[redacted]

MARY DOWNEY and DAVID DOWNEY, **Plaintiffs,** **vs.** **JANSSEN PHARMACEUTICALS, INC. and JOHNSON & JOHNSON** **Defendants.**	**SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MERCER COUNTY** **DOCKET NO:**

COMPLAINT AND JURY DEMAND

COMES NOW, Plaintiffs, MARY DOWNEY and DAVID DOWNEY, by and through the undersigned counsel, and brings this complaint against Defendants Janssen Pharmaceuticals, Inc. and Johnson & Johnson, and alleges as follows:

INTRODUCTION

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

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

3. Elmiron injured Plaintiff Mary Downey by causing harmful, but latent, retinal damage and pigmentary maculopathy, which ultimately resulted in significantly 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 and scientific studies 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 and prescribers about the risk of pigmentary maculopathy or the need for medical, ophthalmological monitoring. Prior to June 2020, 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, Plaintiffs have been injured and suffered damages from Plaintiff Mary Downey's use of Elmiron.

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

PARTIES, JURISDICTION AND VENUE

9. At all relevant times hereto, Plaintiffs MARY DOWNEY and DAVID DOWNEY ("Plaintiffs") were residents and citizens of the state of West Virginia. Plaintiff David Downey is the lawful spouse of Plaintiff Mary Downey.

10. Plaintiff Mary Downey consumed and regularly used Defendants' Elmiron (pentosyn polysulfate sodium) product. As a result of her use of Defendants' Elmiron product, she suffered and continues to suffer severe physical and emotional injuries, including but not limited to, pigmentary maculopathy and blurred vision.

11. 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 Bear Tavern Road, Titusville, New Jersey 08560.

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

13. 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.

14. 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.

15. Upon information and belief, at all relevant times, Janssen Pharma is a wholly owned subsidiary of defendant Johnson & Johnson with its profits inuring to Johnson & Johnson's benefit.

16. Johnson & Johnson and its "family of companies" does business in New Jersey 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.

17. Venue in this action properly lies in Mercer County, as the Defendant Janssen Pharma, the current NDA holder, conducts substantial business and is headquartered in this county.

GENERAL ALLEGATIONS

A. Interstitial Cystitis

18. Interstitial cystitis ("IC") is a medical condition in the bladder that causes bladder pressure, bladder pain, and sometimes pelvic pain.

19. 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.

20. 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.

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

B. Elmiron

22. Elmiron (pentosyn polysulfate sodium, hereafter "PPS") was approved in 1996 to be used as a treatment for IC and painful bladder symptoms.

23. Elmiron is a low molecular weight heparin-like compound. It has anticoagulant and fibrinolytic effects. However, the mechanism of action of pentosan polysulfate sodium in interstitial cystitis is not known.

24. Defendants market Elmiron as "The Only Oral Medication FDA Approved to Treat the Bladder Pain or Discomfort of Interstitial Cystitis (IC)."[1] Although Elmiron is the only oral medication approved by the FDA *specifically* for the purpose of treating IC, that statement is misleading in that Elmiron is not the only oral medication approved by the FDA that can be used to treat IC, and it is not the only IC treatment option.

25. 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 contains multiple treatment options within a line.

26. Upon information and belief, the original NDA was submitted in 1991 which was deemed non-approvable in 1993. A second non-approvable letter was sent in 1994 over concerns about the lack of data on efficacy of the drug. Elmiron was granted an Orphan Drug designation by the FDA in 1995.

27. Upon information and belief, Elmiron was first approved by the FDA in September 1996 for painful bladder symptoms at which time Baker Norton Pharmaceuticals was the sponsor of the New Drug Application.

28. Upon information and belief, in 1997 Elmiron was purchased from Baker Norton Pharmaceuticals and Ivax by Alza Pharmaceuticals (hereinafter "Alza").

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

29. Upon information and belief, Alza held the NDA for Elmiron from approximately April 1998 until August 2002.

30. Upon information and belief, in 2002, Alza Corporation was acquired by Ortho-McNeil Pharmaceuticals, Inc., a subsidiary of Janssen Pharmaceuticals.

