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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CAROL WARE and **TOM WARE**, *Plaintiffs*, v. **JANSSEN PHARMACEUTICALS, INC.**, f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.; **JOHNSON & JOHNSON** d/b/a Alza Corporation, d/b/a Janssen Ortho LLC, d/b/a Janssen Research & Development LLC, d/b/a Ortho-McNeil Pharmaceuticals, Inc.; and **BAYER HEALTHCARE PHARMACEUTICALS, INC.** f/k/a Bayer Pharmaceuticals Corporation; **BAYER CORPORATION**; **BAYER U.S. L.L.C.**; and **JOHN DOE DRUG COMPANY DEFENDANTS #1–10**, *Defendants.*	EASTERN DISTRICT OF PENNSYLVANIA PHILADELPHIA DIVISION CIVIL ACTION NO. 2:20-cv-04053 Civil Action *Filed Electronically* **COMPLAINT AND JURY DEMAND**

Plaintiffs CAROL WARE and TOM WARE, by and through Plaintiffs' undersigned counsel, brings this civil action against Defendants above-named for personal injuries and damages suffered by Plaintiffs CAROL WARE and TOM WARE, and allege as follows:

INTRODUCTION

1. This an action for damages related to Defendants' wrongful conduct in connection with the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of pentosan polysulfate sodium ("PPS") as Defendants' prescription drug Elmiron® (hereinafter "Elmiron").

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

3. Elmiron injured Plaintiff Carol Ware (hereinafter "Plaintiff") by causing harmful, but latent, retinal damage and maculopathy, which ultimately resulted in impaired vision.

4. Defendants knew or should have known that Elmiron, when taken as prescribed and intended, causes harmful retinal damage and maculopathy.

5. Numerous patient reports, scientific studies, and even alerts by governmental agencies have established that Elmiron causes retinal damage, including Pentosan Polysulfate Sodium Maculopathy (hereinafter "PPS Maculopathy" or "pigmentary maculopathy"), a signature condition caused by Elmiron toxicity.

6. Nevertheless, Defendants failed to warn, instruct, advise, educate, or otherwise inform Elmiron users, Elmiron prescribers, or United States governmental regulators about the risk of pigmentary maculopathy or the need for medical, ophthalmological monitoring. At all relevant times, the U.S. label for Elmiron made no mention of risk to patients' eyes or vision.

7. As a proximate result Defendants' wrongful actions and inactions, Plaintiff was injured and suffered damages from Plaintiff Carole Ware's use of Elmiron.

8. Plaintiffs therefore demand judgment against Defendants and request, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

(i) Plaintiffs

9. Plaintiffs, CAROL WARE and TOM WARE (together, "Plaintiffs"), at all times relevant hereto, are residents and citizens of the state of Kentucky. Plaintiffs have been married since 1981. Plaintiff Carole Ware ("Plaintiff") has suffered and continues to suffer from severe injuries as a direct result of Plaintiff's ingestion of the pharmaceutical product Elmiron.

(ii) Defendants

Janssen and Johnson & Johnson Defendants

10. Defendant Johnson & Johnson d/b/a Alza Corporation (hereinafter "Alza") d/b/a Janssen Ortho, LLC (hereinafter "Janssen Ortho") d/b/a Janssen Research & Development LLC (hereinafter "Janssen R&D") d/b/a Ortho-McNeil Pharmaceutical, LLC (hereinafter "Ortho Pharma"), is a corporation organized under New Jersey law with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

11. Upon information and belief, at all relevant times, Janssen Pharmaceuticals, Inc., Ortho Pharma, Janssen R&D, Alza, and Janssen Ortho have been wholly owned subsidiaries of Johnson & Johnson with their profits inuring to Johnson & Johnson's benefit.

12. Defendant Johnson & Johnson and its "family of companies" do business in Pennsylvania and other states by, among other things, designing, developing, testing,

manufacturing, labeling, packaging, distributing, marketing, selling and/or profiting from Elmiron in Pennsylvania and throughout the United States.

13. Defendant Janssen Pharmaceuticals, Inc., f/k/a Ortho-McNeil-Janssen Pharmaceutical, L.L.C., f/k/a Janssen Pharmaceutica Inc., (hereinafter "Janssen Pharma") is a corporation organized under Pennsylvania law with its principal place of business at 800 Ridgeview Drive, Horsham, PA 19044. Janssen Pharma is a subsidiary of Defendant Johnson & Johnson.

14. 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 Pennsylvania and throughout the United States.

15. Janssen Pharma has held the New Drug Application ("NDA") for Elmiron since approximately August 2008. Janssen Pharma is the current NDA holder for Elmiron.

16. Elmiron® is a Registered Trademark of non-party Teva Branded Pharmaceutical Products R&D, Inc., licensed by Teva to Janssen Pharma.

17. In September 1997, non-party Ivax LLC f/k/a Ivax Corp. (hereinafter "Ivax") licensed the rights to Elmiron in the United States and Canada to Alza, for $75 Million in up-front payments.

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

19. Defendant Alza held the NDA for Elmiron from approximately April 1998 until August 2002.

20. Janssen R&D held the NDA for Elmiron from approximately August 2002 until

August 2004.

21. Ortho Pharma held the NDA for Elmiron from approximately July 2004 until August 2008.

Bayer Defendants

22. Defendant Bayer Healthcare Pharmaceuticals, Inc. f/k/a Bayer Pharmaceuticals Corporation (hereinafter "Bayer Pharma") is a corporation organized under Delaware law with its principal place of business at 100 Bayer Boulevard, Whippany, New Jersey 07981. Bayer Pharma is the U.S.-based pharmaceuticals operation of Defendant Bayer Healthcare LLC (hereinafter "Bayer HC").

23. Bayer Pharmaceuticals Corporation (hereinafter "Bayer Pharmaceuticals Corp."), a U.S. subsidiary of Bayer AG, merged into Defendant Bayer Pharma on January 1, 2008. As the surviving company, Defendant Bayer Pharma assumed the assets and liabilities of Bayer Pharmaceuticals, including those assets and liabilities related to Elmiron.

24. Upon information and belief, in or around 2005, Bayer Pharmaceuticals Corp. contracted on a co-exclusive basis with defendant Johnson & Johnson to advertise, promote, market, sell, distribute, and report adverse events for, the drug Elmiron to urologists in the United States under a co-promotion agreement (hereinafter the "Co-Promotion Agreement").[1]

25. Under the terms of the Co-Promotion Agreement, Bayer Pharmaceuticals Corp. received the rights to co-promote Elmiron to urologists in the United States and receive full profit for prescription sales of Elmiron in the urology sector in the United States.

26. Upon information and belief, Bayer Pharma continues to receive full profit for

[1] *See Bayer Stockholders' Newsletter 2005, Interim Report as of Sept. 30, 2005 (2005)*, WWW.BAYER.COM, file:///C:/Users/millis/Downloads/ab-q3-2005-en%20(2).pdf (last visited Aug. 19, 2020), at 22.

prescription sales of Elmiron in the urology sector in the United States.

27. Upon information and belief, Bayer Pharmaceuticals Corp. and Bayer Pharma promoted and continue to promote Elmiron through its network of pharmaceutical sales representatives, and would have been in direct contact with prescribing physicians and have access to adverse reaction information from those health care providers.

28. At all times relevant and material hereto, Bayer 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 Pennsylvania and throughout the United States.

29. Defendant Bayer Corporation (hereinafter "Bayer Corp.") is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

30. Bayer Corp. transacts substantial business within Pennsylvania, including the manufacture, sale, distribution and marketing of Elmiron, and at all times relevant and material hereto, Bayer Corp. 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 Pennsylvania and throughout the United States.

