

Administration (hereinafter referred to as "FDA"), to Plaintiff, and/or the public in general. Further, 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.

Throughout the time Defendants marketed Elmiron, Defendants withheld material adverse events from the public, medical community and FDA. Defendants failed to disclose the serious link between Elmiron use and significant visual damage, including pigmentary maculopathy. Ultimately, tens of thousands of patients, including Plaintiff, were placed at risk and harmed as a result of this misleading conduct.

PARTIES

1. At all times relevant hereto, Plaintiff Kimberly Pelczar was a citizen and resident of Hartford County, in the State of Connecticut.

2. Upon information and belief, Plaintiff consumed and regularly used Defendants' Elmiron (pentosyn polysulfate sodium) product. As a result of her use of Defendants' Elmiron product, Plaintiff suffered from severe physical and emotional injuries, including but not limited to loss of vision, including a diagnosis of retinal macula dystrophy due to Elmiron use. Based on information and belief, Plaintiff's ingestion of Elmiron caused her injuries.

3. Defendant Teva Branded Pharmaceutical Products R&D, Inc. is a Delaware corporation with a principal place of business located at 41 Moores Rd., Frazer, PA 19355.

4. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware Corporation with a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

5. Defendant Teva Branded Pharmaceutical Products R&D, Inc. and Teva Pharmaceuticals USA are subsidiaries of the parent company Teva Pharmaceutical Industries Ltd. with Global Headquarters at 5 Basel Street, Petach Tikva 49131, Israel.

6. Defendant Janssen Pharmaceuticals, Inc, is a New Jersey corporation with a principal place of business in Titusville, New Jersey.

7. Defendant Johnson & Johnson, Inc. is a New Jersey corporation with a principal place of business in New Brunswick, New Jersey.

8. Defendants directly or through their agents or employees designed, manufactured, marketed, and sold Elmiron in the United States which is used to manage symptoms of interstitial cystitis and painful bladder syndrome.

JURISDICTION AND VENUE

9. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy exceeds \$75,000.00 and the Parties are citizens of different states.

10. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because Plaintiff purchased and consumed Elmiron in this District, and was prescribed Elmiron and treated for her injuries in this District.

11. Defendants transact business within this District by selling their products within this District and throughout the United States.

GENERAL ALLEGATIONS

A. Interstitial Cystitis

12. Interstitial cystitis is a medical condition in the bladder that causes bladder pressure, bladder pain, and sometimes pelvic pain. There is no known cause of interstitial cystitis. The symptoms can range from mild to debilitating. The disease is known to affect women more often than men. There is no known cure for interstitial cystitis or painful bladder syndrome.

13. The American Urological Association has established guidelines to provide a clinical framework for the diagnosis and treatment of interstitial cystitis. These guidelines were created by a comprehensive review of the literature. The guidelines include principles for the diagnosis of interstitial cystitis. The AUA guidelines further state that initial treatment type and level should depend on symptom severity, clinician judgment, and patient preferences. Treatments that may be offered are divided into first-, second-, third-, fourth-, fifth-, and sixth-line groups based on the balance between potential benefits to the patient, potential severity of adverse events (AEs) and the reversibility of the treatment. Second-line treatment of interstitial cystitis includes multi-modal pain management approaches including manual therapy and pharmacological options including amitriptyline, cimetidine, hydroxyzine, or pentosan polysulfate.

B. Elmiron

14. Elmiron (pentosan polysulfate sodium) was approved in 1996 to be used as a treatment for interstitial cystitis and painful bladder symptoms.

15. Upon information and belief, Elmiron was developed by Defendants Teva Branded Pharmaceuticals R&D, Inc. and licensed to Janssen Pharmaceuticals who submitted the New Drug Application and now manufactures and distributes Elmiron.

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

17. Upon information and belief, Elmiron was first approved by FDA in September, 1996 for painful bladder symptoms.

18. The label and prescribing information that accompany Elmiron when prescribed to patients contains the following: “Warnings: None.”

19. In addition, according to the Drugs@FDA website, the label for Elmiron has been updated on approximately five occasions, at no time has it contained any information about visual loss, including pigmentary maculopathy, in any section of the label.

20. Elmiron is known to take long time to exert an effect and patients who are prescribed Elmiron are advised to take the drug for at least six months in order to determine if there is an effect. For those patients who take the drug, the drug is known to be used for long-term use and in many patients, use is expected to last years, if not decades.

C. Drug-Induced Retinal Toxicity

21. 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. The retina has an extensive blood supply and vascular network. The retina has minimal ability to regenerate and is therefore at high risk of drug toxicity. Thus, it is critical that eye care professionals are aware and monitor for adverse drug effects, especially those affecting the retina.