31. Upon information and belief, non-parties Janssen Research & Development LLC held the NDA from approximately August 2002 until August 2004.

32. Upon information and belief, defendant Ortho Pharma held the NDA from approximately August 2004 until August 2008.

33. Defendant Janssen Pharma has held the NDA Elmiron since approximately August 2008.

34. Throughout the time Defendants marketed Elmiron, Defendants failed to provide adequate warnings to patients and the medical community, including Plaintiff's prescribing physician, of the risks associated with using the drug.

35. Defendants also failed to adequately test Elmiron to investigate the potential for visual damage and pigmentary maculopathy.

36. Defendants are also liable for the conduct of their predecessors who failed to adequately design, test, and warn of the dangers associated with use of Elmiron.

C. The Dangers of Elmiron

(i) The Poor Bioavailability and Low Efficacy of Elmiron

37. Elmiron is thought to be a "chemical bandaid" that coats the epithelial cells of the bladder to provide pain relief. However, 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.

38. 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.

39. Users must ingest Elmiron for at least 3 to 6 months—and, often longer—to achieve any benefit. One cohort reported that pain relief occurred in only 40% to 60% of patients. Populations of patients receiving extended treatment (>2 years) showed no further improvement or worsening of symptoms, yet users often continue the drug for years.[2] 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.

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

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

effect vs placebo for pentosan polysulfate sodium at the currently established dose or at a third of the daily dose.[3]

41. 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.

(ii) Drug-Induced Retinal Toxicity

42. The administration of drugs that are physiologically foreign to the body can lead to adverse side effects or toxicity with significant consequences. The retina is especially susceptible to the effects of systemic drugs. It has a unique dual blood supply and is one of the most metabolically active tissues in the body. The retina has minimal ability to regenerate and is therefore at high risk of drug toxicity.

43. The symptoms of retinal toxicity include visual impairment, diminished color vision, and blindness, among others.

44. Thus, it is critical that eye care professionals are aware and monitor for adverse drug effects, especially those affecting the retina. For example, the anti-malarial drug Plaquenil (hydroxychloroquine) is known to be associated with retinal toxicity. The label that accompanies that drug contains explicit instructions of the risk of injury and monitoring for signs of toxicity.

> 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)

[3] J Curtis Nickel et al., "Pentosan Polysulfate Sodium for Treatment of Interstitial Cystitis/Bladder Pain Syndrome: Insights From a Randomized Double-Blind, Placebo Controlled Study." *Journal of Urology* (published online first September 20, 2014) available at https://pubmed.ncbi.nlm.nih.gov/25245489/.

> 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.

(iii) Elmiron-Induced Macular Toxicity

42. In November 2018, *Pearce, et al.* reported a case series of patients known to be long term users of Elmiron that presented with an atypical maculopathy that resulted in significant vision loss.[4] They concluded that these patients presented "a novel and possibly avoidable maculopathy associated with chronic exposure to PPS."

43. A follow-up study (*Hanif, et al.*) included a retrospective review of 219 patients seen at Emory University and evaluated vision loss as additional support for the association

[4] Pearce, William A., M.D., et al, "Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium," *Ophthalmology,* Vol. 125, No. 11 (Nov. 2018) at 1793-1802, https://www.aaojournal.org/article/S0161-6420(17)33695-3/fulltext

between Elmiron use and vision loss.[5] Their findings "suggest that PPS–associated maculopathy is a vision-threatening condition that can manifest in the setting of long-term exposure to the drug."

44. In *Jain et al.,* the authors reported that a large, administrative, U.S. database was used to examine the association of PPS use and a diagnosis of a macular disorder.[6] Their exposure cohort (PPS users) was matched 1:5 with an unexposed cohort of patients (not necessarily IC/BPS patients). The primary outcome was any new diagnosis of a hereditary or secondary pigmentary retinopathy or any new diagnosis of dry age-related macular degeneration (AMD) or drusen in addition to the previously described retinopathy. At seven years, there was a statistically significant increase in the exposed group in multivariate analysis (odds ratio [OR] 1.41; 95% confidence interval [CI] 1.09–1.83; p=0.009].

