UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ELMIRON (PENTOSAN POLYSULFATE SODIUM) PRODUCTS LIABILITY LITIGATION **LINDA SINGER**, Plaintiff, vs. JANSSEN RESEARCH & DEVELOPMENT f/k/a JOHNSON & JOHNSON RESEARCH & DEVELOPMENT LLC, ORTHO-MCNEIL PHARMACEUTICAL LLC, JANSSEN PHARMACEUTICALS INC f/k/a ORTHO-MCNEIL-JANSSEN PHARMACEUTICAL LLC f/k/a/ JANSSEN PHARMACEUTICA INC, TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D INC f/k/a TEVA GLOBAL RESPIRATORY RESEARCH LLC f/k/a IVAX RESEARCH LLC f/k/a IVAX RESEARCH INC f/k/a IVAX LABORATORIES INC f/k/a BAKER NORTON PHARMACEUTICALS INC, and JOHNSON & JOHNSON Defendants	MDL No. 2973 Case No. 2:20-md-2973 (BRM)(ESK) JUDGE BRIAN R. MARTINOTTI JUDGE EDWARD S. KIEL DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 6 Civil Action No.: 2:22-cv-1199

COMPLAINT

Linda Singer ("Plaintiff"), by and through Plaintiff's undersigned counsel, hereby submits this Complaint against Defendants and alleges as follows:

A. PRELIMINARY STATEMENT

1. This is 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 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 retinal damage, 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's use of Elmiron.

8. Plaintiff therefore demands judgment against Defendants and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

B. PARTIES

a. PLAINTIFF

9. Plaintiff, **Linda Singer,** at all times relevant hereto, was a resident and a citizen of the state of **North Carolina**. Plaintiff suffered severe injuries as a direct result of Plaintiff's ingestion of the pharmaceutical product Elmiron.

10. Plaintiff was diagnosed with interstitial cystitis and took Elmiron as prescribed by Plaintiff's physician for approximately 12 years, from **2008 through 2020**.

11. During the relevant time periods, Plaintiff and Plaintiff's physicians were given no warning and had no knowledge of the serious risk of retinal damage and vision loss posed by Elmiron.

12. Subsequently, and as a result of Plaintiff's ingestion of Elmiron, Plaintiff now suffers from toxic maculopathy, retinal damage, blurred vision, distorted vision, and other visual symptoms.

13. As a proximate result of Defendants' acts and omissions, Plaintiff suffered the injuries described above due to Plaintiff's ingestion of Elmiron. Plaintiff accordingly seeks damages associated with these injuries.

b. DEFENDANTS

14. On approximately June 11, 1991, nonparty Baker Norton Pharmaceuticals, a subsidiary of nonparty Ivax Corporation, submitted the original New Drug Application ("NDA") for pentosan polysulfate sodium (NDA: 020193) (hereinafter "original NDA").

JANSSEN RESEARCH & DEVELOPMENT, LLC

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

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

16. Upon information and belief, Defendant Janssen R&D has transacted and conducted business within the State of New Jersey and has derived substantial revenue from goods and products disseminated and used throughout New Jersey and the United States.

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

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

ORTHO-MCNEIL PHARMACEUTICAL, LLC

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

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

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

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

JANSSEN PHARMACEUTICALS, INC.

23. 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 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

24. Elmiron® is a Registered Trademark currently under license to Defendant JANSSEN PHARMA.

25. JANSSEN PHARMA has held the NDA for Elmiron since approximately August 2008. JASSEN PHARMA is the current NDA holder for Elmiron.

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

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.

27. Defendant TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., f/k/a Teva Global Respiratory Research, LLC, f/k/a Ivax Research LLC, f/k/a Ivax Research Inc., f/k/a Ivax Laboratories Inc., f/k/a Baker Norton Pharmaceuticals, Inc. (hereinafter "TEVA"), is a corporation organized under Delaware law with its principal place of business at 41 Moores Road, Malvern, Pennsylvania 19355-1113.

28. Baker Norton Pharmaceuticals conducted initial studies, obtained orphan drug status, obtained FDA approval for sale and labeling of the drug, handled all regulatory communications, and submitted the original NDA for pentosan polysulfate sodium, or Elmiron.