22. 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) 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.

D. Elmiron-Induced Macular Toxicity

23. 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.

24. A follow-up study by the same authors (*Hanif, et al.*) included a retrospective review of 219 patients seen at Emory and evaluated vision loss as additional support for the association between Elmiron use and vision loss.

25. In *Jain et al.*, the authors reported a large, administrative, U.S. database was used to examine the association of PPS use and a diagnosis of a macular disorder. 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; $p=0.009$).

26. 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. 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 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.

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

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

publications, Defendants have made no change to the label or taken any steps to warn the medical community and users of the drug regarding these effects.

PLAINTIFF SPECIFIC FACTS

29. Upon information and belief, in approximately 2005, Plaintiff's treating medical physician prescribed Elmiron to Plaintiff due to Plaintiff's medically diagnosed painful bladder and/or interstitial cystitis. Defendants represented Elmiron to be an appropriate and suitable product for such purposes.

30. In or about 2015, Plaintiff began to experience visual symptoms, and on various dates between 2015 and 2019, was seen and evaluated for her visual symptoms and ultimately diagnosed with permanent retinal injury and vision loss due to Elmiron toxicity in approximately 2019.

31. As a result of Defendants' actions and inactions, Plaintiff was injured due to Elmiron which caused Plaintiff various injuries and damages due to her vision loss. Plaintiff accordingly seeks damages associated with these injuries.

32. Defendants ignored reports from patients and health care providers throughout the United States of Elmiron's failure to perform as intended, and injuries associated with long term use which led to the severe and debilitating injuries suffered by Plaintiff, and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries or rule out Elmiron's design as the cause of the injuries, Defendants continued to market Elmiron as a safe and effective prescription drug for interstitial cystitis.

33. Defendants did not timely or adequately apprise the public and physicians, including Plaintiff's physicians, of the adverse effect or defects in Elmiron despite Defendants' knowledge that it was associated with visual effects following use. Defendants did not timely

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

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

35. Plaintiff and Plaintiff's physicians foreseeably used the Defendants' Elmiron, and did not misuse, or alter the Elmiron in an unforeseeable manner.

36. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and his/her physicians the true and significant risks associated with Elmiron consumption.

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

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

39. Plaintiff, as a direct and proximate result of Elmiron, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress, along with economic loss due to medical expenses and living-related expenses due to her new lifestyle.

40. Plaintiff's physicians would not have prescribed Elmiron had Defendants properly disclosed the risks associated with its use or in the alternative, would have actively monitored her vision with regular eye exams.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

41. Defendants failed to disclose a known defect and affirmatively misrepresented that Elmiron was safe for its intended use. Further, Defendant actively concealed the true risks associated with the use of Elmiron. Neither Plaintiff nor the prescribing physician had knowledge that Defendants were engaged in the wrongdoing alleged herein.

42. Because of Defendant's concealment of and misrepresentations regarding the true risks associated with Elmiron, Plaintiff could not have reasonably discovered Defendants' wrongdoing at any time prior to the commencement of this action.

43. Thus, because Defendants fraudulently concealed the defective nature of Elmiron and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendants are estopped from relying on any statute of limitations.

44. Additionally, and alternatively, Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Elmiron caused the appreciable harm sustained by Plaintiff. Plaintiff did not have actual or constructive knowledge of acts indicating to a reasonable person that Plaintiff was the victim of a tort. Plaintiff was unaware of the facts upon which a cause of action rests until less than the applicable limitations period prior to the filing of this action. Plaintiff's lack of knowledge was not willful, negligent, or unreasonable.

COUNT 1 CONNECTICUT PRODUCTS LIABILITY ACT

45. Plaintiff incorporates by reference every preceding paragraph as though fully set forth herein.

46. Plaintiff brings this action pursuant to Connecticut Product Liability Act,

Connecticut General Statutes §§ 52-572m et seq, including those encompassed within the statutory scheme for strict liability and negligence.

A. Plaintiff's Strict Liability Claims

47. At all times relevant hereto, Defendants manufactured, designed, distributed, and/or sold Elmiron.

48. At all times relevant hereto, the dangerous properties of Elmiron were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug to their patients.

49. The Elmiron product as distributed by Defendants was a defective and unreasonably dangerous product, to render the products reasonably safe for its ordinary, intended, and reasonably foreseeable uses; in particular the common, foreseeable and intended use of Elmiron to treat painful bladder syndrome and interstitial cystitis.

50. The Elmiron product, as distributed by Defendants, was dangerous at the time it left the Defendants' control.

51. Plaintiff did not misuse or materially alter the Elmiron as prescribed and dispensed to Plaintiff and used by Plaintiff.

