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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

BEVERLY N. ZEKOFF,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION NO.:**
	)	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, INC., TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, and TEVA PHARMACEUTICALS USA, INC.	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

COMPLAINT

COMES NOW THE PLAINTIFF, Beverly N. Zekoff ("Plaintiff"), and by and for her Complaint against Defendants, states and alleges as follows:

INTRODUCTION

This is a personal injury action for damages arising from Plaintiff's use of Defendants' (Teva Branded Pharmaceutical Products R&D, Teva Pharmaceuticals USA, Inc., Janssen Pharmaceuticals, Inc, and Johnson & Johnson, Inc. (collectively "Defendants")) dangerously defective prescription drug, Elmiron (pentosyn polysulfate sodium), prescribed for the treatment of interstitial cystitis and bladder pain. Each of the Defendants designed, marketed, and distributed Elmiron in the United States, all the while knowing significant risks that were never disclosed to the medical and healthcare community, including Plaintiff's prescribing doctor, Food and Drug Administration (hereinafter referred to as "FDA"), to Plaintiff, and/or the public in general. Further, all of the 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, all of the Defendants withheld material adverse events from the public, medical community and FDA. All of the Defendants failed to disclose the serious link between Elmiron use and significant visual damage, including pigmentary maculopathy and toxic 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 Beverly Zekoff was a citizen and resident of Jefferson County, Alabama and is domiciled in Alabama.

2. Plaintiff consumed and regularly used Defendants' Elmiron (pentosyn polysulfate sodium) product.

3. 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, lighting adjustment problems, color discernment loss, loss of nighttime vision, and loss of balance including a diagnosis of toxic maculopathy in June of 2020 due to Elmiron use.

4. Plaintiff's ingestion of Elmiron caused her injuries.

5. Defendant Teva Branded Pharmaceutical Products R&D, Inc. (hereinafter referred to as "Teva Branded") is a Delaware corporation with a principal place of business located at 41 Moores Rd., Frazer, PA 19355.

6. Defendant Teva Branded is domiciled in Delaware and Pennsylvania.

7. Defendant Teva Pharmaceuticals USA, Inc. (hereinafter referred to as "Teva USA") is a Delaware Corporation with a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

8. Defendant Teva USA is domiciled in Delaware and Pennsylvania.

9. Defendants Teva Branded and Teva USA are subsidiaries of the parent company Teva Pharmaceutical Industries Ltd. with Global Headquarters at 5 Basel Street, Petach Tikva 49131, Israel.

10. Defendant Janssen Pharmaceuticals, Inc, (hereinafter referred to as "Janssen") is a New Jersey corporation with a principal place of business in Titusville, New Jersey.

11. Defendant Janssen is domiciled in New Jersey.

12. Defendant Johnson & Johnson, Inc. (hereinafter referred to as "J&J") is a New Jersey corporation with a principal place of business in New Brunswick, New Jersey.

13. Defendant J&J is domiciled in New Jersey.

14. Defendants Teva Branded, Teva USA, Janssen, and J&J designed, manufactured, marketed, and sold Elmiron to the Plaintiff.

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

JURISDICTION AND VENUE

16. 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.

17. 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.

18. All Defendants transact business within this District by selling their products

within this District and throughout the United States.

GENERAL ALLEGATIONS

A. Interstitial Cystitis

19. 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.

20. 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 pentosyn polysulfate.

B. Elmiron

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

22. Elmiron was first developed by Defendant Teva Branded and licensed to Janssen who submitted the New Drug Application and now manufactures and distributes Elmiron.

23. As mentioned previously, Defendants Teva Branded, Teva USA, Janssen, and

J&J designed, manufactured, marketed, and sold the Elmiron which caused Plaintiff's injuries.

24. 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.

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

26. The label and prescribing information that accompany Elmiron when prescribed to patients contains the following: "Warnings: None."

27. Prior to June 2020, the "Warnings: None" labeling was affixed to the Elmiron products sold to Plaintiff by Defendants Teva Branded, Teva USA, Janssen, and J&J.

28. In addition, according to the Drugs@FDA website, the label for Elmiron was updated on approximately five occasions prior to June 16, 2020, and at no time prior June 16, 2020, has it contained any information about visual loss, including pigmentary maculopathy and toxic maculopathy, in any section of the label.