29. Upon information and belief, Ivax later continued to manufacture, package, and

provide data for stability reports for Elmiron in Doral Miami, Florida and JOLCC, Puerto Rico through at least 2010.

30. Upon information and belief, Defendant TEVA receives royalties from the sale of Elmiron amounting to $10% of net sales up to $50 million and 20% of net sales over $50 million. Upon information and belief, peak sales of Elmiron have reached approximately $250 million.

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

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

JOHNSON & JOHNSON

33. Defendant JOHNSON & JOHNSON 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.

34. Upon information and belief, at all relevant times, JANSSEN PHARMA, ORTHO PHARMA, and JANSSEN R&D, have been wholly owned subsidiaries of JOHNSON & JOHNSON with their profits inuring to JOHNSON & JOHNSON'S benefit.

35. Upon information and belief, Elmiron was manufactured in Defendant JOHNSON & JOHNSON's Gurabo plant located in Puerto Rico.

36. Furthermore, JOHNSON & JOHNSON analyzed Elmiron from a business perspective, conducted valuation reviews of Elmiron, evaluated whether to sell or "swap" Elmiron with other pharmaceutical manufacturers, and conducted market research on generic competition

for Elmiron directly through its partnership with Janssen, "Johnson and Johnson Innovation, Janssen Business Development."

37. Johnson and Johnson Innovation, Janssen Business Development is a partnership run by Defendant JOHNSON & JOHNSON. Its website and email address link to a JOHNSON & JOHNSON domain.[1]

38. Johnson & Johnson Innovation, Janssen Business Development is a partnership that seeks to "create real value in Janssen's six defined therapeutic areas." By "form[ing] active partnerships where we can bring the full strength of Johnson & Johnson to bear to create a lasting and valuable relationship."[2] The partnership emphasizes that "[o]ur direct access to decision makers within Johnson & Johnson allows for creative and timely problem solving, and we integrate deal makers with science leaders from the very beginning to optimize success."[3]

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

DEFENDANTS

40. 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.

41. At all times alleged herein, Defendants shall include any and all named or un-named parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises,

[1] *See* https://jnjinnovation.com/janssenbusinessdevelopment.

[2] *Id.*

[3] *Id.*

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.

42. 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.

43. 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.

44. 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 New Jersey, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the pharmaceutical Elmiron.

C. JURISDICTION AND VENUE

45. This court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy as to Plaintiff 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 **North Carolina**, where Plaintiff is a citizen.

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

47. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), because

many of the Defendants reside there, all Defendants transact and conduct business in New Jersey, and a substantial part of the acts and omissions giving rise to this Complaint occurred in New Jersey.

D. NATURE OF THE CASE

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

49. 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.

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

E. RELEVANT FACTUAL BACKGROUND

A BRIEF HISTORY OF ELMIRON

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

52. 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.

53. 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.

54. Elmiron is not a first-line treatment for IC. Rather, Elmiron is one of ten suggested second-line treatments, including three other oral medications: amitriptyline, cimetidine, and hydroxyzine.

55. The guidelines further include numerous third-, fourth-, fifth-, and sixth-line treatments. When first- 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.

56. Defendants market Elmiron as "The Only Oral Medication FDA Approved to Treat the Bladder Pain or Discomfort of Interstitial Cystitis (IC)."[4] However, while Elmiron is the only oral medication approved by the FDA *specifically* for the purpose of treating IC, 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.***

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

58. Indeed, in a March 2012 Citizen's Petition to the FDA, JANSSEN PHARMA did

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

not make the same misrepresentation it has 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." (emphasis added).[5]

POOR BIOAVAILABILITY AND EFFICACY OF ELMIRON

59. Though Defendants admit that the mechanism of action for Elmiron is unknown, Elmiron is thought to be a "chemical band-aid" 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.

60. 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.

61. 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.[6] Populations of patients receiving extended treatment (>2 years) showed no further improvement or worsening of symptoms, yet users often continue the drug for years.[7] 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.

