UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ELMIRON (PENTOSAN POLYSULFATE SODIUM) PRODUCTS LIABILITY LITIGATION	MDL No. 2973 Case No. 2:20-md-02973 (BRM)(ESK)
JULIA MANNING and BRIAN MANNING, Plaintiffs, vs. TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., f/k/a Teva Global Respiratory Research, LLC, f/k/a Ivax Research LLC, f/k/a Ivax Research Inc., f/k/a Ivax Laboratories Inc., f/k/a Baker Norton Pharmaceuticals, Inc.; IVAX LLC, f/k/a Ivax Corporation; JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a Johnson & Johnson Research & Development, L.L.C.; ALZA CORPORATION; JANSSEN ORTHO LLC; and, JOHNSON & JOHNSON, Defendants.	JUDGE BRIAN R. MARTINOTTI JUDGE EDWARD S. KIEL DIRECT FILED COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 6 Civil Action No:

COMPLAINT

JULIA MANNING ("Plaintiff") and BRIAN MANNING ("Plaintiff Spouse," and, together with Plaintiff, "Plaintiffs") hereby sue TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., f/k/a Teva Global Respiratory Research, LLC, f/k/a Ivax Research LLC, f/k/a Ivax Research Inc., f/k/a Ivax Laboratories Inc., f/k/a Baker Norton Pharmaceuticals, Inc.;

IVAX LLC, f/k/a Ivax Corporation; JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a Johnson & Johnson Research & Development, L.L.C.; ALZA CORPORATION; JANSSEN ORTHO LLC; and, JOHNSON & JOHNSON (collectively, "Defendants"), and allege as follows:

INTRODUCTION

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 specific eye injury.

4. Defendants knew or should have known that Elmiron, when taken as prescribed and intended, causes eye injury.

5. Elmiron is capable of causing medically confirmed eye injury. Indeed, Pentosan Polysulfate Sodium Maculopathy (hereinafter "PPS Maculopathy" or "pigmentary maculopathy") is a signature pathological abnormality caused by Elmiron toxicity and often leading to serious eye injury.

6. Nevertheless, at all relevant times, DEFENDANTS failed to warn, instruct, advise, educate, or otherwise inform Elmiron users, Elmiron prescribers, or United States governmental regulators about the risk of eye injury or the need for medical and ophthalmological monitoring.

7. At all relevant times, Elmiron was misbranded under Title 21, United States Code, Section 352, because its label did not bear the quantity or proportion of each active ingredient, its label was false and misleading; its labeling did not bear adequate directions for use; it was dangerous to health when used in the dosage and manner, and with the frequency and duration prescribed, recommended, and suggested in its labeling; and, DEFENDANTS were in violation of requirements relating to post-marketing studies.

8. Further, at all relevant times, Elmiron was defective in that it was 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 eye injury.

9. As a proximate result of DEFENDANTS' wrongful actions and inactions, Plaintiffs were injured and suffered damages from the use of Elmiron.

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

PARTY PLAINTIFFS

11. Plaintiffs are citizens and residents of Wayne County, Georgia ("Plaintiff Home State").

12. Plaintiff took Elmiron as prescribed by her physician from approximately 2008 through 2014. At all relevant times, Plaintiff was given no warning and had no knowledge of the serious risk of eye injury posed by Elmiron. As a result of her exposure to Elmiron, Plaintiff suffered injury to both eyes.

13. At all relevant times, Plaintiff Spouse was the lawful spouse of Plaintiff.

PARTY DEFENDANTS

Teva Defendants

14. 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 BRANDED") is a former Florida limited liability company and corporation and a current Delaware corporation with a current principal place of business in New Jersey.

15. On approximately June 11, 1991, TEVA BRANDED submitted the original New Drug Application ("NDA") for pentosan polysulfate sodium (NDA: 020193) to the U.S. Food and Drug Administration (FDA), which was approved in 1996.

16. TEVA BRANDED held the NDA for Elmiron from 1996 through 1998.

17. Defendant IVAX LLC f/k/a Ivax Corporation (hereinafter "IVAX" or "IVAX LLC") is a Florida limited liability company with a current principal place of business in New Jersey with no members who are a citizen of Plaintiffs' home state.

18. Upon information and belief, at all relevant times, TEVA BRANDED was a subsidiary of IVAX LLC. IVAX and TEVA BRANDED conducted clinical trials on Elmiron that were used to support FDA approval of the drug.