31. Defendant Bayer US L.L.C. (hereinafter "Bayer US") is a Delaware limited liability company with principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

32. Bayer US transacts substantial business within Pennsylvania, including the manufacture, sale, distribution and marketing of Elmiron and at all times relevant and material hereto, Bayer US 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 Pennsylvania and throughout the United States.

Doe Defendants

33. On information and belief, John Doe Drug Company Defendants #1–10, whose specific identities are currently unknown to Plaintiffs, are the individuals, business entities, and corporations within the chain of commerce, that were involved in manufacturing, marketing, selling, and/or distributing Elmiron to Plaintiff and the general public, including, other United States consumers. The pseudonymous designations are being used to preserve claims against these parties who will be named more fully if and when their identities are uncovered.

All Defendants

34. All of the above Defendants (collectively, "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.

35. At all times alleged herein, Defendants shall include any and all named or un-named parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

36. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessor in interest, aider and abettor, co-conspirator, and joint venturer of each of the remaining Defendants herein.

37. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessor in interest, aider and abettor, co-conspirator, and joint venturer of each of the

remaining Defendants thereby operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

38. At all times relevant and material hereto, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and or introducing into interstate commerce throughout the United States, and in the state of Pennsylvania, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the pharmaceutical Elmiron.

JURISDICTION AND VENUE

39. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than Kentucky, where the Plaintiffs are citizens.

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

41. Venue is proper in this Court pursuant to 28 U.S.C. § 139l, because many of the Defendants reside in this District, Defendant Janssen Pharma is a Pennsylvania Corporation, all Defendants transact and conduct business in this District, and a substantial part of the acts and omissions giving rise to this Complaint occurred in this District.

GENERAL ALLEGATIONS

42. The Plaintiffs bring this case against Defendants for damages associated with Plaintiff's use of the pharmaceutical drug Elmiron, which was designed, manufactured, marketed, sold and/or distributed by Defendants. Specifically, Plaintiff Carol Ware has suffered

various injuries, serious physical pain and suffering, medical, and hospital expenses as a direct result of Plaintiff's use of Elmiron.

43. At all relevant times, all Defendants were in the business of and, indeed, did design, research, manufacture, test, advertise, promote, market, sell and/or distribute Elmiron for the treatment of the bladder pain and/or discomfort associated with interstitial cystitis ("IC").

44. Defendants' fraudulent and illegal conduct with respect to Elmiron caused thousands of individuals, including Plaintiff Carol Ware, to develop severe vision and retinal injuries.

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

45. 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.

46. 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).

47. 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).

48. 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.

49. 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.

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

51. 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]

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

53. 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 should change drug labeling in order "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).

54. 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

[2] *See In re Fosamax (Alendronate Sodium) Products Liability Litigation*, 852 F.3d 268, 283 (3d Cir. 2017), vacated and remanded sub nom *Merck Sharp & Dohme Corp. v. Albrecht*, __ U.S.___, 139 S.Ct. 1668, 203 L.Ed.2d 822 (2019).

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).

55. 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).

56. 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).

57. 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]

[3] *Guidance Document: Warnings and, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products– Content and Format*, October 2011, WWW.FDA.GOV, https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf (last visited, August 18, 2020).

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

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

B. History of Elmiron Approval

60. In September of 1996, the FDA approved Elmiron for treatment of interstitial cystitis ("IC"), also known as "bladder pain syndrome" or "painful bladder syndrome."

61. 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.

62. 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 severe pain, and can include increased frequency and urgency of urination.

63. Under the IC treatment guidelines established by the American Urological Association (AUA), there are six lines of treatment for IC. 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.

64. Elmiron is not a first-line treatment for IC. And it is not the only treatment for IC that is available to physicians and patients. Rather, Elmiron is one of ten suggested second-line treatments, including three other oral medications: amitriptyline, cimetidine, and hydroxyzine.

65. The guidelines further include numerous third-, fourth-, fifth-, and sixth-line treatments. When first-line and second-line treatments fail to provide relief, the third-, fourth-, fifth-, and sixth-line treatments involve more invasive procedures such as the use of a catheter to deliver medicated solutions directly to the bladder; Botox injections to the muscle wall of the bladder; implantation of neurostimulation devices to control muscle contractions in the bladder; or, in rare cases, surgery to remove ulcers from the bladder or augment the bladder wall with an intestinal patch.

66. Defendants market Elmiron as "The Only Oral Medication FDA Approved to Treat the Bladder Pain or Discomfort of Interstitial Cystitis (IC)."[4] Although Elmiron is the only oral medication approved by the FDA *specifically* for the purpose of treating IC, that statement is misleading in that Elmiron is not the only oral medication approved by the FDA that can be used to treat IC, and it is not the only IC treatment option.

67. Elmiron is in fact one of *five* oral medications approved by the AUA Guidelines for use in treating IC, all of which are FDA-approved oral medications. Furthermore, the AUA

[4] Janssen Pharmaceuticals, Inc., *About ELMIRON®*, WWW.ORHTOELMIRON.COM, https://www.orthoelmiron.com/patient/about-elmiron (last visited Aug. 19, 2020).

Guidelines list *six lines* of treatment for IC, each of which contains multiple treatment options within a line.

68. Indeed, in a March 26, 2012 Citizen Petition to the FDA, Defendant Janssen Pharma did not make the same misrepresentation it made to the public, but rather qualified that "Although other medications may treat discrete symptoms [of IC], ELMIRON is the only orally-administered medication that is specifically approved for treatment of IC patients." As discussed below, Defendant Janssen Pharma's March 26, 2012 Citizen Petition also contains admissions that Defendants were aware of Elmiron's low efficacy and poor bioavailability. A copy of Defendant Janssen Pharma's March 26, 2012 Citizen Petition is attached hereto as Exhibit A.

69. 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.

70. In or around 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.

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

72. 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.

73. 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.

74. 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.

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

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

77. 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.

78. 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 its 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.

79. 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.

80. 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.

81. 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.

82. 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 were clearly positive and otherwise acceptable it, along with study E-002, would provide sufficient evidence for approval.

83. 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).

84. 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."

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

86. 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.

87. 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 Corporation for $75 million up front and continued to receive milestone and royalty payments thereafter.

C. The Dangers of Elmiron

(i) The Poor Bioavailability and Low Efficacy of Elmiron

88. Although Defendants admit that the mechanism of action for Elmiron is unknown, Elmiron is thought to be a "chemical bandaid" that coats the epithelial cells of the bladder to provide pain relief. The drug has poor oral bioavailability and absorption, requiring users to take long-term high doses of the drug, resulting in accumulation and ultimate toxicity over time.

89. Typical users take 100mg doses, 3 times per day, because only about 6% of the drug is absorbed to the epithelial cells of the bladder; the majority of the drug is excreted. However, the drug is also absorbed into retinal epithelial cells, which can result in retinal toxicity.

90. Users must ingest Elmiron for at least 3 to 6 months—and, often longer—to achieve any benefit. One cohort reported that pain relief occurred in only 40% to 60% of patients. Populations of patients receiving extended treatment (>2 years) showed no further improvement

or worsening of symptoms, yet users often continue the drug for years.[5] In other trials, the improvement of certain IC symptoms with Elmiron was significant compared to Placebo (28% of treated subjects versus 13% of placebo controls), but the overall degree of improvement was not dramatic from a clinical standpoint.

91. In its March 2012 Citizen's Petition to the FDA requesting a bioequivalence study for any new generics coming to market—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." Exhibit A (Janssen Citizen Petition), at 8.