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

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

[7] *Id.*

62. 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***."[8] (emphasis added)

63. JANSSEN PHARMA further elaborated:

> ***ELMIRON has not yet been fully characterized***. ELMIRON contains a mix of many components, which vary in chain length (molecular weight), number and location of glucuronic acid sidechains, and number of location of sodium sulfate groups.
>
> ***Moreover, no definitive information exists to identify which of the components are active (i.e., responsible for the safety and efficacy of ELMIRON)*** . . .
>
> The information presented above demonstrates that due to the ***unknown etiology of IC, the inability to characterize ELMIRON and understand how it works in the body, the difficulty of measuring PPS in plasma, blood, or urine, and the lack of a reliable bioassay to measure the product's effects***, conventional methods of determining bioequivalence are inadequate."[9]

64. 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.

DEFENDANTS' FAILURE TO TEST ELMIRON

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

[8] Janssen Citizen Petition (emphasis added).

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

mechanism of action of the drug.

66. 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.

67. 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.

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

> The Phase III studies on which the ELMIRON approval was initially based assessed the effect of the drug on subjects' pain and discomfort levels, as measured by the subjects' individual assessments. ***Pain and discomfort, while key symptoms of the IC diagnosis, are inherently subjective elements***. Therefore, while patients' individual assessments based on these subjective impressions were useful in the Phase III ELMIRON trials to demonstrate a clinical benefit as compared to placebo, ***an objective measure is more appropriate*** for studies with clinical endpoints to assess bioequivalence.[10]

69. 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*** …

[10] Janssen Citizen Petition (emphasis added).

> 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***.[11]

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

THE DANGERS OF ELMIRON

71. Despite study after study providing clear evidence of the dangers of PPS, Defendants failed to 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.

72. 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.[12]

73. 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."[13]

74. As early as 1991, available medical research also identified that PPS inhibits

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

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

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

regrowth and proliferation of retinal pigment epithelial ("RPE") cells,[14] and could thereby impair an important physiological pathway for retinal health.

75. 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.

76. 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.

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

78. 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.

79. Almost immediately after the FDA approved Elmiron, patients and doctors began reporting serious complications relating to eye and vision problems in patients taking Elmiron.[15]

80. From January 1997 through March 2020, 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.[16]

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[14] 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).

[15] According to the FDA Adverse Events Reporting System (FAERS) Public Dashboard, eight patients taking Elmiron reported serious adverse effects to their vision in the 1997 calendar year: https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/6b5a135f-f451-45be-893d-20aaee34e28e/state/analysis.

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

81. 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.[17]

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

> We wish to alert readers to a concerning new observation of ***vision threatening retinal changes associated with long-term exposure to [Elmiron]***. We recently reported our findings of retinal pigmentary changes in six patients undergoing long-term therapy with [Elmiron]. These patients primarily described difficulty reading and/or trouble adjusting to dim lighting. Each patient had received a standard dosage of [Elmiron], ranging from 200 to 400 mg daily, for a median duration of 15.5 years. . .. ***Examination findings in patients with this condition are suggestive of injury to the retina and the underlying retinal pigment epithelium***. . .. After extensive investigations, which included molecular testing for hereditary retinal disease, ***we found these cases to resemble no other retinal disease***.[18]

83. The study, "Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium [Elmiron]," focused on six women with IC who presented to the Emory Eye Center between May 2015 and October 2017 with pigmentary maculopathy.[19] 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.

84. 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.

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

[18] 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) (emphasis added).

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

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).

85. 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.

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

87. 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)."[20]

88. 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.[21]

89. All eyes of two patients showed RPE atrophy that was noted to "increase in area and encroach on the central fovea over time."[22] Retinal imaging also found clear diseased regions, atrophy, or both.[23]

90. 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.[24]

[20] *Id*. at 1798.

[21] *Id*.

[22] *Id*.

[23] *Id*.

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

91. The authors expressed concern that "the region of affected tissue may expand centrifugally over time."[25]

92. 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."[26]

93. They also encouraged "drug cessation in affected patients," and "recommend[ed] that any patient with suggestive visual symptoms undergo a comprehensive ophthalmic examination."[27]

94. 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***."[28]

95. 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.[29]

96. 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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[25] *Id*. at 1800.

[26] *Id*. at 1801.

[27] 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).

[28] 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) (emphasis added).

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

97. 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*.

98. 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.

