UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ANGELO ZENEZ, Plaintiff, v. JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a Johnson & Johnson Research & Development, L.L.C.; JANSSEN ORTHO LLC; and JOHNSON & JOHNSON, Defendants.	**JURY DEMAND**

COMPLAINT

ANGELO ZENEZ ("Plaintiff"), by and through his attorneys, SMITH LACIEN LLP, hereby sues JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc.; ORTHO-MCNEIL PHARMACEUTICALS, INC.; JANSSEN RESEARCH & DEVELOPMENT LLC f/k/a Johnson & Johnson Research & Development, L.L.C.; JANSSEN ORTHO LLC; and JOHNSON & JOHNSON, (collectively, "Defendants"), and alleges as follows:

INTRODUCTION

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

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

3. Elmiron injured Plaintiff by causing harmful, but latent, eye issues, which ultimately resulted in 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, scientific studies, and even alerts by governmental agencies have established that Elmiron causes retinal damage.

6. Nevertheless, to date, Defendants have failed to warn, advise, educate, or otherwise inform Elmiron users, prescribers, or governmental regulators in the United States about the risk of pigmentary maculopathy or the need for medical, ophthalmological monitoring. As of the filing of this Complaint, the U.S. label for Elmiron makes no mention of risk to patients' eyes or vision.

7. As a proximate result Defendants' wrongful actions and inactions, Plaintiff was injured and suffered damages from her use of Elmiron.

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

PARTY PLAINTIFF

9. Plaintiff ANGELO ZENEZ is an Illinois citizen residing in Cook County, Illinois. Plaintiff took Elmiron as prescribed by his physician due to health issues and took Elmiron from approximately 1997 through 2003. Plaintiff was given no warning and had no knowledge of the serious risk of retinal damage and vision loss posed by Elmiron. As a result of his exposure to Elmiron, Plaintiff suffers from, without limit, difficulty adapting to dim lighting, difficulty reading, and blurred, distorted and cloudy vision.

PARTY DEFENDANTS

10. Defendant JANSSEN PHARMACEUTICALS, INC., f/k/a Ortho- McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc., (hereinafter "JANSSEN PHARMA") is a corporation organized under Pennsylvania law with its principal place of business in New Jersey. JANSSEN PHARMA has held the U.S. Food and Drug Administration (FDA) New Drug Application (NDA) for Elmiron since approximately August 2008.

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

12. JANSSEN RESEARCH & DEVELOPMENT LLC, f/k/a Johnson & Johnson Research & Development, L.L.C. (hereinafter "JANSSEN R&D") is a limited liability company organized under the laws of New Jersey with its principal place of business in New Jersey. JANSSEN R&D's sole member is Centocor Research & Development, Inc., a Pennsylvania corporation with its principal place of business in Pennsylvania. JANSSEN R&D held the NDA for Elmiron from approximately August 2002 until August 2004.

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

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

15. Upon information and belief, at all relevant times, JANSSEN PHARMA, ORTHO PHARMA, JANSSEN R&D, and JANSSEN ORTHO have been wholly owned subsidiaries of JOHNSON & JOHNSON with their profits inuring to Johnson & Johnson's benefit.

16. Defendants were jointly engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Elmiron, and controlling the Elmiron NDA.

JURISDICTION & VENUE

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

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

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

FACTUAL ALLEGATIONS

A. Brief History of Elmiron

20. In September of 1996, the FDA approved Elmiron for treatment of interstitial cystitis (IC), also known as bladder pain syndrome.

21. Interstitial cystitis 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 debilitating pain.

22. Under the IC treatment guidelines established by the American Urological Association (AUA), Elmiron is not a first-line treatment. Rather, Elmiron is one of ten suggested second-line treatments, including three other oral medications: amitriptyline, cimetidine, and hydroxyzine. The guidelines further include numerous third-, fourth-, fifth-, and sixth-line treatments. 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.

23. When medications fail to provide relief, the third-, fourth-, fifth-, and sixth-line treatments involve invasive procedures such as the use of a catheter to deliver medicated solutions directly to the bladder; Botox injections to the muscle wall of the bladder; implantation of neurostimulation devices to control muscle

contractions in the bladder; or, in rare cases, surgery to remove ulcers from the bladder or augment the bladder wall with an intestinal patch.

24. Defendants market Elmiron as "The Only Oral Medication Approved to Treat the

Bladder Pain or Discomfort of Interstitial Cystitis (IC)."[1] However, while Elmiron is the only oral medication approved by the FDA specifically for the purpose of treating IC, as set forth above, it is not the only oral medication approved by the FDA which can be used to treat IC, and it is not the only IC treatment.

B. The Dangers of Elmiron

25. Despite study after study providing clear evidence of the dangers of PPS, Defendants have failed to adequately investigate the threat that PPS poses to patients' vision or warn patients of the risk that they would suffer retinal injury and vision impairment.