19. Upon information and belief, at all relevant times, Defendant IVAX was actively involved in TEVA BRANDED's business operations, including the early testing, developing, manufacturing, marketing, distributing, and selling of Elmiron.

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

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

22. TEVA BRANDED has owned the U.S. Trademark for "Elmiron" from 1992 through the present today and continues to be listed on the package insert as the licensor of the trademark.

23. At all relevant times, TEVA BRANDED and IVAX were pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States.

Johnson & Johnson Defendants

24. Defendant ALZA CORPORATION (hereinafter "ALZA") is a corporation organized under Delaware law with its principal place of business in California. ALZA held the NDA for Elmiron from 1998 through 2002.

25. 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 in New Jersey. JANSSEN R&D's sole member is Centocor Research & Development, Inc., a Pennsylvania corporation with its principal place of business in Pennsylvania. JANSSEN R&D held the NDA for Elmiron from approximately August 2002 until August 2004.

26. Defendant ORTHO-MCNEIL PHARMACEUTICALS, INC. (hereinafter "ORTHO PHARMA") is a corporation organized under Delaware law with its principal place of business in New Jersey. ORTHO PHARMA held the NDA for Elmiron from approximately July 2004 until August 2008.

27. Defendant JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc., (hereinafter "JANSSEN PHARMA") is a corporation organized under Pennsylvania law with its principal place of business in New Jersey.

JANSSEN PHARMA has held the NDA for Elmiron from approximately August 2008 through the present.

28. Defendant JANSSEN ORTHO, LLC (hereinafter "JANSSEN ORTHO") is a limited liability company organized under Delaware law with its principal place of business in Puerto Rico. JANSSEN ORTHO's sole member is OMJ PR Holdings, a corporation incorporated in Ireland with a principal place of business in Puerto Rico. JANSSEN ORTHO manufacturers and packages Elmiron for Janssen Pharmaceuticals, Inc.

29. Defendant JOHNSON & JOHNSON is a corporation organized under New Jersey law with its principal place of business in New Jersey.

30. Upon information and belief, at all relevant times, ALZA, JANSSEN R&D, ORTHO PHARMA, JANSSEN PHARMA, and JANSSEN ORTHO have been wholly owned subsidiaries of JOHNSON & JOHNSON with their profits inuring to JOHNSON & JOHNSON'S benefit. Collectively, these Defendants are referred to as the "J&J DEFENDANTS".

31. Upon information and belief, and at all relevant times, the J&J DEFENDANTS were pharmaceutical companies involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in New Jersey and throughout the United States.

JURISDICTION & VENUE

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

33. This Court has *in personam* jurisdiction over Defendants because they were and/or still are pharmaceutical companies involved in the manufacturing, research, development,

marketing distribution, sale, and release for use to the general public of pharmaceuticals, including Elmiron, in Plaintiff Home State. Further, this action arose from Defendants' activities in Plaintiff Home State. Accordingly, each Defendants has voluntarily subjected itself to the jurisdiction of this Court; regularly transacts business within this District, and/or has purposefully availed itself of the jurisdiction of this Court for the matters at issue.