29. On June 16, 2020, the Defendants were instructed to add the following warnings to each package of Elmiron sold in the United States: "Retinal Pigmentary Changes".

30. Specifically, the warning states that "Pigmentary changes in the retina, reported in the literatures as pigmentary maculopathy, have been identified with long-term use of ELMIRON".

31. Unfortunately, this warning was issued far too late for the Plaintiff, as she began taking Elmiron in 2001.

32. Elmiron is known to take a 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.

33. In the case of the Plaintiff, she took Elmiron for nineteen (19) years before any of the Defendants decided to warn her of the risk of pigmentary changes, pigmentary maculopathy, or toxic maculopathy associated with the use of Elmiron.

C. Drug-Induced Retinal Toxicity

34. 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.

35. 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.

36. 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.

37. 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).

38. 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.

39. 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

40. 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.

41. 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.

42. 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].

43. 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. Dr. Yora states that 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.

44. 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.

45. *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. The authors of that publication reported that several known FGF antagonists are associated with significant ocular side effects.

46. 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.

47. Despite these publications, Defendants only made the change to the labeling in June of 2020.

PLAINTIFF SPECIFIC FACTS

48. In 2001, Plaintiff's treating medical physician prescribed Elmiron to Plaintiff due to Plaintiff's medically diagnosed painful bladder and/or interstitial cystitis.

49. All Defendants represented Elmiron to be an appropriate and suitable product for such purposes.

50. Plaintiff suffered visual symptoms and was seen and evaluated for her visual symptoms and ultimately diagnosed with permanent retinal injury and vision loss due to Elmiron toxicity in June of 2020.

51. 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.

52. Specifically, Defendants Teva Branded, Teva USA, Janssen, and J&J each failed to warn the Plaintiff that there was a risk of pigmentary maculopathy or toxic maculopathy associated with the use of Elmiron.

53. Plaintiff accordingly seeks damages associated with these injuries.

54. All of the 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.

55. Rather than doing adequate testing to determine the cause of these injuries or rule out Elmiron's design as the cause of the injuries, the Defendants collectively and individually continued to market Elmiron as a safe and effective prescription drug for interstitial cystitis.

56. All of the Defendants did not timely or adequately apprise the public and

physicians, including Plaintiff's physicians, of the adverse effect or defects in Elmiron despite their knowledge that it was associated with pigmentary changes following use.

57. The 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.

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

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

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

61. Specifically, Defendants Teva Branded, Teva USA, Janssen, and J&J each failed to warn the Plaintiff and her physician that Elmiron use can result in retinal pigmentary changes and/or toxic maculopathy.

62. 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.

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

64. 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.

65. 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.

66. All of the Defendants failed to disclose a known defect and affirmatively misrepresented that Elmiron was safe for its intended use.

67. Further, each Defendant actively concealed the true risks associated with the use of Elmiron.

68. Neither Plaintiff nor the prescribing physician had knowledge that Defendants were engaged in the wrongdoing alleged herein.

69. By failing to warn Plaintiff of the risk of retinal pigmentary changes, pigmentary maculopathy, and toxic maculopathy prior to June of 2020, Defendants Teva Branded, Teva USA, Janssen, and J&J restricted the risks associated with taking Elmiron from the Plaintiff.

70. When in reality, Elmiron is a drug that has significant side effects that make its manufacture and design harmful to those who use it, like the Plaintiff.

COUNT 1

Violations of Alabama Extended Manufacturer's Liability Doctrine

71. Plaintiff incorporates by reference paragraphs 1-70 as pertinent to the allegations in this Count and as though fully set forth herein.

72. Defendants Teva Branded, Teva USA, Janssen, and J&J designed, manufactured, marketed, labeled, and sold Elmiron to the Plaintiff.

73. At the time the Defendant sold the Elmiron drugs to the Plaintiff, they contained manufacturing and design defects.

74. The Elmiron products reached Plaintiff without substantial change in the condition in which they were sold.

75. The Emilron products were not reasonably safe when used in a foreseeable manner. In that there were foreseeable defects in the design of the drug which could cause and did cause undisclosed ophthalmological side effects including pigmentary maculopathy and toxic maculopathy and other significant eye and vision problems.

76. The Elmiron products were in an unreasonably dangerous condition at the time the drug left Defendants' control and were placed in the stream of commerce, and at the time it was prescribed to and purchased by Plaintiff.