26. A physician's usage study of PPS conducted in the late 1980s and early 1990s noted adverse effects affecting vision, including optic neuritis and retinal hemorrhage. Defendants relied upon this very study when seeking FDA approval for Elmiron, and therefore had direct knowledge of the adverse effects.[2]

27. The reported adverse effects included:[3]

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

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

28. Available medical research also identified as early as 1991, that PPS inhibits

[1] https://www.orthoelmiron.com/patient/about-elmiron.
[2] A Statistical and Medical Review of an Amendment to the New Drug Application for Elmiron ® (Pentosan Polysulfate), NDA #20193, Appendix D (January 1996).
[3] *Id*.

regrowth and proliferation of retinal pigment epithelial (RPE) cells,[4] and could thereby impair an important physiological pathway for retinal health.

29. Almost immediately after the FDA approved Elmiron, patients and doctors began reporting serious complications relating to eye and vision problems in patients taking Elmiron.[5]

30. Nearly 150 cases of eye disorders were reported to the FDA as adverse effects of Elmiron, ranging from blurred vision to maculopathy and blindness. Other reported symptoms include visual impairment, halo vision, and reduced visual acuity.[6]

31. In 2018, researchers from the Emory Eye Center published their concerns about the presentation of a unique eye disease they were seeing inpatients taking Elmiron in the Journal of Ophthalmology.[7]

32. The researchers also summarized their findings in a letter to the editor of the Journal of Urology:

> We wish to alert readers to a concerning new observation of vision threatening retinal changes associated with long-term exposure to [Elmiron]. We recently reported our findings of retinal pigmentary changes in six patients undergoing long-term therapy with [Elmiron]. These patients primarily described difficulty reading and/or trouble adjusting to dim lighting. Each patient had received a standard dosage of [Elmiron], ranging from 200 to 400 mg daily, for a median duration of 15.5 years. . . . Examination findings in patients with this condition are suggestive of injury to the retina and the underlying retinal pigment epithelium. . . . After extensive investigations, which included molecular testing for hereditary retinal disease, we found these cases to resemble no other retinal disease.[8]

---

[4] Katrinka H. Leschey, John Hines, Jeff H. Singer, Sean F. Hackett, and Peter A. Campochiaro, *Inhibition of Growth Factor Effects in Retinal Pigment Epithelial Cells*, 32 INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCIENCE 1770–1778 (1991).

[5] According to the FDA Adverse Events Reporting System (FAERS) Public Dashboard, eight patients taking Elmiron reported serious adverse effects to their vision in the 1997 calendar year. https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/6b5a135f-f451- 45be-893d-20aaee34e28e/state/analysis.

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

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

[8] William A. Pearce, Adam M. Hanif, and Nieraj Jain, Letter to the Editor Re: *FDA BRUDAC 2018 Criteria*

33. The study, "Pigmentary Maculopathy Associated with Chronic Exposure to [Elmiron]," focused on six women with IC who presented to the Emory clinic between May 2015 and October 2017 with pigmentary maculopathy.[9] Maculopathy is a general term referring to any pathological condition that affects the macula, the central portion of the retina upon which visual acuity and sensitivity depend.

34. Most of these patients had difficulty reading and difficulty seeing in darkness. Two patients experienced a generalized dimming of their vision as the first symptom. Two others had difficulty with near vision: one had paracentral scotomas (vision loss) in part of her eye, while the other had metamorphopsia (distorted vision where straight lines become wavy).

35. All six patients underwent rigorous diagnostic imaging and DNA testing to determine if they had any genes associated with hereditary retinal loss. None had a family history of retinal disease or the discovery of any pathogenic process.

36. What they had in common was a use of Elmiron.

37. Examinations of their eyes showed clear changes: "Nearly all eyes (10 eyes of 5 patients) showed subtle parafoveal pigmented deposits at the level of the retinal pigment epithelium (RPE)."[10] All eyes "showed subtle viteliform deposits that increased in number and extended beyond the major arcade of vessels in cases judged to be more severe. Four eyes of 2 patients showed RPE atrophy that was noted to increase in area and encroach on the central fovea over time."[11] Retinal imaging also found clear diseased regions, atrophy, or both.[12]

---

for Interstitial Cystitis/Bladder Pain Syndrome Clinical Trials, 200 UROLOGY 1122 (2018).

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

[10] *Id*. at 1798.

[11] *Id.*

[12] *Id*.

38. The youngest patient in the study was 37 years old. Diagnosed with IC at the age of 23 and on a steady dosage of Elmiron, she began showing visual symptoms (difficulty with near vision and difficulty reading) at the age of 30 — just six years after she was diagnosed. She had the most severe damage in the study with deep scotomas of both eyes.[13]

39. The authors expressed concern that "the region of affected tissue may expand centrifugally over time."[14]

40. They concluded that "[c]linicians should be aware of this condition because it can be mistaken for other well-known macular disorders such as pattern dystrophy and age-related macular degeneration."[15]

41. They also encouraged "drug cessation in affected patients," and "recommend that any patient with suggestive visual symptoms undergo a comprehensive ophthalmic examination."[16]

42. IC experts Robert Moldwin and Curtis Nickel responded to the Emory findings with concern: "It is quite unlikely that urologists treating patients with [IC] ever would have made this association . . . yet the implications are either frightening if our treatment is causing this condition or instructive if this condition is a previously unknown manifestation of [IC]."[17]