92. Janssen's Citizen Petition elaborates,

> As discussed above, 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.

Exhibit A (Janssen Citizen Petition), at 8–11 (internal citations omitted).

93. 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.

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[5] Philip M. Hanno, *Analysis of Long-Term Elmiron Therapy for Interstitial Cystitis*, Vol. 49, Issue 5, Supplement 1, UROLOGY 93-99 (1997).

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

95. 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."[6]

(ii) Defendants' Failures to Test Elmiron and to Update Warnings

96. Defendants admit, "the mechanism of action of PPS and the pathophysiology of IC is unknown," (Ex. A at 8) and Defendants have failed to conduct tests to determine the mechanism of action of the drug.

97. 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.

[6] 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) *available at* https://pubmed.ncbi.nlm.nih.gov/25245489/.

98. 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 effects.

99. Defendants acknowledged that their Phase III testing of Elmiron was "subjective" and that "an objective measure" may be more appropriate. Defendant 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.

Ex. A (Janssen Citizen Petition), at 11.

100. 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.

Ex. A (Janssen Citizen Petition), at 7–8 (internal citations omitted).

101. 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 evaluating potential risks associated with the drug.

102. Furthermore, despite the fact that studies emerged providing evidence of the dangers of PPS, Defendants failed adequately investigate the threat that PPS poses to patients' eyes and vision or warn patients of the risk that they would suffer retinal injury and vision impairment.

103. For example, a physician's usage study of PPS conducted in the late 1980s and early 1990s noted adverse events affecting vision, including optic neuritis and retinal hemorrhage. Defendants relied upon this very study when seeking FDA approval for Elmiron and therefore had direct notice of the potential adverse effects.[7]

104. Reported adverse effects on vision included:

> ***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.
>
> ***"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.

Id.

105. As early as 1991, available medical research also identified that PPS inhibits regrowth and proliferation of retinal pigment epithelial (RPE) cells,[8] and could thereby impair an important physiological pathway for retinal health.

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[7] U.S. Food & Drug Administration, *A Statistical and Medical Review of an Amendment to the New Drug Application for Elmiron ® (Pentosan Polysulfate), NDA #20193* (January 1996), Appendix F, at 55, attached hereto as Exhibit B.

[8] 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).

106. 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 regrown and proliferation of retinal pigment epithelial (RPE) cells and could thereby impair an important physiological pathway for retinal health.

107. Indeed, as set forth above, Defendants were on notice from the FDA of the possible effect on other epithelial cells, corroborating the risk Elmiron posed specifically to the RPE cells of the eye.

108. 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.

109. The FDA had serious concerns about Elmiron and rejected several applications for its approval, finding the conduct of some the clinical trials "worrisome."

110. Nevertheless, the FDA ultimately approved Elmiron in September of 1996. After that, new information continued to reveal the serious risk of eye and vision injuries related to Elmiron use.

111. Almost immediately after the FDA approved Elmiron, patients and doctors began reporting serious complications relating to eye and vision problems in patients taking Elmiron.[9]

[9] According to the FDA Adverse Events Reporting System (FAERS) Public Dashboard, at least eight patients taking Elmiron reported serious adverse effects to their vision in the 1997 calendar year. *See FDA Adverse Events Reporting System (FAERS) Public Dashboard*, U.S. FOOD & DRUG ADMINISTRATION, https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/8eef7d83-7945-4091-b349-e5c41ed49f99/state/analysis (last visited Aug. 18, 2020).

112. From January 1997 through March 2020, at least 164 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.[10]

113. 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.[11]

114. 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 PPS [Elmiron]. We recently reported our findings of retinal pigmentary changes in six patients undergoing long-term therapy with PPS [Elmiron]. These patients primarily described difficulty reading and/or trouble adjusting to dim lighting. Each patient had received a standard dosage of PPS, 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.[12]

115. The study, "Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium [Elmiron]," focused on six women with IC who presented to the

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[10] To date, at least 123 patients have reported "serious" adverse effects to their vision.

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

[12] 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).

Emory Eye Center between May 2015 and October 2017 with pigmentary maculopathy.[13] 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.

116. 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).

117. 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.

118. What they had in common was the use of Elmiron.

119. Examinations of their eyes showed clear changes to the retinal pigment epithelium: "Nearly all eyes (10 eyes of 5 patients) showed subtle parafoveal pigmented deposits at the level of the retinal pigment epithelium (RPE)."[14]

120. 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.[15]

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

[14] *Id.* at 1798.

[15] *Id.*

121. All eyes of two patients showed RPE atrophy that was noted to "increase in area and encroach on the central fovea over time."[16] Retinal imaging also found clear diseased regions, atrophy, or both.[17]

122. 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 with IC. She had the most severe damage in the study with deep scotomas of both eyes.[18]

123. The authors expressed concern that "the region of affected tissue may expand centrifugally over time."[19]

124. 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."[20]

125. They also encouraged "drug cessation in affected patients," and "recommend[ed] that any patient with suggestive visual symptoms undergo a comprehensive ophthalmic examination."[21]

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[16] *Id.*

[17] *Id.*

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

[19] *Id.* at 1800.

[20] *Id.* at 1801.

[21] 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).

126. IC experts Robert Moldwin and Curtis Nickel responded to the Emory findings with concern: "It is quite unlikely that urologists treating patients with [IC] ever would have made this association."[22]

127. 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 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."[23]

128. 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.[24]

129. The patients in that study 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.

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[22] 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).

[23] Tyler Greenlee, Grant Hom, Thais Conti, Amy S. Babiuch, and Rishi Singh, Letter to the Editor Re: Pearch et al.: *Pigmentary maculopathy associated with chronic exposure to pentosan Polysulfate sodium* (Ophthalmology. 2018; 125:1793-1802) (published online April 24, 2019).

[24] 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), *available at* https://www.auajournals.org/doi/pdf/10.1097/01.JU.0000556315.46806.ca.

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

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

132. The Emory team most recently published a July 2019 study in the Review of Ophthalmology.[25]

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

134. 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 to Elmiron in the US. The team also recognized a study finding that Elmiron-exposed patients had a significantly increased risk of being diagnosed with a new macular disease after seven years.

135. In September 2019, the Emory team published further research in the Journal of American Medical Association Ophthalmology ("JAMA Ophthalmology"), concluding that PPS

[25] 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, *available at* https://www.reviewofophthalmology.co m/article/clinical-pearls-for-a-new-condition.

maculopathy, "is a vision-threatening condition that can manifest in the setting of long-term exposure to the drug."[26]

136. In November of 2019, a team from Emory and the University of Pennsylvania published an epidemiological study in the British Journal of Ophthalmology concluding that "PPS [Elmiron] users had significantly increased odds of having atypical maculopathy . . . ."[27]

137. 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.[28] 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."[29]

138. Another team of researchers found a 20% prevalence of a unique PPS-associated maculopathy among a cohort of patients being treated at the University of California, Los Angeles.[30] 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."

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[26] Adam M. Hanif *et al. Phenotypic Spectrum of Pentosan Polysulfate Sodium-Associated Maculopathy: A multicenter Study,* 137 JAMA OPHTHALMOLOGY 1275, 1282 (Sep. 5, 2019), *available at* https://jamanetwork.com/journals/jamaophthalmology/article-abstract/2749093.

[27] 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), *available at* https://jamanetwork.com/journals/jamaophthalmology/article-abstract/2749093.

[28] 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), *available at* http://www.sciencedirect.com/science/article/pii/S2451993620300086?via%3Dihub.