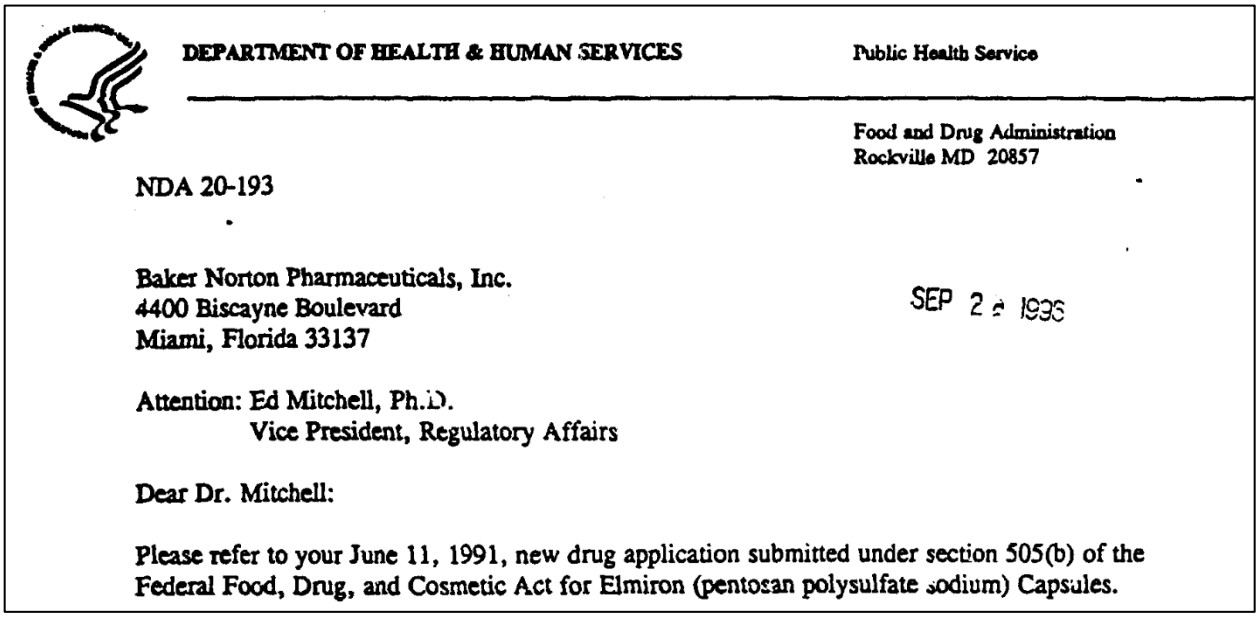
34. Venue is proper in this forum pursuant to 28 U.S.C. § 1391 because the Defendants transact business in this District, and a substantial portion of the practices, events, and omissions complained of herein occurred in this judicial district.

35. All conditions precedent to this action have occurred, been performed, or have been waived.

FACTUAL ALLEGATIONS

A. Brief History of Elmiron

36. In September of 1996, the FDA approved Elmiron for treatment of interstitial cystitis ("IC"), also known as bladder pain syndrome. The approval letter was directed to BAKER NORTON, which had spent years attempting to gain approval for the drug:



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-193

Baker Norton Pharmaceuticals, Inc.
4400 Biscayne Boulevard
Miami, Florida 33137

SEP 2 6 1996

Attention: Ed Mitchell, Ph.D.
Vice President, Regulatory Affairs

Dear Dr. Mitchell:

Please refer to your June 11, 1991, new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Elmiron (pentosan polysulfate sodium) Capsules.

37. 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.

38. 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.

39. 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.

40. 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 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.

41. Defendants market Elmiron as "The Only Oral Medication FDA Approved to Treat the Bladder Pain or Discomfort of Interstitial Cystitis (IC)."[1] 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 it 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. Rather, Elmiron is in fact one of *five* oral medications

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

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.

42. Indeed, in a March 2012 Citizen's Petition to the FDA, 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." (emphasis added)

B. Poor Bioavailability and Efficacy of Elmiron

43. Though 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.

44. 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.

45. 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.[2] Populations of patients receiving extended treatment (>2 years) showed no further improvement or worsening of symptoms, yet users often continue the drug for years.[3] In other trials, the improvement of certain IC symptoms with Elmiron was significant compared to Placebo (28% of

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

[3] *Id.*

treated subjects versus 13% of placebo controls), but the overall degree of improvement was not dramatic from a clinical standpoint.

46. In the 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— 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***."[4]

47. 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."[5]

48. The low efficacy and bioavailability of Elmiron are particularly 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.

C. Defendants' Failure to Test Elmiron

[4] March 26, 2020 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).

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

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

50. 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. 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.

51. 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.[6]

52. 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***

[6] Janssen Citizen Petition (emphasis added).

pharmacodynamic marker other than clinical effect measured as reduction of pain. (emphasis added)

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

D. The Dangers of Elmiron

54. 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.

55. 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]

56. The reported adverse effects included:[8]

a. Blurred Vision. Left Central Optic Vein Occlusion: A 32 year old white female without a prior history of eye trauma, hypertension, diabetes or previous significant ophthalmologic history complained of experiencing blurred vision.

b. "Filmy Sensation Over Left Eye" Possible Left Optic Neuritis: A 21 year old white female without any history of ophthalmological problems, head trauma, diabetes, or any previous neurological symptoms experienced a "filmy sensation over the left eye."