45. At a recent meeting of the American Academy of Ophthalmologists in San Francisco, *Vora et al*. presented their findings using data from Kaiser Permanente and identified 140 patients (from the database of 4.3 million) who had taken an average of 5000 pills over a 15-year period.[7] Of the 140 exposed patients, 91 agreed to an examination and of those, 22 patients showed clear evidence of this specific maculopathy, which authors believe was associated with PPS exposure. This work has since been published in the journal, *Ophthalmology* in January 2020. According to Dr. Vora:

> You have a patient with a chronic condition like interstitial cystitis, for which there is no cure and no effective treatment. They get put on these medications because it's thought to have few side effects

[5] Hanif, Adam M, et al., "Phenotypic Spectrum of Pentosan Polysulfate Sodium-Associated Maculopathy: A Multicenter Study," *JAMA Ophthalmol*, 2019: 137 (11), https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2749093.

[6] Jain, N., et al., "Association of macular disease with long-term use of pentosan polysulfate sodium: Findings from a U.S. cohort," *Br J Ophthalmol.* 2019 Nov 6, 2019, https://bjo.bmj.com/content/104/8/1093.abstract.

[7] American Academy of Ophthalmology, "More evidence linking common bladder medication to a vision threatening eye condition: New study shows about a quarter of patients with significant exposure to the drug show signs of retinal damage." ScienceDaily; Oct 12, 2019, www.sciencedaily.com/releases/2019/10/191012141218.htm.

> and few risks, and no one thinks about it again. And year after year, the number of pills they're taking goes up and up.

Because it's unclear how much medication is too much, Dr. Vora is reported to recommend patients who show no signs of toxicity be screened for retina damage at least once a year. For those who do show some signs of damage, he recommends they speak with their urologist or OB/GYN about discontinuing the medication.

46. *Greenlee et al.* postulated that the mechanism of toxicity of pentosyn polysulfate may relate to the antagonist properties of pentosyn polysulfate towards the fibroblast growth factors 1, 2, and 4.[8] The authors of that publication reported that several known FGF antagonists are associated with significant ocular side effects.

47. In *Lyons, et al.*, published in *Obstetrics and Gynecology* in 2020, the authors made the following screening and follow-up recommendations:

a. Providers discuss the risks associated with pentosan polysulfate with their patients and prescribe the lowest necessary dose and duration of pentosan polysulfate for patients who require long-term treatment. Providers may discuss alternative treatments for interstitial cystitis at their discretion.

b. A baseline examination with fundus photography, optical coherence tomography, and fundus autofluorescence imaging.

c. Testing is repeated within 5 years after pentosan polysulfate initiation and annually, thereafter. Some patients may be at higher risk for developing pentosan polysulfate maculopathy and may benefit from either more frequent screening examinations or drug avoidance.

d. We recommend that patients diagnosed with pentosan polysulfate maculopathy stop taking the drug and discuss alternative interstitial cystitis management options with their treating physician.[9]

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[8] Greenlee, et al., "Letter to the Editor- Re: Pearce et al.: Pigmentary maculopathy associated with chronic exposure to pentosan polysulfate sodium," *Ophthalmology,* https://www.aaojournal.org/article/S0161-6420(18)32881-1/pdf

[9] Lyons, et al. "Pentosan Polysulfate–Associated Macular Disease in Patients With Interstitial Cystitis," *Obstetrics & Gynecology*, Vol. 135:5 (May 2020) at 1091-94, https://journals.lww.com/greenjournal/Abstract/2020/05000/Pentosan_Polysulfate_Associated_Macular_Disease_in.14.aspx

48. Since the original report, there have been more than a dozen papers published in the medical literature regarding atypical maculopathy associated with Elmiron use.

D. Defendants' Failure to Test Elmiron

49. Defendant Janssen Pharma admits, "the mechanism of action of PPS and the pathophysiology of IC is unknown,"[10] 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.

51. 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.

52. Defendant Janssen Pharma acknowledged that its 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.[11]

[10] 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") available at file:///C:/Users/dgold/Downloads/FDA-2012-P-0295-0001_attachment_1.pdf

[11] *Id.* at 11.