99. The Emory team most recently published a July 2019 study in the Review of Ophthalmology.[30]

100. "Our subsequent investigations," the team wrote, "demonstrated that this unique maculopathy is strongly associated with chronic [Elmiron] exposure, not IC itself or its other therapies. In fact, ***this characteristic maculopathy has, to date, been exclusively diagnosed in patients reporting prior [Elmiron] exposure***."[31]

101. 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.

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

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

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

maculopathy "is a vision-threatening condition that can manifest in the setting of long-term exposure to the drug."[32]

103. In November of 2019, a team from Emory and the University of Pennsylvania published an epidemiological study in the British Journal of Ophthalmology which concluded that "PPS [Elmiron] users had significantly increased odds of having [maculopathy]."[33]

104. 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.[34] 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***."[35]

105. 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.[36] Their study suggests "a significant risk of macular toxicity for PPS-treated patients," and that "more significant PPS exposure was associated with more severe atrophy."

106. Most recently, two physicians from Harvard Medical School published a case study indicating that the damage caused by Elmiron continues to progress long after cessation of

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

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

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

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

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

the drug.[37] 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.

107. The doctors noted "the present case adds a new layer of concern by demonstrating progressive maculopathy continuing for up to 6 years after cessation of PPS . . . this case emphasizes the need for a screening regimen that balances the demands on patients and physicians with the importance of prompt identification of early toxicity."[38]

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

109. Patient reports on the IC Network Support Forum include (all [*sic*]):[39]

> **June 23, 2019**: "I have been diagnosed with macular degeneration and no one in my family has it. I have been on elmiron for 15 years. I decided even though the correlation is not extremely strong to go off it for the sake of my eyes . . . am hoping the degeneration will slow if not stop. Am not looking for it reverse course. Am also hoping that I do not go back to the pain . . . all I can do is try. I feel to be between a rock and a hard place. I am an artist so my eyes are truly needed to continue my work."
>
> **February 3, 2019**: "I saw the article too and took it to my ophthalmologist. She was very excited to see the research. She said that my macular degeneration that had occurred after 18 years of taking Elmiron was an unusual shape that they had not seen before. She said that while it won't heal me, they hoped that they could stop this from happening to other patients."
>
> **March 25, 2019**: "After 4 excruciating years, I was diagnosed with IC in 2003. I started on Elmiron and have taken it since then. I was diagnosed with macular degeneration in 2014. My severity is mild to moderate. The left eye is definitely worse. I can no longer drive at night. I'm pretty comfortable driving to places I am familiar with during the day. I am only 58. I dread the day I will not be able to

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

[38] *Id*. at 658.

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

drive."

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

111. Furthermore, the European Medicines Agency, a decentralized agency of the EU responsible for scientific evaluations, supervision, and safety monitoring of medicines in the EU, specifically warns patients about Elmiron:

> All 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.[40]

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

113. 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.

114. 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

[40] EUROPEAN MEDICINES AGENCY, PRODUCT INFORMATION. ELMIRON- PENTOSAN POLYSULFATE SODIUM 3, https://www.ema.europa.eu/en/documents/product-information/elmiron-epar-product-information_en.pdf.

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.[41]

115. In stark contrast, until June 2020, The Elmiron label read:[42]

WARNINGS

None.

116. 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.

[41] Plaquenil Patient Package Insert, revised June 2018.

[42] Elmiron Patient Pakage Insert, revised August 2004.

117. 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.

118. Defendants failed to mention 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.

119. 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.

120. 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.

121. At all relevant times, 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.

122. 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.

123. Defendants' sNDA dated June 24, 2019 was not approved by the FDA until June 16, 2020. 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 June 16, 2020.

124. 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.

125. 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.

126. 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.

127. 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 the same.

128. 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.

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

DEFENDANTS HAD A DUTY TO PROTECT U.S. CONSUMERS, BUT DID NOT

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

131. 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.

132. 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.

133. 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.

134. 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.

135. Upon information and belief, despite understanding Elmiron could cause 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.

136. Accordingly, pursuant N.J.S. §2A:58C-5(c), Defendants are liable to Plaintiff for punitive damages.

HOW DEFENDANTS' MISCONDUCT ENDANGERED U.S.CONSUMERS

137. 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.

