UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

MARY LEE ALLEN, Plaintiff, v. JANSSEN PHARMACEUTICALS, INC. and JOHNSON & JOHNSON, Defendants.	**Case Number:** **Judge:** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

COMES NOW THE PLAINTIFF, Mary Lee Allen ("Plaintiff"), and by and for her Complaint against Defendants, states and alleges upon information and belief and based upon the investigation of counsel, as follows:

INTRODUCTION

1. This is a class action to allow Plaintiff and Class members (defined below) to seek and receive appropriate diagnostic services and other declaratory relief they require as a direct and proximate result of the negligent and wrongful misconduct of Defendants in connection with the development, design, promotion, marketing, and sale of Defendants' dangerously defective prescription drug, Elmiron (pentosyn polysulfate sodium) (the "drug").

2. Elmiron is prescribed for the treatment of interstitial cystitis and bladder pain. Defendants designed, marketed, and distributed Elmiron in the United States, all the while knowing significant health risks were never disclosed to: 1) Plaintiff and other Class Members' prescribing doctors; 2) the Food and Drug Administration (the "FDA"); 3) Plaintiff and other Class Members; and/or 4) the general public . Defendants failed to provide adequate

warnings to patients and the medical community—including Plaintiff's prescribing physician—regarding the risks associated with using Elmiron.

3. Throughout the time Defendants marketed Elmiron, Defendants withheld material adverse events from the public, medical community, and the 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.

4. As demonstrated in the medical literature, many patients experiencing retinal damage can be asymptomatic prior to the manifestation of significant injuries. As such, Plaintiff and Class Members are entitled to diagnostic testing to determine the state of their visual health, including the retina and macula of their eyes. The notice plan and diagnostic program described below will arm Plaintiff, Class members, and their doctors with the knowledge they need to take steps to protect themselves from future harm as a result of the design defects inherent in Elmiron. As described below, each patient is in need of a regular eye exam to monitor for any signs of early retinal damage or damage that may occur after stopping Elmiron use.

5. The relief Plaintiff seeks on her own behalf and on behalf of the Class is reasonable and consistent with the FDA's approved labeling on other drugs associated with retinal damage. Those labels, described below, generally require patients receive regular eye exams to monitor for signs of retinal damage and that they should cease use of the drug at the first sign of damage.

PARTIES

6. At all times relevant hereto, Plaintiff and proposed Class Representative Mary Lee Allen, was a citizen and resident of the State of Illinois.

7. Upon information and belief, Plaintiff consumed and regularly used Defendants' Elmiron (pentosyn polysulfate sodium) product from 2009 to the present. As a result of her use of Elmiron, Plaintiff is at risk of severe visual injuries, including but not limited to loss of vision, retinal macular dystrophy, pigmentary maculopathy, or atypical macular degeneration.

8. Defendant Janssen Pharmaceuticals, Inc, is a Pennsylvania domestic business corporation with a principal place of business in Horsham, Pennsylvania.

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

10. Defendants directly or through their agents or employees designed, manufactured, marketed, and sold Elmiron in the United States to manage symptoms of interstitial cystitis and painful bladder syndrome. It was marketed and sold to patients such as Plaintiff throughout the United States, including in the states for which Plaintiff seeks certification of statewide classes, as set forth below.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.§ 1332(d)(2), because this is a class action filed under Rule 23 of the Federal Rules of Civil Procedure; where there are hundreds, if not thousands, of proposed Class Members; the aggregate amount in controversy exceeds the jurisdictional amount or $5,000,000.00; and the Defendants are citizens of a State different from that of Plaintiff and the Class.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendant Janssen Pharmaceuticals, Inc., is a domestic business corporation in this District and regularly transacts business within this District.

GENERAL ALLEGATIONS

A. Interstitial Cystitis.

13. 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.

14. 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.

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

16. Upon information and belief, Elmiron was granted an Orphan Drug designation in 1995. 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 originally submitted for approval by Baker Norton Pharmaceuticals, a

division of Ivax Pharmaceuticals that has since been purchased by Teva Pharmaceuticals, Inc. Elmiron was ultimately licensed to Janssen Pharmaceuticals who is the current holder of the NDA and now manufactures and distributes Elmiron.

17. 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.

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

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

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

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

26. 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].

27. 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.

28. Importantly, Dr. Vora's research published in the *Ophthalmology* journal in January 2020, demonstrated that more than 23 percent of the screened patients (Elmiron users) had definite evidence of maculopathy. Further, visual acuity was generally preserved even in patients with signs of toxicity, meaning the subjects had not yet begun to notice a significant change in their sharpness of vision.

29. *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.

30. 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, recommending guidelines for visual examinations to monitor for signs of visual toxicity.