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

> A PK study, while generally appropriate for drugs that are systemically absorbed, is inappropriate for determining bioequivalence of an oral dosage form of PPS. Although PPS is systemically absorbed and distributed to the bladder, it has extremely low bioavailability; even with the use of radioactive drug, PPS is difficult to detect in blood or plasma. Due to low serum concentration and the inherent complexity of the product, attempts by the manufacturer of the product, bene, to develop a sensitive and reliable bioassay have been futile. Indeed, Janssen is not aware of any analytical techniques presently available to predict or measure systemic concentration of PPS. . . . Finally, because the mechanism of action of PPS and the pathophysiology of IC is unknown, there is no known pharmacodynamic marker other than clinical effect measured as reduction of pain.[12]

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

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

E. Defendants' Belated Disclosure of Elmiron's Health Risks

56. Prior to June 2020, the label and prescribing information that accompanied Elmiron when prescribed to patients contained the following: "Warnings: None."

[12] *Id.* at 7-8 (internal citations omitted).

57. According to the Drugs@FDA website, the label for Elmiron has been updated on approximately five occasions.[13] Prior to June 2020, Elmiron's label contained no information about vision loss, including pigmentary maculopathy. Prior to June 2020, the label's sole reference to visual adverse events was a disclosure in the Adverse Reactions section that clinical trial patients reported conjunctivitis, optic neuritis, amblyopia, and retinal hemorrhage. However, none of these adverse events were related to pigmentary maculopathy.

58. Despite multiple publications, Defendants' knowledge of countless adverse event reports, and other data to be ascertained through discovery, prior to June 2020 there was no change to the U.S. Elmiron label related to maculopathy and/or vision issues and Defendants failed to take any steps to otherwise warn the medical community and Elmiron users of these significant health risks.

59. On June 16, 2020, the FDA advised of significant changes to Elmiron's label to disclose the risk of retinal pigmentary changes. Among other things, the "Warnings" section of the label, which was previously blank, now warns of irreversible vision changes that can progress even after patients stop taking Elmiron:

> **WARNINGS**
> **Retinal Pigmentary Changes**
> Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON® (see ADVERSE REACTIONS). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor. Visual symptoms in the reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. The visual consequences of these pigmentary changes are not fully characterized. Caution should be used in patients with retinal pigment changes from other causes in which examination findings

[13] *See* Drugs@FDA:FDA-Approved Drugs- Elmiron, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020193 (last visited Sept. 9, 2020).

> may confound the appropriate diagnosis, follow-up, and treatment. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON® . If there is a family history of hereditary pattern dystrophy, genetic testing should be considered. For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, ocular coherence tomography (OCT), and auto-fluorescence imaging) is recommended prior to starting therapy. A baseline retinal examination (including OCT and auto-fluorescence imaging) is suggested for all patients within six months of initiating treatment and periodically while continuing treatment. If pigmentary changes in the retina develop, then risks and benefits of continuing treatment should be re-evaluated, since these changes may be irreversible. Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.

60. Defendants' U.S. label change came too late to prevent Plaintiff and thousands of other Elmiron users from suffering significant injuries and damages.

61. Prior to June 2020, Defendants were long aware of the risks of visual injury with Elmiron. Indeed, prior to June 2020, Defendants made label changes in other countries to warn users of serious vision injury. For example, in September 2019, Defendants changed the label of Elmiron in Canada to reflect the following warning:

Ophthalmologic

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

PLAINTIFF SPECIFIC FACTS

62. In or around April 2010, Plaintiff Mary Downey was diagnosed with interstitial cystitis and was prescribed Elmiron for treatment of her condition.

63. At all times relevant, Defendants represented Elmiron to be appropriate, safe and suitable for such purposes.

64. Plaintiff Mary Downey regularly took Elmiron from approximately April 2010 through October 2019 in accordance with her physician's prescriptions until she was informed by her ophthalmologist that use of Elmiron had caused her vision loss.

65. On October 21, 2019, Plaintiff Mary Downey was diagnosed with pentosane maculopathy.

66. Plaintiff Mary Downey now suffers from blurred vision, difficulty distinguishing colors from one another, difficulty reading, and inability to go outdoors without sunglasses.