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

[8] *Id.*

57. As early as 1991, available medical research also identified that PPS inhibits regrowth and proliferation of retinal pigment epithelial (RPE) cells,[9] and could thereby impair an important physiological pathway for retinal health.

58. Indeed, as set forth above, *see supra* ¶ 69, 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.

59. 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.

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

61. 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.

62. Almost immediately after the FDA approved Elmiron, patients and doctors began reporting serious complications relating to eye and vision problems in patients taking Elmiron.[10]

63. 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

[9] 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).

[10] 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.

blindness. Other reported symptoms include visual impairment, halo vision, and reduced visual acuity.[11]

64. 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.[12]

65. 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***.[13]

66. The study, "Pigmentary Maculopathy Associated with Chronic Exposure to [Elmiron]," focused on six women with IC who presented to the Emory clinic between May 2015 and October 2017 with pigmentary maculopathy.[14] Maculopathy is a general term referring to any

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

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

[13] 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).

[14] 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

pathological condition that affects the macula, the central portion of the retina upon which visual acuity and sensitivity depend.

67. 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).

68. 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.

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

70. Examinations of their eyes showed clear changes: "Nearly all eyes (10 eyes of 5 patients) showed subtle parafoveal pigmented deposits at the level of the retinal pigment epithelium (RPE)."[15] All eyes "showed subtle vitelliform deposits that increased in number and extended beyond the major arcade of vessels in cases judged to be more severe. Four eyes of 2 patients showed RPE atrophy that was noted to increase in area and encroach on the central fovea over time."[16] Retinal imaging also found clear diseased regions, atrophy, or both.[17]

71. 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]

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[15] *Id*. at 1798.

[16] *Id.*

[17] *Id.*

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

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

73. 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]

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

75. 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]

76. 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.[23]

77. The patients in this 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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[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).

[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) (emphasis added).

[23] 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

78. 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*.

79. 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 the course of the damage. They encouraged affected patients to discontinue the use of medications and to undergo comprehensive ophthalmic examinations.

80. The Emory team most recently published a July 2019 study in the Review of Ophthalmology.[24]

81. "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***."[25]

82. 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.

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

[24] 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.

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

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

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

85. 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]

86. 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."

87. 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 the

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[26] 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.

[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), https://bjo.bmj.com/content/early/2019/11/06/bjophthalmol-2019-314765.

[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), http://www.sciencedirect.com/science/article/pii/S2451993620300086?via%3Dihub.

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

[30] 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.

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

88. 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."[32]

89. 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.

90. Patient reports on the IC Network Support Forum include (all [*sic*]):[33]

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

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

c. March 25, 2019: "After 4 excruciating years, I was diagnosed with IC in 2003. I started on Elmiron and have taken it since then. I was diagnosed with macular degeneration in 2014. My severity is mild to moderate. The left eye is definitely worse. I can no longer drive at night. I'm pretty

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

[32] *Id*. at 658.

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

> comfortable driving to places I am familiar with during the day. I am only 58. I dread the day I will not be able to drive."

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

92. 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 advising that "[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."[34]

93. 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 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***.

94. 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.

95. 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

[34] 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.

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.[35]

96. In stark contrast, until June 2020, the Elmiron label read:[36]

WARNINGS

None.

97. 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.

[35] Plaquenil Patient Package Insert, revised June 2018, Concordia Pharmaceuticals, Inc., https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/009768Orig1s051lbl.pdf.

[36] Elmiron Patient Package Insert, revised August 2004.

98. 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.

99. 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 physicians and patients.

100. 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.

101. 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.

102. 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.

103. 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.

104. 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 packaging referencing the risk of vision threatening retinal changes associated with Elmiron use until June 16, 2020.

105. 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.

106. 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.

107. 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.

108. 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.

109. 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.

110. 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.

TOLLING OF THE STATUTE OF LIMITATIONS

A. Discovery Rule Tolling

111. As a result of the acts and omissions of Defendants, Plaintiffs could not have discovered, through the exercise of reasonable due diligence, that exposure to Elmiron was associated with increased exposure to vision threatening retinal changes as set forth above. Thus, the applicable limitations periods did not begin to accrue until Plaintiffs discovered, or through the exercise of reasonable diligence should have discovered, Defendants' wrongful acts and omissions.

B. Fraudulent Concealment Tolling

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

113. Defendants are under a continuing duty to disclose the true character, quality, and nature of Elmiron to Plaintiffs. At all relevant times, Defendants nevertheless failed to inform patients and doctors about the vision threatening retinal changes associated with Elmiron, as discussed above.