31. 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.

32. In addition, a recent case report by *Wingelaar, et al.* in *Urology*, notes a patient with retinal toxicity who was completely asymptomatic.

33. 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 risks which is particularly troubling because patients may be asymptomatic even with retina damage.

34. More troubling, Defendants made label changes in other countries to warn of these injuries. 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.

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action pursuant to Fed. R. Civ. P. 23 on her own behalf and on behalf of the classes defined as follows:

> **Illinois Class**
> *All individuals in Illinois who were prescribed and took Elmiron who are currently asymptomatic for pigmentary maculopathy and have not received a diagnosis of retinal toxicity due to Elmiron use. Claims for actual injury from Elmiron use are excluded from the claims brought in this Class Action.*
>
> **National Class**
> *All individuals within the U.S. who were prescribed and took Elmiron who are currently asymptomatic for pigmentary maculopathy and have not received a diagnosis of retinal toxicity due to Elmiron use. Claims for actual injury from Elmiron use are excluded from the claims brought in this Class Action.*

36. The Class claims all derive directly from a single uniform and standardized course of conduct by the Defendants towards the Class. Defendants did not differentiate, in degree of care or candor, its actions or inactions among individual Class members. The objective facts are the same for all Class members. Within each Claim for Relief, the same legal standards under Illinois and/or federal law govern.

37. The prerequisites to maintaining a class action under Fed. R. Civ. P. 23(a) and (b) regarding numerosity, commonality, typicality, adequacy, predominance, and superiority are met.

38. *Numerosity:* Upon information and belief, Plaintiff states there are thousands of individuals who were prescribed and consumed Elmiron during the relevant time period. Therefore, the proposed Class is so numerous that joinder of all individual members is impractical, and the disposition of their claims as a Class will benefit the parties and the Court.

39. *Commonality/Predominance:* Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to Plaintiff and Class Members are:

a. The degree of risk of visual injury they were exposed to during Elmiron use;

b. Whether they are at a greater risk of visual injuries, including macular degeneration and maculopathy at rates higher than, or through a more dangerous manner than, the general population;

c. Whether Defendants knew or should have known of visual injuries associated with Elmiron use;

d. Whether their risk of visual injuries was caused by the negligence of the Defendants;

e. Whether Elmiron is defectively designed;

f. Whether safer alternative designs for the treatment of interstitial cystitis existed which do not carry a risk of visual injuries;

g. Whether Elmiron is unsafe for its intended use; and

h. Whether Defendants are legally responsible for implementing and maintaining a medical monitoring fund to provide visual examination to monitor visual health.

40. *Typicality:* Plaintiff's claims are typical of the claims of Class Members because she was prescribed and consumed Elmiron during the time period in which the allegedly defective prescription drug was un-labeled as to risks of maculopathy Plaintiff alleges that her exposure to Elmiron occurred in substantially the same way. As such, the claims or defenses of the representative party is typical of the claims or defenses of the class.

41. *Adequacy:* Plaintiff will fairly and adequately protect the interests of Class Members. Plaintiff has retained counsel competent and experienced in complex class action litigation and with adequate resources to assure the interests of the Class will not be harmed. The named Plaintiff is typically situated and has no conflict of interest with the Class as a whole.

42. *Superiority:* A class action is superior to other available methods for the fair and efficient adjudication of the controversy, because, inter alia, it is economically infeasible for Class Members to prosecute individual actions of their own. Given the material similarity of the Class Members' claims, even if each Class member could afford to litigate a separate claim, this Court should not countenance or require the filing of thousands of identical actions. Individual litigation of the legal and factual issues raised by Defendants' conduct would cause unavoidable delay, a significant duplication of efforts, and an extreme waste of resources. Alternatively, proceeding by way of a class action would permit the efficient supervision of the putative class' claims, create significant economies of scale for the Court and the parties, and result in a binding, uniform adjudication on all issues

43. The case will be manageable as a class action. A class action is appropriate because common questions of law and fact predominate over any individual questions affecting only

individual members. Class treatment is superior to the alternatives for the fair and efficient adjudication of the controversy alleged herein. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the duplication of effort and expense that numerous individual actions would entail. No difficulties are likely to be encountered in the management of this class action that would preclude its maintenance as a class action, and no superior alternative exists for the fair and efficient adjudication of this controversy. Without a class action, Defendants will remain free from responsibility for exposing thousands of patients to visual injuries that may result in complete loss of vision and Class Members, who have limited resources, will either be forced to fund their own medical screening or forgo the necessary screening due to financial constraints.

44. By negligently exposing Plaintiff and Class Members to a risk of visual injury as a result of Elmiron use, Defendants acted or refused to act on grounds generally applicable to the Class, thereby making the implementation and maintenance of a medical monitoring fund and declaratory relief the appropriate remedies for the Class.