67. As a result of Defendants' actions and inactions, Plaintiffs suffered various injuries and damages due to Plaintiff Mary Downey's vision loss. Plaintiffs seek damages associated with these injuries.

68. Defendants ignored reports from patients and health care providers throughout the United States which indicated that Elmiron failed to perform as intended. Defendants also knew or should have known of the effects associated with long term use of Elmiron, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather than conducting adequate testing to determine the cause of these injuries for which it had notice or rule out Elmiron's design as the cause of the injuries, Defendants continued to falsely and misleadingly market Elmiron as a safe and effective prescription drug for interstitial cystitis and painful bladder syndrome.

69. Defendants failed to timely or adequately warn the public and medical community, including Plaintiff Mary Downey's physicians, of the adverse effect or defects in Elmiron despite Defendants' knowledge that it was associated with visual effects following use.

Defendants failed to timely or adequately apprise the public and medical community, including Plaintiff's physicians, to monitor Elmiron users' vision and eyes with regular examination.

70. Defendants' Elmiron was at all times utilized and prescribed in a manner foreseeable to Defendants, as Defendants generated the instructions for use for Plaintiff Mary Downey to take Elmiron.

71. Plaintiff Mary Downey and Plaintiff's physicians foreseeably used Elmiron, and did not misuse, or alter Elmiron in an unforeseeable manner.

72. Through its affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and her physicians the true and significant risks associated with Elmiron consumption.

73. As a result of Defendants' actions, Plaintiff Mary Downey and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff Mary Downey would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' conduct.

74. As a direct result of being prescribed and consuming Elmiron, Plaintiff Mary Downey has been permanently and severely injured, having suffered serious consequences.

75. As a direct and proximate result of her Elmiron use, Plaintiff Mary Downey suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress, loss of earnings, loss of ability to earn money and other economic losses including past and future medical expenses.

76. Despite diligent investigation by Plaintiff Mary Downey into the cause of these injuries, including consultations with medical providers, the nature of the Plaintiff's injuries and

damages and their relationship to Elmiron was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

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

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

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

80. 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.

81. Defendants failed to disclose a known defect and, instead, affirmatively misrepresented that Elmiron was safe for its intended use. Defendants disseminated labeling, marketing, promotion and/or sales information to Plaintiff, her healthcare providers, and the general public regarding the safety of Elmiron knowing such information was false, misleading,

and/or inadequate to warn of the safety risks associated with long-term Elmiron use. Defendants did so willfully, wantonly, and with the intent to prevent the dissemination of information known to them concerning Elmiron's safety.

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

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

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

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

COUNT I
STRICT LIABILITY – FAILURE TO WARN

86. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

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

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

89. Plaintiff Mary Downey 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.

90. 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.

91. Defendants had a continuing duty to provide consumers, including Plaintiff Mary Downey, 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.

92. 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 Mary Downey, 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 Mary Downey.

93. Defendants knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, or otherwise, that Elmiron created a risk of serious and potentially irreversible vision issues, retinal harm and dystrophy, 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.

94. 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 providing adequate clinically relevant information and data or recommending patients be monitored.

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

96. The Elmiron supplied to Plaintiff Mary Downey 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.

97. 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.

98. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff Mary Downey and to Plaintiff's intermediary physicians.

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

100. 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.

101. 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.

102. Defendants had an obligation to provide Plaintiff Mary Downey 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.

103. 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.

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

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

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

107. 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, Plaintiffs 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, loss of consortium, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT II
STRICT LIABILITY – DESIGN DEFECT

108. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

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

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

111. Elmiron was designed in such a way that posed an unreasonable risk of permanent vision and retinal injuries and by placing and keeping Elmiron on the market despite Elmiron being in a defective condition.

112. 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.

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

114. Defendants sold, marketed and distributed a product that is unreasonably dangerous for its normal, intended, and foreseeable use.

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

116. The Elmiron supplied to Plaintiff Mary Downey 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 Mary Downey and other consumers.

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

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

119. 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 Mary Downey and other consumers.

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

121. The Elmiron supplied to Plaintiff Mary Downey 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 Mary Downey and other consumers.