114. Plaintiffs reasonably relied upon Defendants' knowing, affirmative, or active concealment when they continued to use Elmiron as prescribed.

115. Because Defendants actively concealed the vision threatening retinal changes associated with Elmiron, they are estopped from relying on any statutes of limitations defense.

C. Estoppel

116. Defendants were, and are, under a continuous duty to disclose to Plaintiffs the vision threatening retinal changes associated with Elmiron. Instead, they actively concealed the true character, quality, and nature of Elmiron and knowingly made misrepresentations and/or omissions about the safety of Elmiron and the vision-threatening retinal changes associated with it.

117. Plaintiffs reasonably relied upon Defendants' knowing and affirmative misrepresentations and active concealment of material facts. Therefore, Defendants are estopped from relying on any defense based on statutes of limitations in this action.

COUNT 1
Strict Liability – Failure to Warn

118. Plaintiff incorporates the above as if fully set forth herein and further alleges as follows.

119. 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.

120. 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.

121. The Elmiron drug supplied to Plaintiff by Defendants was defective due to inadequate warnings, labeling, or instructions concerning the foreseeable risks of its use. Defendants' failure to provide these adequate warnings and/or instructions made Elmiron unreasonably dangerous.

122. 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.

123. 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.

124. 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.

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

126. 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.

127. The Elmiron designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate postmarketing 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 products, and continued to improperly advertise, market and/or promote Elmiron.

128. 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.

129. 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.

130. 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 2
Strict Liability – Design Defect

131. Plaintiff incorporates the above as if fully set forth herein and further alleges as follows.

132. 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.

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

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

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

136. 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.

137. 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.

138. 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.

139. 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.

140. 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.

141. 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.

142. 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.

143. 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.

144. 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.

145. 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 3
Negligent Failure to Warn

146. Plaintiff incorporates the above as if fully set forth herein and further alleges as follows.

147. 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 her physicians, obtained accurate information and adequate instructions for the safe use or non-use of Elmiron.

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

149. Defendants had a duty to warn Plaintiff, her 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.

150. 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.

151. 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. Failure to adequately warn of the potentially dangerous, defective, unsafe, and deleterious propensity of Elmiron and of the risks associated with its use;

b. 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;

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

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

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

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

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

152. 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 4
Negligent Design

153. Plaintiff incorporates the above as if fully set forth herein and further alleges as follows.

154. 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 her physicians, obtained accurate information and adequate instructions for the safe use or non-use of Elmiron.

155. 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.

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

a. Negligent and careless research and testing of Elmiron;

b. Negligent and careless design or formulation of Elmiron;

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

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

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

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

158. 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 5
Negligence – Unreasonable Marketing of a Dangerous Drug and Unreasonable Failure to Remove the Drug from the Market

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

160. Defendants owed a duty to the general public, and specifically to Plaintiff, not to introduce a drug into the market, or continue a previous tender of a drug, including the Elmiron at issue in this lawsuit, that was unreasonably dangerous for any person to use it and was capable of causing serious personal injuries such as those suffered by Plaintiff during foreseeable use.

161. Defendants breached their duty of care and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiff:

a. Failing to exercise reasonable and ordinary care in that the drug Elmiron was so unreasonably dangerous and defective in design that it never should have been on the market or taken by anyone;

b. Failing to exercise reasonable and ordinary care in the design, research, development, manufacture, sale, testing and or distribution of the drug Elmiron;

c. Tendering into the market a drug which Defendants knew or should have known was so dangerous that it shouldn't have been taken by anyone.

d. Violating its duty of care in design by tendering into market a drug which it knew or should have known should not have been taken by anyone.

e. Violating its duty of care in design in marketing by tendering into the market a drug which it knew or should have known should not have been taken by anyone.

f. Violating its duty of care in design by placing an unsuitable product into the market for public consumption.

162. The Elmiron that Plaintiff ingested was in substantially the same condition when she ingested it as it was in when it left the control of Defendants. Elmiron's ability to cause serious personal injuries and damages such as those suffered by Plaintiff was not due to any voluntary action or contributory negligence of Plaintiff. Plaintiff consumed the Elmiron as directed and without change in its form or substance.