[29] *Id.*

[30] Derrick Wang *et al., Pentosan-Associated Maculopathy: Prevalence, Screening Guidelines, and Spectrum of Findings Based on Prospective Multimodal Analysis,* CANADIAN

139. 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.[31]

140. 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.[32]

141. On October 1, 2019, two physicians from Harvard Medical School published a case study indicating that the damage caused by Elmiron continues to progress long after cessation of the drug.[33] 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.

JOURNAL OF OPHTHALMOLOGY (in press, published online January 2020), *available at* https://www.sciencedirect.com/science/article/pii/S0008418219312724.

[31] *Product Monograph: Elmiron*, HEALTH CANADA, https://pdf.hres.ca/dpd_pm/00053268.PDF (last visited Aug. 19, 2020).

[32] *Health Product Advisory*, HEALTH CANADA, https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch/health-product-infowatch-october-2019.html#elmiron (last visited Aug. 19, 2020).

[33] 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), *available at* https://www.healio.com/ophthalmology/journals/osli/2019-10-50-10/%7B324bde2e-2389-4815-bf5e-fe3b2eb18062%7D/progressive-maculopathy-after-discontinuation-of-pentosan-polysulfate-sodium.

142. 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 . . . . [T]his case emphasizes the need for a screening regimen that balances the demands on patients and physicians with the importance of prompt identification of early toxicity."[34]

143. 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. And since at least September 2018, the IC Network Support Forum has published numerous posts by patients describing retinal injuries caused by Elmiron use.[35]

144. All of this information was known by, and available to, Defendants at all relevant times.

145. The European Medicines Agency, a decentralized agency of the EU responsible for scientific evaluations, supervision, and safety monitoring of medicines in the EU, is specifically warning patients about Elmiron and is advising, "[a]ll patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly those with longterm use of PPS**.** In such situations, treatment cessation should be considered."[36]

146. Despite numerous signs of the potential for severe retinal side effects; multiple studies conducted at top research institutes; research being published in major peer-reviewed

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[34] *Id.* at 658.

[35] *Interstitial Cystitis Network Patient Support Forum*, INTERSTITIAL CYSTITIS NETWORK, https://forum.ic-network.com/ (last visited Aug. 19, 2020).

[36] *Elmiron Product Characteristics,* EUROPEAN MEDICINES AGENCY, https://www.ema.europa.eu/en/documents/product-information/elmiron-epar-product-information_en.pdf (last visited Aug. 19, 2020), at 3.

journals; and public warnings from a prominent EU health agency, Defendants failed to reasonably investigate the issue and warn patients and healthcare providers at all relevant times.

147. At all relevant times, Defendants also failed to alert patients to the need for ophthalmological monitoring while taking Elmiron or whether risks increase with higher doses or longer durations.

148. Other medications affecting vision have included instructions and warnings for users and prescribers. For example, the anti-malaria drug Plaquenil (hydroxychloroquine) is likewise associated with retinal toxicity. In the labeling for Plaquenil, manufacturer Concordia Pharmaceuticals, Inc., provides the following warning:

> Irreversible retinal damage has been observed in some patients who had received hydroxychloroquine sulfate. Significant risk factors for retinal damage include daily doses of hydroxychloroquine sulfate greater than 6.5 mg/kg (5 mg/kg base) of actual body weight, durations of use greater than five years, subnormal glomerular filtration, use of some concomitant drug products such as tamoxifen citrate and concurrent macular disease.
>
> A baseline ocular examination is recommended within the first year of starting PLAQUENIL. The baseline exam should include: best corrected distance visual acuity (BCVA), an automated threshold visual field (VF) of the central 10 degrees (with retesting if an abnormality is noted), and spectral domain ocular coherence tomography (SD-OCT).
>
> For individuals with significant risk factors (daily dose of hydroxychloroquine sulfate greater than 5.0 mg/kg base of actual body weight, subnormal glomerular filtration, use of tamoxifen citrate or concurrent macular disease) monitoring should include annual examinations which include BCVA, VF and SD-OCT. For individuals without significant risk factors, annual exams can usually be deferred until five years of treatment.
>
> In individuals of Asian descent, retinal toxicity may first be noticed outside the macula. In patients of Asian descent, it is recommended that visual field testing be performed in the central 24 degrees instead of the central 10 degrees.

> It is recommended that hydroxychloroquine be discontinued if ocular toxicity is suspected and the patient should be closely observed given that retinal changes (and visual disturbances) may progress even after cessation of therapy.[37]

149. In stark contrast, until June 16, 2020, The Elmiron Label read:[38]

WARNINGS None.

150. At all relevant times, Defendants have failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that Elmiron causes, is linked to, and is associated with vision threatening retinal changes, including vision loss.

151. At all relevant times, Defendants have failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that patients taking Elmiron should undergo regular ophthalmological testing to detect pigmentary changes and discontinue use if such changes occur.

152. Defendants failed to mention potentially permanent, vision-threatening retinal changes, or the need for ophthalmological monitoring in any of the patient materials—including the Patient Education Flyer and Patient Brochure—the sources of information most likely viewed by physician and patients.

153. At all relevant times, the labeling for Elmiron listed serious side effects that have been reported with Elmiron, but did not list vision threatening retinal changes.

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[37] *Plaquenil Patient Package Insert (as of Jan. 2017)*, U.S. FOOD & DRUG ADMINISTRATION, https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/009768s037s045s047lbl.pdf (last visited Aug. 19, 2020).

[38] *Elmiron Patient Package Insert (as of December 2008)*, U.S. FOOD & DRUG ADMINISTRATION, https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020193s009lbl.pdf (last visited Aug. 19, 2020).

154. At all relevant times, the labeling for Elmiron failed to provide adequate warnings and instructions, failed to caution that patients should be closely monitored, failed to adequately inform patients and physicians that vision threatening retinal changes have been associated with Elmiron use, and failed to contain any proper dosing considerations.

155. At all relevant times, Defendant Janssen Pharma maintained a website promoting Elmiron, www.orthoelmiron.com, which included, among other topics, "About Elmiron," "How Elmiron Works," "Important Safety Information," and "Patient Information." Nowhere on the website did Defendants mention the potential for vision-threatening retinal changes associated with Elmiron use.

156. On June 24, 2019, Defendant Janssen Pharma submitted its Supplemental New Drug application (sNDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elmiron (PPS) 100 mg capsules. This Prior Approval labeling supplement to its application provided revisions to the package insert Warnings section and Post-Marketing section, as well as an update to the Patient Labeling finally addressing the risk of vision threatening retinal changes associated with Elmiron use.

157. Defendants did not provide warnings anywhere on its product label or packing referencing the risk of vision threatening retinal changes associated with Elmiron use until at least June 16, 2020.

158. As of no later than June 24, 2019, when Defendants submitted their sNDA to include warnings referencing the risk of vision threatening retinal changes associated with Elmiron use, Defendants knew of the risk of injury associated with their drug and failed to warn consumers and physicians, including Plaintiff, Plaintiff's physicians, and the public in general of same.

159. The FDA has established reporting categories for post-approval changes to a drug's label. The Changes Being Effected supplement ("CBE") (21 CFR § 314.70(c)(3)) allows for changes in the labeling of a drug product to reflect newly acquired information without prior approval from the FDA.

160. The CBE process allows for drug manufacturers to change a drug label more quickly than the sNDA process based on newly acquired information about the drug.

161. Defendants should have changed the Elmiron label to include warnings and instructions addressing the risk of injury associated with the drug as soon as they had notice of adverse reports relating to same.

162. 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 of human life, and of the safety of persons exposed to its dangerous drug.

163. 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, and/or a grossly careless disregard for the public's safety and welfare.