122. The Elmiron supplied to Plaintiff Mary Downey by Defendants was defective in design or formulation in that it's 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.

123. Elmiron's design is more dangerous than a reasonably prudent consumer would expect when used in its intended or reasonably foreseeable manner. It was more dangerous than Plaintiff Mary Downey expected.

124. The intended or actual utility of Elmiron is not of such benefit to justify the risk of retinal damage that may be irreversible and permanently disabling thereby rendering the product unreasonably dangerous.

125. 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.

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

127. Elmiron is defective and unreasonably dangerous to Plaintiff Mary Downey 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.

128. Defendants acted unreasonably in its design of Elmiron in that Defendants failed to adopt a safer design for the product that was practical, feasible, and otherwise a reasonable alternative design or formulation that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

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

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

131. 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, Plaintiffs 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, loss of consortium, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT III
NEGLIGENCE

131. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

132. At all times relevant hereto, it was the duty of Defendants to use reasonable care in the design, labeling, manufacturing, testing, marketing, distribution and/or sale of Elmiron.

133. Defendants failed to exercise ordinary care in the labeling, design, manufacturing, testing, marketing, distribution and/or sale of Elmiron in that Defendants knew or should have known that Elmiron created a high risk of unreasonable harm to Plaintiff Mary Downey and other users.

134. Defendants had no reason to believe that intended and foreseeable users of Elmiron, such as Plaintiff Mary Downey, would realize the potential harms from use of Elmiron.

135. Defendants failed to exercise reasonable care to inform users, such as Plaintiff Mary Downey, of Elmiron's risk of serious and potentially irreversible vision issues and retinal harm.

136. Defendants breached its duty of care to the Plaintiff Mary Downey and her physicians, in the testing, monitoring, and pharmacovigilance of Elmiron.

137. In disregard of its duty, Defendants committed one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Elmiron without thorough and adequate pre- and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Elmiron while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Elmiron;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Elmiron was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Elmiron was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e. Failing to warn Plaintiff Mary Downey, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative products available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Elmiron;

g. Advertising, marketing, and recommending the use of Elmiron, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Elmiron;

h. Representing that Elmiron was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing to manufacture and sell Elmiron with the knowledge that Elmiron was unreasonably unsafe and dangerous;

j. Failing to use reasonable and prudent care in the design, research, testing, manufacture, and development of Elmiron so as to avoid the risk of serious harm associated with the use of Elmiron. Failing to design and manufacture Elmiron so as to ensure the drug was at least as safe and effective as other similar products;

k. Failing to design and manufacture Elmiron reasonably safe for its intended purpose in violation of objective safety standards;

l. Failing to ensure the product was accompanied by proper and accurate warnings about requiring baseline visual examinations and regular eye examinations while using the drug to monitor for retinal or macular toxicity associated with the use of Elmiron;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Elmiron and that use of Elmiron created a high risk of severe injuries; and

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Elmiron.

138. A reasonable manufacturer, designer, distributor, promotor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

139. As a direct and proximate result of the Defendants' negligent testing, monitoring, and pharmacovigilance of Elmiron, Defendants introduced a product that they knew or should have known would cause maculopathy and/or serious and permanent injuries to an individual's vision, and Plaintiff Mary Downey has been injured catastrophically and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

140. 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, Plaintiffs 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, loss of consortium, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT IV
CONSUMER FRAUD ACT

141. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

142. Plaintiff Mary Downey purchased and used Elmiron primarily for personal use and therefore suffered ascertainable losses as a result of Defendants' actions in violation of N.J.S.A. 56:8 *et seq*.

143. Had Defendants not made affirmative misrepresentations, material omissions, and engaged in the deceptive conduct described herein, Plaintiff Mary Downey would not have purchased Elmiron, and would not have incurred damages.

144. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiff Mary Downey that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

145. Despite knowing the falsity and misleading nature of their claims, Defendants engaged in unconscionable commercial practices, deception, fraud, false promise, misrepresentation and/or the knowing concealment, suppression or omission of material facts relative to the safety and efficacy of Elmiron.