163. Defendants' violation of its duty of care resulted in an untenably dangerous product being placed into the marketplace which was a proximate cause of Plaintiff's injuries and damages.

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

COUNT 6
Fraudulent Misrepresentation

165. Plaintiff incorporates the above as if fully set forth herein and further alleges as follows.

166. Defendants misrepresented to consumers and physicians, including Plaintiff and her 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.

167. Defendants misrepresented to consumers and physicians, including Plaintiff and her 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)."

168. Defendants knew or ought to 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.

169. Defendants knew or ought to 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 the Elmiron was a first-line treatment for IC.

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

171. At the time Defendants promoted Elmiron as safe or 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 because Defendants relied on a study noting adverse events affecting vision, including optic neuritis and retinal hemorrhage, in their own Amendment to the New Drug Application.

172. 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, her 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.

173. Defendants made the aforesaid representations during 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.

174. At the time the aforesaid representations were made, Defendants intended to induce Plaintiff or her physicians to rely upon such representations in an effort to increase its sales of Elmiron.

175. At the time the aforesaid representations were made by Defendants, and at the time Plaintiff received Elmiron, Plaintiff or her 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.

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

177. 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.

COUNT 7
Fraudulent Misrepresentation

178. Plaintiff incorporates the above as if fully set forth herein and further alleges as follows.

179. 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.

180. 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.

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

182. 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.

183. 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.

184. At the time the aforesaid representations were made by Defendants, and at the time Plaintiff received Elmiron, Plaintiff or her physicians, and the public in general, reasonably believed them to be true.

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

186. 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.

COUNT 8
Loss of Consortium

187. Plaintiff Spouse incorporates the above as if fully set forth herein and further alleges as follows.

188. As a direct and proximate result of the acts, misrepresentations, and negligence of the Defendants as alleged in Counts above, Plaintiff Spouse has been in the past and will be in the

future deprived of the comfort, care, consortium, companionship, society, attention, and services of his wife, Plaintiff. The losses are either permanent or continuing, and Plaintiff Spouse will suffer the losses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek judgment in their favor as follows:

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

b. Awarding punitive damages;

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

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

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

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

DEMAND FOR JURY TRIAL

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

Dated: May 28, 2021 Respectfully submitted,

/s/*Benjamin Widlanski*
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Counsel for Plaintiffs

JS 44 (Rev. 10/20)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

JULIA MANNING and BRIAN MANNING

(b) County of Residence of First Listed Plaintiff Wayne County, Georgia
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Colson Hicks Eidson, 255 Alhambra Cir., PH, Coral Gables, FL 33134 (305) 476-7400

DEFENDANTS

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., f/k/a Teva Global Respiratory Research et al.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

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

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

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Pharmaceutical Product Liability Action

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Brian R. Martinotti DOCKET NUMBER 2:20-md-02973

DATE
5/28/2021

SIGNATURE OF ATTORNEY OF RECORD
/s/ Francisco R. Maderal, Esq.

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

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

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

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

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

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

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

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ELMIRON (PENTOSAN POLYSULFATE SODIUM) PRODUCTS LIABILITY LITIGATION	**Case No. 2:20-md-02973 (BRM)(ESK)** **MDL No. 2973** **JUDGE BRIAN R. MARTINOTTI** **JUDGE EDWARD S. KIEL**

ATTACHMENT A – DESIGNATION OF FORUM

Plaintiffs file this Designation of Forum pursuant to CMO No. 6 and are to be bound by the rights, protections and privileges and obligations of that CMO. Consistent with that CMO, Plaintiffs state as follows:

CASE IDENTIFICATION

1. Party that ingested Elmiron (name only one): JULIA MANNING

2. Case Caption: JULIA MANNING, et al. v. TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., et al.

JURISDICTION AND VENUE

3. Basis for jurisdiction:

   ☑ Diversity of citizenship

   ☐ Other:

   _____

   (The basis of any additional ground for jurisdiction must be pled in sufficient detail in the complaint as required by the applicable Federal Rules of Civil Procedure.)

4. Federal district and division in which the action would have been brought but for CMO 6 permitting direct filing in MDL-2973 ("Designated Forum"): United States District Court for the Southern District of Georgia, Brunswick Division

   (Pursuant to CMO No. 6, the Designated Forum shall be the presumptive place of remand absent a showing by Plaintiffs or Defendants that the place of remand should be elsewhere.)