(iii) Defendants Had a Duty to Protect U.S. Consumers, But Did Not

164. At all relevant times, Defendants had a duty to craft an adequate label with respect to Elmiron.

165. At all relevant times, Defendants had a duty to ensure that the warnings in the Elmiron label were adequate, at all times, for as long as the drug remained available for sale in the United States.

166. At all relevant times, Defendants had a responsibility to conduct post-marketing surveillance and to continue to study the safety and efficacy of Elmiron, after the Elmiron NDA was approved, for as long as the drug remained available for sale in the United States.

167. At all relevant times, Defendants had a duty to revise the Elmiron label to include a warning regarding the risk of serious vision-related injuries as soon as there was reasonable evidence of a causal association between vision-related injuries and Elmiron use.

168. Upon information and belief, despite reasonable evidence of causal association, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious vision-related injuries as a result of taking Elmiron.

169. Upon information and belief, despite understanding Elmiron could cause potentially permanent vision-related injuries, Defendants knowingly withheld and/or misrepresented information required to be submitted under FDA NDA regulations, concerning the safety and efficacy of Elmiron, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Elmiron users suffering vision-related injuries as a result of their Elmiron use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious vision-related injuries as a result of taking Elmiron.

170. Accordingly, Defendants are liable to Plaintiffs for punitive damages.

(iv) Defendants' Misconduct Endangered U.S. Consumers

171. Upon information and belief, had Defendants exercised reasonable care in testing and studying Elmiron, they would have discovered prior to seeking FDA approval, that long-term Elmiron use can cause serious vision and retinal injuries, including, but not limited to, pigmentary maculopathy.

172. Upon information and belief, despite understanding patients taking Elmiron would likely remain on the medication for long periods of time, Defendants' failed to test and study the long-term safety and efficacy of the drug, prior to seeking FDA approval.

173. Upon information and belief, despite post-approval adverse event reports and other clinical evidence, Defendants failed to continue to test and study the safety and efficacy of Elmiron, particularly in patients who used the drug for long periods of time.

174. Upon information and belief, from the date all Defendants received FDA-approval to market Elmiron in the United States, Defendants each made, distributed, marketed, and sold Elmiron without adequate warning to Plaintiff's prescribing physicians or to Plaintiffs that Elmiron was associated with and/or could cause serious vision and retina damage in patients who used it, and that all Defendants had not adequately conducted complete and proper testing and studies of Elmiron with regard to retina damage.

175. Upon information and belief, Elmiron concealed and/or failed to completely disclose their knowledge that Elmiron was associated with and/or could cause retina damage as well as their knowledge that they had failed to fully test or study said risk.

176. Upon information and belief, all Defendants ignored the association between the use of Elmiron and the risk of developing permanent and disfiguring visual complications, including, but not limited to, pigmentary maculopathy and retina damage.

177. Upon information and belief, all Defendants failed to warn Plaintiff and Plaintiff's healthcare providers regarding true risk of retina damage of Elmiron, but similar efficacy compared to less potent products.

178. Upon information and belief, all Defendants failed to provide adequate instructions to U.S. healthcare professionals and patients regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

179. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely monitor and identify signs of potentially serious visual complications associated with long-term Elmiron use.

180. Upon information and belief, all Defendants failed to warn and/or to provide adequate instructions to U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely stop taking Elmiron in the event that potentially serious visual complications developed while using Elmiron.

181. Upon information and belief, all Defendants failed to warn U.S. healthcare professionals and patients, including Plaintiff's prescribing physicians and Plaintiff, of the true risk of retina damage to patients taking Elmiron as compared to other similarly efficacious pharmaceutical products.

182. All of Defendants' failures to provide adequate instructions and/or disclose information—which Defendants each possessed regarding the failure to adequately test and study Elmiron for the risk of serious visual complications—rendered the Elmiron Package Insert, Medication Guide, and other educational and/or promotional materials inadequate.

183. Despite AERs from healthcare professionals and consumers around the world, from approximately 1997 until approximately September 2019, Elmiron never warned—in any country or market—of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy.

184. In the United States, Defendants have failed to warn about the risk of serious, potentially permanent visual complications, including, but not limited to, pigmentary maculopathy, until approximately June 16, 2020.

(v) June 16, 2020 Label Change

185. 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.

186. Defendants' sNDA was not approved until June 16, 2020.

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

> **WARNINGS**
> **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. 4 Reference ID: 4625741 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.

188. 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).

189. 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.

190. 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.

191. The delay also afforded Defendants additional time to capitalize on Elmiron's profitability, and afforded Defendants additional time—pre-warning change—to place profits over patient safety and sell numerous more Elmiron dosage units.

192. 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.

PLAINTIFF SPECIFIC FACTS

193. Plaintiff Carol Ware was prescribed Elmiron to treat interstitial cystitis, and consistently ingested Elmiron for approximately 17 years.

194. As a result of ingesting Elmiron, Ms. Ware began developing severe vision problems.

195. Leading up to her diagnosis of macular degeneration, Plaintiff had begun developing severe vision problems, which began to cause Plaintiff difficulty doing many things, including, but not limited to, difficulty reading print, newspapers and books; difficulty writing; difficulty recognizing people; difficulty seeing steps or curbs; difficulty driving on bright sunny days; difficulty driving at night; difficulty doing normal activities, such as, playing card games, and playing sports she previously enjoyed, such as tennis; difficulty watching television; and difficulty cooking; among many other activities.

196. Plaintiff's ophthalmologist diagnosed Plaintiff, *inter alia*, with "Elmiron toxicity with typical RPE/Drusen changes" and macular degeneration.

197. Plaintiff Tom Ware is Plaintiff Carol Ware's husband, and has been married to Plaintiff Carol Ware at all times material, including, since 1981.

198. Due to the severity of Plaintiff Carol Ware's Elmiron-related injuries, Plaintiff Tom Ware has suffered damages as well, including, the loss of consortium, services, and society.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

199. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold information from the Plaintiffs, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

200. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold safety-related warnings from the Plaintiff, her family members, and the general public concerning the known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

201. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold instructions from the Plaintiff, her family members, and the general public concerning how to identify, mitigate, and/or treat known hazards associated with the use of, and exposure to, Elmiron, particularly over extended periods of time.

202. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately not study the long-term safety and efficacy of Elmiron, particularly in chronic long-term users of Elmiron.

203. Defendants failed to disclose a known defect and, instead, affirmatively misrepresented that Elmiron was safe for its intended use. Defendants disseminated labeling, marketing, promotion and/or sales information to Plaintiff, her healthcare providers, and the general public regarding the safety of Elmiron knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with long-term Elmiron use. They did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Elmiron's safety.

204. Further, Defendants actively concealed the true risks associated with the use of Elmiron, particularly as they relate to the risk of serious vision-related injuries, by affirmatively representing in numerous communications, which were disseminated to Plaintiff, her healthcare providers, and which included, without limitation, the Package Insert and the Medication Guide, that there were no warnings required to safely prescribe and take Elmiron and no vision-related adverse side effects associated with use of Elmiron.

205. Due to the absence of any warning by the Defendants as to the significant health and safety risks posed by Elmiron, Plaintiffs were unaware that Elmiron could cause serious vision-related injuries, as this danger was not known to Plaintiff, Plaintiffs healthcare providers, or the general public.

206. Due to the absence of any instructions for how to identify and/or monitor Elmiron patients for potential vision-related complications, Plaintiffs were unaware that Elmiron could cause serious, vision-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

207. Given Defendants' conduct and deliberate actions designed to deceive Plaintiff, Plaintiff's healthcare providers, and the general public, with respect to the safety and efficacy of Elmiron, Defendants are estopped from relying on any statute of limitations defenses.