146. Defendants intended such actions to mislead patients, healthcare providers, and the

general public with respect to the safety and efficacy of Elmiron.

147. Such actions did, in fact, mislead patients, healthcare providers, and the general public with respect to the safety and efficacy of Elmiron.

148. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Elmiron.

149. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff Mary Downey constituted unfair and deceptive acts and trade practices in violation of N.J.S.A. 56:8 *et seq*.

150. 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, Plaintiffs 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, loss of consortium, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT V
FRAUDULENT MISREPRESENTATION

151. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

152. The Defendants falsely and fraudulently has and continues to represent to the medical and healthcare community, Plaintiff Mary Downey and her physicians, and/or the public that Elmiron has been appropriately tested and was found to be safe and effective.

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

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

155. The representations were, in fact, false. When the Defendants made these representations, it knew and/or had reason to know that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of Elmiron.

156. Prior to Plaintiff's use of Elmiron, Defendants knew or should have known of adverse event reports indicating damage to the retinas and vision of individuals who had taken Elmiron.

157. These representations were made by the Defendants with the intent of defrauding and deceiving the medical community, Plaintiff Mary Downey, and the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public, to recommend, prescribe, dispense, and purchase Elmiron for use as a treatment interstitial cystitis and bladder pain while concealing the drug's known propensity to cause damage to the retina, maculopathy, and vision issues, including potential blindness.

158. Despite the fact that the Defendants knew or should have known of Elmiron's propensity to cause damage to the retina, maculopathy, and vision issues, including potential blindness, the label did not contain any of this information in the "Warnings" section. In fact, after its introduction, the label for Elmiron was updated in 2004, 2006, 2008 (twice), yet at no point did Defendants provide any of the foregoing information in the "Warnings" section. It was not until June 2020 that the Elmiron label began to include warnings and adverse reactions that indicate the dangers of retinal pigmentary changes, damage to the retina, and the need for ongoing retinal examination both during and after using Elmiron.

159. In representations to Plaintiff Mary Downey and/or to her healthcare providers, including Plaintiff's prescribing physician, the Defendants fraudulently stated that Elmiron was safe and omitted warnings related to damage to the retina, maculopathy and vision issues, including potential blindness.

160. In representations to Plaintiff Mary Downey and/or to her healthcare providers, including Plaintiff's prescribing physician, Defendants fraudulently stated that Elmiron was safe and concealed and intentionally omitted material information from the Elmiron product labeling in existence at the time Plaintiff was prescribed Elmiron in 2010, including the warnings and adverse reaction information that now appears on the label.

161. Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of Elmiron, including but not limited to, damage to the retina, maculopathy and vision issues, including potential blindness, and its ability to cause debilitating and/or permanent injuries.

162. The Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

163. The Defendants knew or had reason to know of the dangerous side effects of Elmiron as a result of information from case studies, clinical trials, literature, and adverse event reports available to the Defendants at the time of the development and sale of Elmiron, as well as at the time of Plaintiff's prescription.

164. Defendants' concealment and omissions of material facts concerning the safety of the Elmiron were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff Mary Downey, Plaintiff's physicians, surgeons and healthcare providers and to induce them to purchase, prescribe, and/or use the drug.

165. At the time these representations were made by Defendants, and at the time Plaintiff Mary Downey and/or her physicians used Elmiron, Plaintiff and/or her physicians were unaware of the falsehood of these representations.

166. In reliance upon these false representations, Plaintiff Mary Downey was induced to, and did use Elmiron, thereby causing severe, debilitating, and potentially permanent personal injuries and damages to Plaintiff. The Defendants knew or had reason to know that the Plaintiff had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of Elmiron as described in detail herein.

167. In comporting with the standard of care for prescribing physicians, Plaintiff Mary Downey's prescribing physician relied on the labeling for Elmiron in existence at the date of prescription that included the aforementioned fraudulent statements and omissions.

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

169. Plaintiff Mary Downey did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations and omissions of the Defendants, nor could Plaintiff with reasonable diligence have discovered the true facts about the Defendants' misrepresentations at the time when Elmiron was prescribed to her.