138. 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.

139. 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.

140. 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 Plaintiff 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.

141. 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.

142. 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.

143. 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 other products.

144. 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.

145. 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.

146. 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.

147. 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 to compared to other similarly efficacious pharmaceutical products.

148. 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— further, rendered the Elmiron Package Insert, Medication Guide, and other educational and/or promotional materials inadequate.

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

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

150. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold information from Plaintiff, 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.

151. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold safety-related warnings from Plaintiff, Plaintiff's 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.

152. Defendants willfully, wantonly and intentionally conspired, and acted in concert, to withhold instructions from Plaintiff, Plaintiff's 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.

153. 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.

154. 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, Plaintiff's 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.

155. Further, Defendant 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 that there were no warnings required to safely prescribe and take Elmiron and no vision-related adverse side effects associated with use of Elmiron. These communications were disseminated to Plaintiff, Plaintiff's healthcare providers, and the general public and included, without limitation, the Package Insert and the Medication Guide.

156. Due to the absence of any warning by Defendants as to the significant health and safety risks posed by Elmiron, Plaintiff was 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.

157. Due to the absence of any instructions for how to identify and/or monitor Elmiron patients for potential vision-related complications, Plaintiff was 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.

158. 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 ONE: STRICT LIABILITY – FAILURE TO WARN

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

160. 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.

161. Defendants, as manufacturers and distributers 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.

162. 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.

163. 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.

164. 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.

165. 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.

166. 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.

167. 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.

168. Defendants knew or should have known that consumers, Plaintiff specifically,

would foreseeably and needlessly suffer injury as a result of Defendants' failures.

169. 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.

170. 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 Defendants, and in that the risk of danger outweighs the benefits.

171. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in the following ways:

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

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

c. 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.

172. 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.

173. 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.

174. 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 Plaintiff and Plaintiff's 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.

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

176. 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.

177. 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.

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

179. 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 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.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount which will compensate Plaintiff for Plaintiff's injuries:

COUNT TWO: STRICT LIABILITY – DESIGN DEFECT

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

181. 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.

182. 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 Plaintiff.

183. 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 in a defective condition.

184. 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.

185. 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.

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

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

188. 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.

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

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

191. Elmiron is a medication prescribed primarily for IC, a bladder condition.

192. 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.

193. 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.

194. 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.

195. 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.

196. 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.

197. 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.

198. 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.

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

200. 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.

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

202. As a direct and proximate result of Defendants' conduct, including the 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 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.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount which will compensate Plaintiff for Plaintiff's injuries.

COUNT THREE: NEGLIGENT FAILURE TO WARN

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

204. 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.

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

206. 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.

207. 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.

208. 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.

209. Elmiron was defective and unreasonably dangerous when it left the possession of 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 Defendans' knowledge of the risk of these injuries over other IC therapies available.

210. 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 Plaintiff's prescribing physician, knowing the product could cause serious injury.

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

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

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

214. 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.

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

216. 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.

217. 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.

218. 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 Defendants.

219. 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 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.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount which will compensate Plaintiff's injuries.

COUNT FOUR: NEGLIGENT DESIGN

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

221. 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.

222. 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.

223. 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.

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

225. 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.

226. 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 Defendants.

227. 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 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.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and severally, in an amount which will compensate Plaintiff's injuries.

COUNT FIVE: PUNITIVE DAMAGES

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

229. 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.

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

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

232. 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.

233. 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.

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

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

236. 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.

237. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured.

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

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

240. 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

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

DAMAGES

242. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate plaintiff:

a. Medical Expenses;

b. Pain and Suffering;

c. Mental Anguish, Anxiety, and Discomfort;

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre and post judgment interest;

g. Exemplary and Punitive Damages;

h. Reasonable and necessary attorneys' fees, costs, pre-judgement interest; and

i. Such other relief to which Plaintiff may be justly entitled.

WHEREFORE, Plaintiff demands 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; Plaintiff's 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

Plaintiff hereby demands a trial by jury on all counts and as to all issues.

Dated: March 4, 2022

RESPECTFULLY SUBMITTED,

/s/ Stacy K. Hauer
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