COUNT I
STRICT LIABILITY – FAILURE TO WARN

208. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

209. 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 Elmiron into the stream of commerce in a defective and

unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

210. Defendants, as manufacturers, distributers, and marketers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that warnings and other clinically relevant information and data which they distributed regarding the risks associated with the use of Elmiron were inadequate.

211. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

212. Defendants had a duty to provide adequate warnings and instructions for Elmiron, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately understand, test, and monitor their product.

213. Defendants had a continuing duty to provide consumers, including Plaintiff, and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Elmiron, as it became or could have become available to Defendants.

214. Defendants marketed, promoted, distributed and sold an unreasonably dangerous and defective prescription drug, Elmiron, to health care providers empowered to prescribe and dispense Elmiron, to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omission and affirmative misstatements, Defendants misled the medical community about the risk and benefit balance of Elmiron, which resulted in injury to Plaintiff.

215. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, public warnings from a prominent EU health agency, 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.

216. Despite the fact that Defendants knew or should have known that Elmiron caused unreasonable and dangerous side effects, they continued to promote and market Elmiron without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

217. Defendants knew or should have known that consumers, Plaintiff, specifically, would foreseeably and needlessly suffer injury as a result of Defendants' failures.

218. The Elmiron supplied to Plaintiff by Defendants was defective, unreasonably dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendants also acquired additional knowledge and information confirming the defective and unreasonably dangerous nature of Elmiron. Despite this knowledge and information, Defendants failed and neglected to issue adequate warnings that Elmiron causes serious and potentially irreversible vision issues and retinal harm and/or instructions concerning the need for ophthalmological monitoring and potential discontinuation of use of Elmiron.

219. Defendants' failure to provide adequate warnings or instructions rendered Elmiron unreasonably dangerous in that it failed to perform as safely as an ordinary patient, prescriber, and/or other consumer would expect when used as intended and/or in a manner reasonably foreseeable by the Defendants, and in that the risk of danger outweighs the benefits.

220. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiffs intermediary physicians, in the following ways.

221. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiffs physicians to the dangerous risks of Elmiron including, among other things, potentially irreversible vision issues and retinal harm.

222. Defendants failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of, among other things, potentially irreversible vision issues and retinal harm.

223. Defendants continued to aggressively promote and sell Elmiron, even after they knew or should have known of the unreasonable risks of potentially irreversible vision issues and retinal harm from the drug.

224. Defendants had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Elmiron, and/or that there existed safer and more or equally effective alternative drug products.

225. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with exposure to Elmiron, and/or that there existed safer and more or equally effective alternative drug products, Defendants breached their duty of reasonable care and safety.

226. By failing to adequately test and research harms associated with Elmiron, and by failing to provide appropriate warnings and instructions 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 issues and retinal harm might be associated with use of Elmiron. Nor were the medical community, patients, patients' families, or regulators appropriately informed that serious and potentially irreversible vision issues and retinal harm might be a side effect of Elmiron and should or could be reported as an adverse event.

227. The Elmiron products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent vision and retinal injuries from ingesting Elmiron, Defendants failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote Elmiron.

228. Elmiron is defective and unreasonably dangerous to Plaintiff and other consumers regardless of whether Defendants had exercised all possible care in its preparation and sale.

229. The foreseeable risk of serious and potentially irreversible vision issues and retinal harm caused by Elmiron could have been reduced or avoided by Plaintiff, prescribers, and/or other consumers had Defendants provided reasonable instructions or warnings of these foreseeable risks of harm.

230. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of Plaintiff and the general public.

231. 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 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 II
STRICT LIABILITY – DESIGN DEFECT

232. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

233. 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 Elmiron into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendants.

234. Defendants, as manufacturers, designers, distributers, marketers, and promoters of pharmaceutical drugs, had a duty to design a product free from a defective condition that was unreasonably dangerous to the Plaintiff.

235. Defendants breached this duty by designing Elmiron in such a way that posed an unreasonable risk of permanent vision and retinal injuries and by placing and keeping Elmiron on the market despite Elmiron being in a defective condition.

236. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended, and foreseeable use. Defendants knew or should have known that the Elmiron they developed, manufactured, labeled, marketed, sold, and/or promoted was defectively designed in that it posed a serious risk of severe and permanent vision and retinal injuries.

237. Defendants had a continuing duty to use reasonable care to design a product that is not unreasonably dangerous to users and to adequately understand, test, and monitor their product.

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

239. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Elmiron, 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.

240. 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.

241. The Elmiron ingested by Plaintiff was expected to, and did, reach Plaintiff without substantial change in the condition in which it is sold.

242. The Elmiron ingested by Plaintiff was in a condition not contemplated by the Plaintiff in that it was unreasonably dangerous, posing a serious risk of permanent vision and retinal injuries.

243. 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.

244. 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.

245. 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.

246. 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.

247. 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.

248. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, public warnings from a prominent EU health agency, 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.

249. 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.

250. Defendants knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Elmiron's defective design.

251. 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.

252. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of Plaintiff and the public.

253. As a direct and proximate result of Defendants' conduct, including the of adequate 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
NEGLIGENT FAILURE TO WARN

254. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

255. 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 warning and post-sale warning 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.

256. Defendants' duty of care was that a reasonably careful designer, manufacturer, seller, importer, distributor and/or supplier would use under like circumstances.

257. Defendants had a duty to warn Plaintiff, Plaintiff's physicians, and consumers of Elmiron' s dangers and serious side effects, including serious and potentially irreversible vision issues and retinal harm, as it was reasonably foreseeable to Defendants that Elmiron could cause such injuries.

258. At all times material herein, Defendants failed to exercise reasonable care and knew, or in the exercise of reasonable care should have known, that Elmiron had inadequate instructions and/or warnings.

259. 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. Failing to accompany their product with proper and adequate warnings, labeling, or instructions concerning the potentially dangerous, defective, unsafe, and deleterious propensity of Elmiron and of the risks associated with its use, including the severity and potentially irreversible nature of such adverse effects;

b. Disseminating information to Plaintiff and Plaintiff 's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

c. Failing to provide warnings or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks;

d. Failing to adequately test and/or warn about the use of Elmiron, including, without limitations, the possible adverse side effects and health risks caused by the use of Elmiron;

e. Failure to adequately warn of the risks that Elmiron could interfere with the normal health, healing, proliferation, migration, and/or growth of cells, including epithelial cells and RPE cells;

f. Failure to adequately warn of the risk of serious and potentially irreversible vision issues and retinal harm;

g. Failure to adequately warn of the risk of PPS-toxicity and/or PPS-maculopathy;

h. Failure to adequately warn and advise of adverse reactions involving vision, eyes, retinas, and maculopathy;

i. Failure to instruct patients, prescribers, and consumers of the need for ophthalmological monitoring when taking Elmiron for pigmentary changes;

j. Failure to instruct patients, prescribers, and consumers of the need to discontinue Elmiron in the event of pigmentary changes;

k. Failing to provide instructions on ways to safely use Elmiron to avoid injury;

l. Failing to explain the mechanism, mode, and types of adverse events associated with Elmiron;

m. Failing to provide adequate training or information to medical care providers for appropriate use of Elmiron and patients taking Elmiron; and

n. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

260. Elmiron was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert patients and prescribing physicians of the dangerous risks associated with Elmiron, including but not limited to the risk of serious and

potentially irreversible vision and retinal harm effects despite the Defendant's knowledge of the risk of these injuries over other IC therapies available.