52. At the time the Elmiron product left Defendants' control, there existed feasible and suitable alternative design for the treatment of interstitial cystitis that was capable of preventing Plaintiff's damages or alternatively a plan for monitoring ocular health in association with use of Elmiron.

53. When compared to other feasible alternatives, the Elmiron product greatly results

in a much higher risk of visual injuries and side effects. Other feasible alternative treatments exist which do not present the same frequency and severity of these risks.

54. At all times relevant to this action, Defendants manufactured, supplied, distributed, and/or sold Elmiron in a defective and dangerous condition, as described above, to Plaintiff.

55. The Elmiron received by Plaintiff did not perform safely as an ordinary consumer would have expected it to perform when used in a reasonably foreseeable way.

56. The incident that caused the harm to the Plaintiff was of a kind that does not ordinarily occur in the absence of a product defect and any defect most likely existed at the time the product left the manufacturer's or seller's control and was not the result of reasonably possible causes not attributable to the manufacturer or seller.

57. Furthermore, a reasonable patient would conclude the possibility and seriousness of harm outweighs the benefit from its normal, intended use.

B. Plaintiff's Design Defect Claims

58. At all times relevant hereto, Defendants manufactured, designed, distributed, and/or sold Elmiron.

59. At all times relevant hereto, the dangerous and defective design of Elmiron was known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their product, and not known to ordinary physicians who would be expected to prescribe the drug to their patients.

60. The Elmiron product as distributed by Defendants was a defective in design and an unreasonably dangerous product, to render the product reasonably safe for its ordinary,

intended, and reasonably foreseeable uses; in particular the common, foreseeable and intended use of Elmiron to treat painful bladder syndrome and interstitial cystitis.

61. The Elmiron product, as distributed by Defendants, was dangerous at the time it left the Defendants' control.

62. Plaintiff did not misuse or materially alter the Elmiron as prescribed and dispensed to Plaintiff and used by Plaintiff.

63. At the time the Elmiron product left Defendants' control, there existed feasible and suitable alternative design for the treatment of interstitial cystitis that was capable of preventing Plaintiff's damages or alternatively a plan for monitoring ocular health in association with use of Elmiron.

64. When compared to other feasible alternatives, the Elmiron product greatly results in a much higher risk of visual injuries and side effects. Other feasible alternative treatments exist which do not present the same frequency and severity of these risks.

65. At all times relevant to this action, Defendants manufactured, supplied, distributed, and/or sold Elmiron in a defective and dangerous condition, as described above, to Plaintiff.

66. The Elmiron received by Plaintiff did not perform safely as an ordinary consumer would have expected it to perform when used in a reasonably foreseeable way.

67. The incident that caused the harm to the Plaintiff was of a kind that does not ordinarily occur in the absence of a product defect and any defect most likely existed at the time the product left the manufacturer's or seller's control and was not the result of reasonably possible causes not attributable to the manufacturer or seller.

68. Furthermore, a reasonable patient would conclude the possibility and seriousness

of harm outweighs the benefit from it's normal, intended use.

C. Plaintiff's Negligence Based Claims

69. Further, at all times relevant hereto, it was the duty of Defendants to use reasonable care in the manufacturing, design, distribution, and/or sale of Elmiron.

70. Defendants failed to exercise ordinary care in the manufacture, sale, labeling, and marketing Elmiron in that Defendants know or should have known that Elmiron created a high risk of unreasonable harm to Plaintiffs and other users.

71. 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, 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 who 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. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative products were available for use for the purpose for which Elmiron was manufactured;
- j. Continuing to manufacture and sell Elmiron with the knowledge that Elmiron was unreasonably unsafe and dangerous;
- k. Failing to use reasonable and prudent care in the design, research, 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;
- 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.

72. As a direct and proximate result of one or more of the above-stated acts by Defendants in violation of the Connecticut Product Liability Act under strict liability and negligence based theories, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at lengthy herein, and prays judgment in her favor and against the Defendants awarding the following:

1. A monetary award, sufficient to compensate plaintiff for the following categories of damages:
 - a. General damages for severe physical pain, mental suffering, inconvenience, and loss of the enjoyment of life;
 - b. Past, present, and future damages for costs of medical and rehabilitative treatment and care for Plaintiff;
 - c. Past wage loss and future loss of earning capacity.
2. Plaintiff's cost of this action, together with interest on past and future special and general damage amounts from the date of injury at the legal rate until paid, interest on any judgment awarded herein at the legal rate until paid, and such other and further relief as the Court deems equitable and just.
3. Any other award this Court deems equitable and just.
4. Plaintiff demands a jury trial.

Date: March 26, 2020

s/ Kathleen Natri
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