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

171. Defendants have engaged in willful, malicious conduct and/or conduct so careless that it demonstrates a wanton disregard for the safety of others, including Plaintiff, such that the imposition of punitive damages is warranted here.

COUNT VI
BREACH OF EXPRESS WARRANTY

172. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

173. 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.

174. Defendants expressly warranted to Plaintiff Mary Downey, Plaintiff's healthcare providers, and the general public, by and through Defendants and/or its authorized agents or sales representatives, in publications, labeling, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that Elmiron was safe, effective, fit and proper for its intended use.

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

176. Defendants expressly warranted that Elmiron was safe and well-tolerated. However, Defendants 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 Mary Downey and others.

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

178. Plaintiff Mary Downey and Plaintiff's physicians justifiably relied on Defendants' representations regarding the safety of Elmiron, and Defendants' representations became part of

the basis of the bargain.

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

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

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

182. 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, Plaintiffs 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, loss of consortium, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiffs will suffer the losses in the future.

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT VII
BREACH OF IMPLIED WARRANTY

183. Plaintiffs incorporate by reference each and every preceding paragraph as though

fully set forth herein.

184. 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.

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

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

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

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

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

190. Defendants' breach of their implied warranties resulted in ingestion of the

unreasonably dangerous and defective product by Plaintiff Mary Downey, which placed Plaintiff's health and safety at risk and resulted in the damages alleged herein.

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

COUNT VIII
LOSS OF CONSORTIUM, SERVICES, AND SOCIETY

192. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

193. Plaintiff David Downey is Plaintiff Mary Downey's husband.

194. As a result of Plaintiff Mary Downey's Elmiron-related injuries, Plaintiff David Downey has suffered damages including, but not limited to, loss of consortium, society, services, guidance, pecuniary losses, and emotional anguish.

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

COUNT IX
PUNITIVE DAMAGES UNDER NEW JERSEY AND WEST VIRGINIA COMMON LAW, PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, et seq.), and PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-1 et seq.)

196. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

197. 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.

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

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

200. 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.

201. 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.

202. Defendants failed to provide warnings that would have dissuaded health care professionals from using Elmiron, thus preventing health care professionals, including Plaintiff

Mary Downey's prescribing physician, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Elmiron.

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

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

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

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

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

208. 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.

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

WHEREFORE, Plaintiffs respectfully request that Plaintiffs be granted relief against Defendants, as contained in the Prayer For Relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants as follows:

a. Awarding compensatory damages;

b. Awarding loss of consortium damages;

c. Awarding actual damages to the Plaintiff Mary Downey incidental to Plaintiff's purchase and use of Elmiron in an amount to be determined at trial;

d. Awarding punitive damages to the Plaintiffs;

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

f. Awarding the costs and the expenses of their litigation to the Plaintiffs;

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

h. Granting all such other relief as the Court deems necessary, just and proper.

[redacted]

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

[redacted]

Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO RULE 4:5-1

The undersigned attorney for Plaintiffs certifies as follows:

1. The matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration proceeding;

2. No other action or arbitration proceeding is contemplated; and

3. There are no known parties who may be liable to any party on the basis of the transaction or events which form the subject matter of their action that should be joined pursuant to R. 4:28.

I certify that the foregoing statements made by me are true to the best of my knowledge, information and belief. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Civil Case Information Statement

Case Details: MERCER | Civil Part Docket# L-001332-21

Case Caption: DOWNEY MARY VS JANSSEN PHARMACEUTIC ALS, INC.

Case Initiation Date: 06/24/2021

[redacted]

Case Type: PRODUCT LIABILITY

Document Type: Complaint with Jury Demand

Jury Demand: YES - 6 JURORS

Is this a professional malpractice case? NO

Related cases pending: YES

If yes, list docket numbers: MER-L-002338-20

Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

Are sexual abuse claims alleged by: Mary Downey? NO

Are sexual abuse claims alleged by: David Downey? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO

If yes, please identify the requested accommodation:

Will an interpreter be needed? NO

If yes, for what language:

Please check off each applicable category: Putative Class Action? NO **Title 59?** NO **Consumer Fraud?** NO

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule* 1:38-7(b)

06/24/2021
Dated

[redacted]