261. Elmiron was defective due to inadequate post-marketing warnings and instruction because Defendants knew or should have known of the risk and danger of serious bodily harm rom the use of Elmiron but failed to provide an adequate warning to patients and prescribing physicians of the product, including Plaintiff and Plaintiffs prescribing physician, knowing the product could cause serious injury.

262. Plaintiff was prescribed and used Elmiron for its intended purpose.

263. Plaintiff could not have known about the dangers and hazards presented by Elmiron.

264. The warnings given by Defendant and/or Defendants were not accurate, clear, or complete and/or were ambiguous.

265. The warnings, or lack thereof, that were given by Defendants failed to properly warn prescribing physicians, including Plaintiff's prescribing physician, of the risk of serious and potentially irreversible vision and retinal harm, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk.

266. The warnings that were given by the Defendants failed to properly warn Plaintiff and prescribing physicians of the prevalence of vision and retinal injuries.

267. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendants. Defendants had a continuing duty to warn Plaintiff and prescribing physicians of the dangers associated with Elmiron. Had Plaintiff

received adequate warnings regarding the risks of Elmiron, Plaintiff would not have used Elmiron.

268. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Elmiron was a proximate cause of Plaintiff's injuries and damages.

269. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

270. 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 IV
NEGLIGENT DESIGN

271. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

272. 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 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.

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 manufactured, designed, compounded, tested, inspected, packaged, 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 negligently and carelessly:

a. Failing to use due care in developing, testing, designing, and manufacturing Elmiron so as to avoid the aforementioned risks to individuals when Elmiron was being used for treatment;

b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Elmiron; and

c. Designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff.

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

276. Defendants' failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Elmiron was a proximate cause of Plaintiff's injuries and damages.

277. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

278. 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 V
FRAUDULENT MISREPRESENTATION

279. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

280. Defendants made the false statement that Elmiron is safe and well-tolerated to the FDA, and ultimately to consumers, physicians, and the public in general, every time Defendants marketed and sold Elmiron without warning of the risks of potentially serious vision issues and retinal harm.

281. Defendants knew that Elmiron is not safe and well-tolerated but that it instead causes significant and irreparable vision loss and eye damage no later than July 2019 when Defendants submitted sNDA #14 to Elmiron, addressing the risk of pigmentary maculopathy associated with the use of Elmiron.

282. Beginning no later than July 2019, Defendants clearly had knowledge of the significant and irreparable damage Elmiron was causing to consumers, including Plaintiff.

283. Nevertheless, rather than use the FDA's Changes Being Effected ("CBE") supplement—which would have enabled Defendants to change their label unilaterally as early as July 2019 to effect a stronger warning vis a vis Elmiron's association with pigmentary

maculopathy—Defendants continued to represent Elmiron as safe and well-tolerated until June 2020.

284. By not using the FDA's CBE process to propose a stronger warning label alerting consumers, physicians, and the public in general to Elmiron' s association with pigmentary maculopathy by at least July 2019 when Defendants submitted this information to the FDA in their sNDA #14, Defendants intended to induce consumers, physicians, and the public in general to purchase Elmiron under the false representation that it is safe and well-tolerated.

285. As a direct and proximate consequence of Defendants' aforementioned fraudulent conduct, Defendants obtained increased sales profits for the sale of Elmiron.

286. At the time the aforesaid representations 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.

287. In reasonable and justified reliance upon the representations that Elmiron is safe and well-tolerated, Plaintiff purchased and used Elmiron.

288. As a direct and proximate result of reliance upon Defendants' misrepresentations, 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.

289. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

COUNT VI
NEGLIGENT MISREPRESENTATION

290. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

291. Defendants misrepresented to consumers and physicians, including Plaintiff and Plaintiff's physicians and the public in general, that Elmiron was safe or well-tolerated when used as instructed, and that Elmiron was safe or well-tolerated, when, in fact, Elmiron was dangerous to the well-being of patients.

292. Defendants misrepresented to consumers and physicians, including Plaintiff and Plaintiff's physicians and the public in general, that Elmiron is "The Only Oral Medication FDA Approved to Treat the Bladder Pain or Discomfort of Interstitial Cystitis (IC)."

293. Defendants knew or should have known of the falsity of such a representation to consumers, physicians, and the public in general since Elmiron is not the only oral medication approved by the FDA that can be used to treat IC, and it is not the only IC treatment option. Nevertheless, Defendants' marketing of Elmiron falsely represented Elmiron to be the only FDA-approved option for the treatment of IC.

294. Defendants knew or should have known that marketing and representing Elmiron as the only FDA-approved option for the treatment of IC was a false representation that would, and did, mislead consumers and physicians to believe there were no other options available to treat the pain and discomfort caused by IC and/or that Elmiron was a first-line treatment for IC.

295. Not only did Defendants know of the falsity of the aforementioned representation, but Defendants purposefully marketed Elmiron as the only FDA-approved drug for the treatment of IC with an intent to induce consumers and physicians, including Plaintiff and Plaintiff's

physicians, and the public in general, to purchase Elmiron over any one of the other treatment options available.

296. In addition, at the time Defendants promoted Elmiron as safe and well-tolerated, they did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Elmiron was dangerous to the well-being of Plaintiff and others. Defendants not only relied on a study noting adverse events affecting vision, including optic neuritis and retinal hemorrhage, in their own Amendment to the New Drug Application but also learned of subsequent adverse events involving vision and eye health through adverse event reports and medical literature.

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 regarding both the fact that other treatment options for IC were available, and the fact that Elmiron was not safe or well-tolerated due to the adverse events affecting vision and eye health.

298. Defendants made the aforesaid representations in the course of Defendants' business as designers, manufacturers, and distributors of Elmiron despite having no reasonable basis for their assertion that these representations were true or without having accurate or sufficient information concerning the aforesaid representations.

299. At the time the aforesaid representations (or misrepresentations) were made, Defendants intended to induce Plaintiff or Plaintiff's physicians to rely upon such representations (or misrepresentations) in an effort to increase its sales of Elmiron.

300. At the time the aforesaid representations (or misrepresentations) 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 the representations that Elmiron is safe and well-tolerated and the only FDA-approved medication to treat bladder pain and discomfort caused by IC, Plaintiff purchased and used Elmiron.

301. As a direct and proximate consequence of Defendants' aforementioned conduct, Defendants obtained increased sales profits for the sale of Elmiron.

302. As a direct and proximate result of reliance upon Defendants' misrepresentations, 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.

303. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

COUNT VII
BREACH OF EXPRESS WARRANTY

304. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

305. 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.

306. Defendants expressly warranted to Plaintiff, Plaintiff's healthcare providers, and the general public, by and through Defendants and/or their authorized agents or sales

representatives, in publications, labeling, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that Elmiron was safe, effective, fit and proper for its intended use.

307. Elmiron materially failed to conform to those representations made by Defendants, in package inserts and otherwise, concerning the properties and effects of Elmiron, which Plaintiff purchased and ingested in direct or indirect reliance upon these express representations. Such failures by Defendants constituted a material breach of express warranties made, directly or indirectly, to Plaintiff concerning Elmiron sold to Plaintiff.

308. Defendants expressly warranted that Elmiron was safe and well-tolerated. However, they did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Elmiron was dangerous to the well-being of Plaintiff and others.

309. Elmiron does not conform to those express representations because it is defective, is not safe, and has serious adverse side effects.

310. Plaintiff and Plaintiff's physicians justifiably relied on Defendants' representations regarding the safety of Elmiron, and Defendants' representations became part of the basis of the bargain.

311. Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendants' representations that Elmiron was safe and well-tolerated in their decision to ultimately prescribe, purchase and use the drug.

312. Plaintiff's healthcare providers justifiably relied on Defendants' representations through Defendants' marketing and sales representatives in deciding to prescribe Elmiron over other alternative treatments on the market, and Plaintiff justifiably relied on Defendants' representations in deciding to purchase and use the drug.

313. Plaintiff purchased and ingested Elmiron without knowing that drug is not safe and well-tolerated, but that Elmiron instead causes significant and irreparable vision loss and eye damage.

314. As a direct and proximate result of Defendants' breached of warranty, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, past and future medical care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

315. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiffs seek actual and punitive damages from the Defendants.

COUNT VIII
BREACH OF IMPLIED WARRANTY

316. Plaintiff incorporates the factual allegations set forth above as if fully set forth herein and further alleges as follows:

317. 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.

318. Defendants were the sellers of the Elmiron and sold Elmiron to be taken for treatment of IC and bladder pain or irritation.

319. When the Elmiron was prescribed by Plaintiff's physician and taken by Plaintiff, the product was being prescribed and used for the ordinary purpose for which it was intended.

320. Defendants impliedly warranted their Elmiron product, which they manufactured and/or distributed and sold, and which Plaintiff purchased and ingested, to be of merchantable quality and fit for the common, ordinary, and intended uses for which the product was sold.

321. Defendants breached their implied warranties of the Elmiron product because the Elmiron sold to Plaintiff was not fit for its ordinary purpose to treat IC and bladder pain/irritation safely and effectively.

322. The Elmiron would not pass without objection in the trade; is not of fair average quality; is not fit for its ordinary purposes for which the product is used; was not adequately contained, packaged and labeled; and fails to conform to the promises or affirmations of fact made on the container or label.

323. Defendants' breach of their implied warranties resulted in ingestion of the unreasonably dangerous and defective product by Plaintiff, which placed Plaintiff's health and safety at risk and resulted in the damages alleged herein.

324. As a direct and proximate result of reliance upon Defendants' breaches of warranty, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, past and future medical care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

325. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

COUNT IX
VIOLATION OF CONSUMER PROTECTION LAWS

326. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

327. Plaintiff purchased and used Elmiron for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

328. Unfair methods of competition or deceptive acts or practices that were proscribed by law include the following:

329. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

330. Advertising goods or services with the intent not to sell them as advertised; and

331. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

332. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Elmiron.

333. Defendants uniformly communicated the purported benefits of Elmiron while failing to disclose the serious and dangerous side effects related to the use of Elmiron and of the true state of its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers, including Plaintiff and Plaintiff's prescribing physicians.

334. Defendants' conduct in connection with Elmiron was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Elmiron, and that Elmiron was the only FDA approved medication to treat IC, or the only oral treatment option for IC.

335. As a direct and proximate result of reliance upon Defendants' breaches of consumer protection laws, Plaintiff suffered bodily injury and resulting pam and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, past and future medical care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and other damages. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

336. Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.

COUNT X
LOSS OF CONSORTIUM, SERVICES, AND SOCIETY

337. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

338. Plaintiff Tom Ware is Plaintiff Carol Ware's husband of approximately 39 years; Tom Ware and Carol Ware have been married since 1981.

339. At all relevant times Plaintiffs, Tom Ware and Carol Ware, have been married.

340. As a result of Plaintiff Carol Ware's Elmiron-related injuries, Plaintiff Tom Ware has suffered damages.

341. Because of Plaintiff Carol Ware's Elmiron-related injuries, Plaintiff Tom Ware has suffered damages, including, but not limited to, loss of consortium, society, services, guidance, pecuniary losses, and emotional anguish.

342. Due to Plaintiff Carol Ware's Elmiron-related injuries, Plaintiffs are unable to do many things together that they used to enjoy together, including, hobbies and activities.

343. Due to Plaintiff Carol Ware's Elmiron-related injuries, Plaintiff Tom Ware has been required to provide aid to Plaintiff Carol Ware, including, but not limited to, aid related to

reading her text she can no longer read, doing chores she can no longer do, driving Plaintiff places she can no longer drive, and by aiding Plaintiff in any task that requires acuity of vision.

344. Plaintiffs' injuries and damages are severe and permanent, and will continue into the future. As a result, Plaintiffs seek actual and punitive damages from the Defendants.

COUNT XI
PUNITIVE DAMAGES

345. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

346. The acts and omissions of Defendants described herein consisted of oppression, fraud, and/or malice, and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

347. Defendants' actions amounted to actual malice or reckless indifference to the likelihood of harm associated with their acts and omissions.

348. Defendants misled both the medical community and the public, including Plaintiff and her physicians, by making false representations about the safety and effectiveness of Elmiron and by failing to provide adequate instructions and training concerning its use.

349. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Elmiron despite available information demonstrating that drug could interfere with the normal health, healing, proliferation, migration, and/or growth of cells, including epithelial cells and RPE cells; cause potentially irreversible vision issues and retinal harm; cause PPS-toxicity and/or PPS-maculopathy; cause irreversible damage to vision, eyes, and retinas; and cause maculopathy.

350. Defendants were or should have been in possession of evidence demonstrating that Elmiron use could interfere with the normal health, healing, proliferation, migration, and/or growth

of cells, including epithelial cells and RPE cells; cause potentially irreversible vision issues and retinal harm; cause PPS-toxicity and/or PPS-maculopathy; cause irreversible damage to vision, eyes, and retinas; and cause maculopathy. Nevertheless, Defendants continued to market Elmiron by providing false and misleading information with regard to its safety and effectiveness.

351. Defendants failed to provide warnings that would have dissuaded health care professionals from using Elmiron, thus preventing health care professionals, including Plaintiffs prescribing physician, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Elmiron.

352. As a proximate result of Defendants' acts and omissions, Plaintiff suffers from retinal damage and other visual symptoms resulting from Plaintiffs ingestion of Elmiron.

353. As a result of Plaintiff's injuries, Plaintiff has endured substantial pain and suffering, has incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

354. Plaintiffs have suffered and will continue to suffer economic loss, and have otherwise been emotionally and economically injured.

355. Defendants' actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

356. Plaintiff's injuries and damages are severe, permanent and will continue into the future. As a result, Plaintiffs seek actual and punitive damages from the Defendants.

357. Defendants' conduct was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

358. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Carol Ware and Tom Ware respectfully request judgment for relief and damages as follows:

1. Medical Expenses;
2. Pain and Suffering
3. Mental Anguish, Anxiety, and Discomfort of Plaintiffs;
4. Physical Impairment;
5. Loss of Enjoyment of Life;
6. Loss of Consortium, Services, and Society;
7. Pre and Post Judgment Interest;
8. Exemplary and Punitive Damages;
9. Treble Damages;
10. Reasonable and necessary attorneys' fees, costs, pre-judgment interest; and
11. Such other relief to which Plaintiffs may be justly entitled.

WHEREFORE, the Plaintiffs demand judgment of and from Defendants in an amount for compensatory damages against all Defendants for pain and suffering actual damages; consequential damages; exemplary damages, jointly and severally against all Defendants; interest on damages (pre- and post-judgment) in accordance with the law; Plaintiffs' reasonable attorney's fees, as well as costs of court and all other costs incurred; and such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

The Plaintiff demands trial by jury on all counts and on all of the triable issues of this Complaint.

Dated: August 19, 2020

Respectfully submitted,

By: *s/Rayna E. Kessler*

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**Pro Hac Vice Motion to be Filed*

Attorney for Plaintiffs Carol Ware and Tom Ware