45. The Class Members are ascertainable based upon objective criteria in that all Class members received the drug through prescriptions from their physicians and proof of use can be supplied through medical or pharmacy records. There is a reliable and administratively feasible mechanism for determining whether putative Class members fall within the class definition based upon the information in their medical records and length of time they used Elmiron.

46. Specifically, Plaintiff seeks a medical monitoring protocol which consists of (1) a notice campaign to all Class members informing them of the availability and necessity of the medical motoring protocol; and (2) a visual examination by a retinal specialist, including an OCT scan and/or fundus photography to be performed on every class member who used Elmiron who

will then consult with the Class members' physician to determine if any treatment is clinically necessary and, if so, to provide the physician with necessary information regarding treatment or monitoring of the visual findings.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

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

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

49. 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 affirmative defense.

50. Additionally, and alternatively, Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Elmiron was capable of causing the appreciable harm for which Plaintiff and the Class are now at risk. 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 I
MEDICAL MONITORING
(Class Action)

51. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth

herein.

52. The latency period for the manifestation of a visual injury, including maculopathy, could occur any time after sustained use of the drug and upon information and belief, can continue to increase even after cessation of the drug.

53. Plaintiff and Class Members have been exposed to Elmiron which induces maculopathy at rates higher than, or in a substantially more dangerous manner than, the general population. Plaintiff's exposure levels are therefore substantial in nature.

54. Plaintiff and the Class Members' exposure to Elmiron with no warning as to the risks of maculopathy and the necessity of regular visual exams was caused by Defendants' negligence as follows: a) Failing to conduct adequate safety and efficacy testing before seeking to have Elmiron put into the stream of commerce; b) Failing to notify the FDA of reports of associations between Elmiron and the risk of maculopathy; and c) Failing to warn Plaintiff and Class Members of the potential for visual injuries including maculopathy and the necessity for ongoing and regular eye examination to monitor visual health.

55. Plaintiff's and the Class Members' exposure to Elmiron was proximately caused by Defendants' negligence as described herein.

56. Monitoring procedures exist that make the detection of visual injuries, including maculopathy, possible.

57. Visual injuries are capable of early detection by way of existing scientific methods including, but not limited to, Optimal Coherence Tomography (OCT) and fundus photography.

58. Because retinal screening is not conducted in routine eye examinations, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and Class Members require specialized screening not within the purview of

routine medical exams.

59. The prescribed monitoring regime is reasonably necessary according to contemporary scientific principles in order to provide early diagnosis of maculopathy leading to benefits in treatment, management, rehabilitation and prevention or mitigation of long-term health consequences, including permanent loss of vision.

COUNT II
DECLARATORY RELIEF PURUSANT TO 28 U.S.C. § 2201, *ET SEQ*.
(Class Action)

60. Plaintiff incorporates by reference the preceding paragraphs as if f

61. ully set forth herein.

62. Pursuant to 28 U.S.C. § 2201, a court may "declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

63. Declaratory relief is intended to minimize "the danger of avoidable loss and unnecessary accrual of damages." 10B Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2751 (3d ed. 1998).

64. Plaintiff alleges that Elmiron is defective in that it significantly increases the risk of visual injury when used as prescribed.

65. There are actual controversies between the Defendants and Plaintiff, including prospective Class members, concerning: 1) whether Elmiron is defective, 2) whether the Defendants knew, or should have known, of defects in Elmiron, and 3) whether the Defendants failed to adequately warn of the risk of visual injuries with Elmiron.

66. The declaratory relief requested herein will generate common answers that will settle the controversy related to the alleged defects in Elmiron. There is an economy to resolving

this issue as it has the potential to eliminate the need for continued and repeated litigation regarding alleged defects in this drug.

67. Plaintiff therefore seeks a declaration that Elmiron is defective, and that the Defendants must expeditiously notify the Classes of such defects.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment against Defendants on behalf of herself and the Classes, awarding the following:

A. An order certifying the proposed Classes and designating Plaintiff as the named representatives of the Classes, and designating the undersigned as Class Counsel;

B. A declaration that Elmiron is defective and unsafe for its intended use;

C. A declaration that Defendants are financially responsible for implementing and maintaining a fund for the medical monitoring of Plaintiff and Class Members;

D. An award to Plaintiff and Class Members of damages, costs and disbursements in this action, including reasonable attorneys' fees, as permitted by law;

E. An award of pre-judgment and post-judgment interest, as provided bylaw; and

F. Such other relief as may be appropriate under the circumstances.

JURY TRIAL DEMANDED

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

Dated: May 6, 2020

Respectfully submitted,

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