77. Plaintiff took Elmiron products as prescribed. At the time she took the drug, it was in substantially the same condition as when it left the control of Defendants.

78. As a direct and proximate cause of these defects, Plaintiff suffered injuries, including but not limited to: toxic maculopathy, loss of vision, blurry vision, loss of nighttime vision, color discernment lighting adjustment problems, loss of balance, emotional distress, loss of money, compensatory damages, punitive damages, attorneys fees and costs, and all other damages a jury determines to be appropriate.

79. Plaintiff's injuries and losses are permanent in nature and Plaintiff will continue to suffer undue duress and losses in the future.

COUNT 2

Failure to Warn

80. Plaintiff incorporates by reference paragraphs 1-70 as pertinent to the allegations

in this Count and as though fully set forth herein.

81. This count applies to Defendants Teva Branded, Teva USA, Janssen, and J&J.

82. Defendants Teva Branded, Teva USA, Janssen, and J&J designed, manufactured, marketed, labeled, and sold Elmiron to the Plaintiff.

83. All Defendants placed Elmiron on the market.

84. All Defendants named in this action had a duty to warn the Plaintiff and her physicians regarding the dangers associated with the customary and intended use of Elmiron.

85. All of the Defendants failed to warn the Plaintiff and her physicians (foreseeable users) that Elmiron causes pigmentary maculopathy and toxic maculopathy.

86. All of the Defendants knew or should have known that Elmiron causes pigmentary maculopathy and toxic maculopathy.

87. By failing to warn the Plaintiff of the risks associated with the intended and customary usage of Elmiron, including that of pigmentary maculopathy and toxic maculopathy, all of the Defendants proximately caused the injuries suffered by the Plaintiff.

88. The Elmiron that the Plaintiff used was substantially unaltered each and every time she used it.

89. The Plaintiff used Elmiron for its intended purpose.

90. Plaintiff's injuries include but are not limited to: toxic maculopathy, loss of vision, blurry vision, loss of nighttime vision, color discernment lighting adjustment problems, loss of balance, emotional distress, loss of money, compensatory damages, punitive damages, attorneys fees and costs, and all other damages a jury determines to be appropriate.

91. Plaintiff's injuries and losses are permanent in nature and Plaintiff will continue to suffer undue duress and losses in the future.

COUNT 3

Negligence/Wantonness

92. Plaintiff incorporates by reference paragraphs 1-70 as pertinent to the allegations in this Count and as though fully set forth herein.

93. This count applies to Defendants Teva Branded, Teva USA, Janssen, and J&J.

94. Defendants Teva Branded, Teva USA, Janssen, and J&J designed, manufactured, marketed, labeled, and sold Elmiron to the Plaintiff.

95. All of the Defendants owed a duty to the Plaintiff to exercise reasonable care to make, design, manufacture, market, promote, label, and distribute Elmiron in a manner that is reasonably safe for the use of the Plaintiff and purpose for which it was intended.

96. All of the Defendants, in breach of the duty described above, negligently, wantonly, and carelessly designed, manufactured, marketed, promoted, labeled, distributed, and sold Elmiron to the Plaintiff for her use.

97. As direct and proximate result of the conduct of the Defendants, Plaintiff ingested Elmiron and was damaged causing Elmiron to be unfit for its intended use.

98. As a direct and proximate result of the conduct of the Defendants, the Elmiron was unfit for its intended use.

99. As a direct and proximate cause of this negligent, willful, and/or wanton breach, Plaintiff has suffered damages that include but are not limited to: toxic maculopathy, loss of vision, blurry vision, loss of nighttime vision, color discernment lighting adjustment problems, loss of balance, emotional distress, loss of money, compensatory damages, punitive damages, attorneys fees and costs, and all other damages a jury determines to be appropriate.

100. Plaintiff's injuries and losses are permanent in nature and Plaintiff will continue

to suffer undue duress and losses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory damages, special damages, exemplary damages, punitive damages, attorneys fees, costs, and all such other damages to which Plaintiff may be entitled under Alabama law, all in an amount to be determined by a jury, and for all such other relief and costs that are deemed just and proper.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues so triable.

Dated: October 30, 2020

Respectfully submitted,
/s/ D.G. Pantazis, Jr.
D.G. Pantazis, Jr.
Attorney for Plaintiff and the Proposed Classes

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