or growth of cells, including epithelial cells and RPE cells, harming Plaintiff and other consumers.

251. Plaintiff, ordinary consumers, and prescribers would not expect an IC drug designed, marketed, and labeled for bladder treatment to cause irreversible vision and retinal damage.

252. The Elmiron supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious and potentially irreversible vision issues and retinal harm to Plaintiff and other consumers.

253. The Elmiron supplied to Plaintiff by Defendants was defective in design or formulation in that its limited and unproven effectiveness, low efficacy, and low bioavailability,

did not outweigh the risks of serious and potentially irreversible vision issues and retinal harm posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of the Elmiron drug makes the product unreasonably dangerous.

254. The design defects render Elmiron more dangerous than other drugs and therapies designed to treat IC and causes an unreasonable increased risk of injury, including but not limited to potentially irreversible vision issues and retinal harm.

255. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, or otherwise, that Elmiron created a risk of serious and potentially irreversible vision issues, retinal harm, PPS toxicity, PPS Maculopathy, and/or could interfere with the normal health, healing, proliferation, migration, and/or growth of cells, including epithelial cells and RPE cells.

256. Elmiron is defective and unreasonably dangerous to Plaintiff and other consumers in that, despite early indications and concerns that Elmiron use could result in vision issues, Defendants failed to adequately test or study the drug, including but not limited to: pharmacokinetics and pharmacodynamics of the drug, its effects on vision and retinal epithelial cells, the potential effects and risks of long-term use, the potential for inter-patient variability, and/or the potential for a safer effective dosing regimen.

257. Elmiron is defective and unreasonably dangerous to Plaintiff and other consumers even if Defendants had exercised all possible care in the preparation and sale of Elmiron.

258. As a direct and proximate result of Defendants' conduct, including the inadequate testing and research and the defective and dangerous nature of Elmiron, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of

earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT III
Breach of Express Warranty

259. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

260. Defendants expressly warranted to physicians and consumers, including Plaintiff and Plaintiff's physicians, that Elmiron was safe, well- tolerated, and does not carry the risk of serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy.

261. Elmiron does not conform to these express representations because it is neither safe, nor well-tolerated, and it significantly increases the risk of serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy.

262. This risk was either known or reasonably scientifically knowable to Defendants at the time Plaintiff was prescribed, purchased, and ingested Elmiron.

263. As a direct and proximate result of the breach of Defendants' warranties, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses and aggravation of previously existing conditions. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT IV
Breach of Implied Warranty

264. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

265. At the time Defendants marketed, sold and distributed Elmiron, Defendants knew of the use for which Elmiron was intended and they impliedly warranted Elmiron to be of merchantable quality, safe and fit for such use.

266. Defendants knew, or had reason to know, that Plaintiff and Plaintiff's physicians would rely on Defendants' judgment and skill in providing Elmiron for its intended use.

267. Plaintiff and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants as to whether Elmiron was of merchantable quality, safe and fit for its intended use.

268. Contrary to such implied warranty, Elmiron was not of merchantable quality or safe or fit for its intended use, because the product was and is, unreasonably dangerous and unfit for the ordinary purposes for which Elmiron was used, was not adequately labeled, as it failed to warn of risks reasonably scientifically knowable to Defendants or instruct users how to minimize the degree of danger, and did not conform to the promises or affirmations of fact made in the label.

269. As a direct and proximate result of the breach of implied warranty, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses and aggravation of previously existing conditions. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT V
Negligence

270. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

271. At all times material herein, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, warning, post-sale warning, testing and research to assure the safety of the product when used as intended or in a way that Defendants could reasonably have anticipated and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Elmiron

272. As more fully alleged above and incorporated herein by reference, Defendants had a duty to warn Plaintiff, Plaintiff's physicians and the public in general of Elmiron's dangers and serious side effects, including serious and potentially irreversible vision issues and retinal harm, and how Elmiron should be used, including how to properly evaluate Elmiron patients, in order to eliminate or reduce the risk of harm and since it was reasonably foreseeable that an injury could occur because of Elmiron's use.

273. At all times material herein, Defendants failed to exercise reasonable care and the duty of an expert and knew, or in the exercise of reasonable care should have known, that Elmiron was not properly tested, inspected, packaged, labeled, warned about, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, or a combination of these acts.

274. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to:

a. Negligent and careless research and testing of Elmiron;

b. Negligent and careless failure to give adequate warnings that would attract the attention of Plaintiff, Plaintiff's physicians and

the public in general of the potentially dangerous, defective, unsafe and deleterious propensity of Elmiron and of the risks associated with its use;

c. Negligent and careless failure to provide instructions on ways to safely use Elmiron to avoid injury, including how to properly evaluate Elmiron patients;

d. Negligent and careless failure to provide instructions regarding the need for ophthalmological monitoring while taking Elmiron;

e. Negligent and careless failure to provide instructions regarding the need for ophthalmological monitoring after discontinuing Elmiron;

f. Negligent and careless failure to explain the mechanism, mode and types of adverse events associated with Elmiron;

g. Negligent representations that Elmiron was safe or well- tolerated; and

h. Negligent and careless failure to issue adequate post-sale warnings that Elmiron causes an increased risk of serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy.

275. As a direct and proximate result of Defendants' negligence, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses and aggravation of previously existing conditions. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT VI
Negligent Design

276. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

277. At all times material herein, Defendants had a duty to exercise reasonable care andhad the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, testing, and research to assure the safety of Elmiron when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including

Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Elmiron.

278. At all times material herein, Defendants failed to exercise reasonable care and the duty of an expert and knew, or in the exercise of reasonable care should have known, that Elmiron was not properly manufactured, designed, compounded, tested, inspected, packaged, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, or a combination of these acts.

279. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to:

a. Negligent and careless research and testing of Elmiron;

b. Negligent and careless design or formulation of Elmiron;

c. Negligent and careless failure to provide instructions on ways to safely use Elmiron to avoid injury;

d. Negligent and careless failure to explain the mechanism, mode, and types of adverse events associated with Elmiron; and

e. Negligent and careless failure to conduct postmarketing surveillance of adverse events associated with Elmiron.

280. Defendants' negligence and Elmiron's failures arise under circumstances precluding any other reasonable inference other than a defect in Elmiron.

281. As a direct and proximate result of Defendants' negligence, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously

existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT VII
Negligence Per Se
(Violations of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1)

282. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

283. At all times herein mentioned, Defendants had an obligation to abide by the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, labeling, packaging, preparation for use, consulting, sale, warning and post-sale warning and other communications of the risks and dangers of Elmiron.

284. By reason of its conduct as alleged herein, Defendants violated provisions of statutes and regulations, including, but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding Elmiron;

b. Defendants failed to follow the "[g]eneral requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.56;

c. Defendants failed to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.57;

d. Defendants advertised and promoted Elmiron in violation of 21 C.F.R. § 202.1; and

e. Defendants violated 21 C.F.R. § 201.57(e) by failing to timely and adequately change the Elmiron label to reflect the evidence of an association between Elmiron and the serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy affecting Plaintiff.

285. These statutes and regulations impose a standard of conduct designed to protect consumers of drugs, including Plaintiff.

286. Defendants' violations of these statutes and regulations constitute negligence per se.

287. As a direct and proximate result of Defendants' statutory and regulatory violations, Plaintiff, a member of the class of persons intended to be protected by the above-mentioned statutes, suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses and aggravation of previously existing conditions. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

COUNT VIII
Fraud and Concealment

288. Plaintiff realleges and incorporates the allegations made above as if fully set forth below.

289. At all relevant times, Defendant had the duty and obligation to truthfully represent the facts concerning Elmiron to Plaintiff and Plaintiff's physicians pursuant to federal and state law.

290. Defendants owed a duty to warn because they were in possession of information about Elmiron that was not readily available to Plaintiff and Plaintiff's physicians, and made partial representations about Elmiron reasonably relied upon by Plaintiff and Plaintiff's physicians.

291. Defendants willfully deceived Plaintiff, her healthcare providers, the medical community, and the public in general, by concealing and/or omitting material information concerning Elmiron, which Defendants had a duty to disclose, thus misrepresenting the true nature of the medications.

292. Indeed, Defendants omission of important safety data served as a misrepresentation to consumers and physicians, including Plaintiff and Plaintiff's physicians and the public in general, that Elmiron was safe or well- tolerated, when, in fact, Elmiron was dangerous to the well-being of patients.

293. Specifically, as more fully alleged above and incorporated herein by reference, Defendants intentionally suppressed, concealed, and omitted material facts in the promotional, marketing, and labeling communications about the risks and benefits of Elmiron to Plaintiff and Plaintiff's doctors, including but not limited to, the risk of serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy associated with Elmiron and instructions on how to safely use Elmiron, including how to properly evaluate Elmiron patients, in order to eliminate or reduce the risk of harm.

294. Defendants had exclusive possession and/or knowledge of this information and material facts.

295. As more fully alleged above and incorporated herein by reference, at the time Defendants promoted Elmiron without disclosing the material facts described above they knew or should have known that Elmiron carried a risk of serious and potentially irreversible vision threatening retinal changes, including vision loss and maculopathy.

296. As more fully alleged above and incorporated herein by reference, at the time Defendants promoted Elmiron without disclosing the material facts described above they knew or should have known that patients taking Elmiron should be provided with instructions regarding how to safely use Elmiron, including how to properly evaluate Elmiron patients, in order to eliminate or reduce the risk of harm.

297. Defendants failed to exercise reasonable care and competence in obtaining or communicating information regarding the safe use of Elmiron and otherwise failed to exercise reasonable care in transmitting information to Plaintiff, Plaintiff's physicians and the public in general.

298. Defendants made the aforesaid misrepresentations by omission in the course of Defendants' business as manufacturers and distributors of Elmiron despite having no reasonable basis to omit this critical information.

299. At the time the aforesaid misrepresentations by omission were made, Defendants intended to induce Plaintiff or Plaintiff's physicians to rely upon such misrepresentations.

300. At the time the aforesaid misrepresentations by omission were made by Defendants and at the time Plaintiff received Elmiron, Plaintiff or Plaintiff's physicians and the public in general, reasonably believed them to be true. In reasonable and justified reliance upon said misrepresentations by omission, Plaintiff used Elmiron.

301. Defendants knew or should have known, that this information was not readily available to Plaintiff and her doctors, and Plaintiff and her doctors did not have an equal opportunity to discover the truth.

302. As a direct and proximate result of reliance upon Defendants' misrepresentations by omission, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses and aggravation of previously existing conditions. The losses are either permanent or continuing and Plaintiff will suffer the losses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment in Plaintiff's favor as follows:

a. Awarding compensatory damages, including but not limited to lost earnings in the past; loss of earning capacity in the future; medical expenses incurred in the past; medical expenses to be incurred in the future; other economic damages; pain and suffering; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a disease or physical defect; loss of capacity for the enjoyment of life sustained in the past and to be sustained in the future; and other non-economic damages;

b. Awarding punitive damages;

c. Awarding the costs and expenses of this litigation to Plaintiff;

d. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law;

e. Awarding pre-judgment and post-judgment interest to Plaintiff; and

f. For such further relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

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

Dated: February 4, 2021

Respectfully Submitted,

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