43. At the American Urology Association 2019 Annual Meeting in May 2019, the Emory team submitted another study of ten IC patients who had taken Elmiron and experienced

[13] *Id*. at 1795, Table 2.
[14] *Id*. at 1800
[15] *Id*. at 1801.
[16] William A. Pearce, Adam M. Hanif, and Nieraj Jain, Letter to the Editor Re: *FDA BRUDAC 2018 Criteria for Interstitial Cystitis/Bladder Pain Syndrome Clinical Trials*, 200UROLOGY 1122 (2018).
[17] J.C. Nickel and R. Moldwin, Reply to Letter to the Editor Re: *FDA BRUDAC 2018 Criteriafor Interstitial Cystitis/Bladder Pain Syndrome Clinical Trials*, 200 UROLOGY 1122, 1123 (2018).

macular disease.[18]

44. The patients had a median age of 59 years (range 38–68), and median time since IC diagnosis of 19 years (range 4–40). The most commonly reported symptoms were difficulty reading and difficulty adapting to dim lighting.

45. Eye examinations showed symmetric pigmentary changes in the retina. Retinal imaging demonstrated that the abnormalities were primarily in the retinal pigment epithelium. They note that their clinic has seen 156 patients with IC who did not have any Elmiron exposure—and these patients showed no pigmentary maculopathy.

46. The Emory team concluded that structural changes of the retina are occurring in patients taking Elmiron, and they are unclear if stopping the medication will alter the course of the damage. They encouraged affected patients to discontinue the use of medications and to undergo comprehensive ophthalmic examinations.

47. The Emory team most recently published a July 2019 study in the Review of Ophthalmology.[19]

48. "Our subsequent investigations," the team wrote, "demonstrated that this unique maculopathy is strongly associated with chronic [Elmiron] exposure, not IC itself or its other therapies. In fact, this characteristic maculopathy has, to date, been exclusively diagnosed in

[18] Jenelle Foote, Adam Hanif, and Nieraj Jain, *Chronic Exposure to Pentosan Polysulfate Sodium is Associated with Retinal Pigmentary Changes and Vision Loss*, 201 UROLOGY e688 (2019), https://www.auajournals.org/doi/10.1097/01.JU.0000556315.46806.ca

[19] Adam M. Hanif and Nieraj Jain, *Clinical Pearls for a New Condition. Pentosan Polysulfate Therapy, a Common Treatment for Interstitial Cystitis, Has Been Associated with a Maculopathy*, REVIEW OF OPHTHALMOLOGY July 10, 2019, https://www.reviewofophthalmology.com/article/clinical-pearls-for-a-new-condition.

patients reporting prior [Elmiron] exposure."[20]

49. The team further observed that claims data from a nationally-present U.S. insurance company suggested that hundreds of thousands of individuals have likely been exposed to Elmiron in the US, and recognized a study finding that Elmiron-exposed patients were found to have a significantly increased risk ofbeing diagnosed with a new macular disease after seven years.

50. In September 2019, the Emory team published further research in the Journal of American Medical Association Ophthalmology ("JAMA Ophthalmology"), concluding that Elmiron-associated macular degeneration "is a vision-threatening condition that can manifest in the setting of long-term exposure to the drug."[21]

51. In November of 2019, a team from Emory and the University of Pennsylvania published an epidemiological study in the British Journal of Ophthalmology which concluded that "PPS users had significantly increased odds of having [maculopathy]."[22]

52. Also in 2019, a team from Kaiser Permanente Northern California treated a patient who was previously misdiagnosed with Stargardt disease, but was actually suffering from Elmiron-related maculopathy.[23] In their case report, the ophthalmologists stressed that "failure to diagnose

---

[20] *Id*.
[21] Adam Hanif et al., *Phenotypic Spectrum of Pentosan Polysulfate Sodium-Associated Maculopathy: A multicenter Study*, 137 JAMA OPHTHALMOLOGY 1275, 1282 (Sep. 5, 2019), https://jamanetwork.com/journals/jamaophthalmology/article-abstract/2749093.
[22] Nieraj Jain et al., *Association of Macular Disease with Long-Term Use of Pentosan Polysulfate Sodium: Findings from a U.S. Cohort*, BRITISH JOURNAL OF OPHTHALMOLOGY (published online first, November 6, 2019), https://bjo.bmj.com/content/early/2019/11/06/bjophthalmol-2019-314765.
[23] Robin A. Vora et al., *A Case of Pentosan Polysulfate Maculopathy Originally Diagnosed as Stargardt Disease*, 17 AMERICAN JOURNAL OF OPHTHALMOLOGY CASE REPORTS 100604 (published online first, January 2020), http://www.sciencedirect.com/science/article/pii/S2451993620300086?via%3Dihub.

a medication toxicity in a timely fashion may lead to preventable irreversible vision loss."[24]

53. Another team of researchers found a 20% prevalence of a unique PPS- associated maculopathy among a cohort of patients being treated at the University of California, Los Angeles.[25] Their study suggests "a significant risk of macular toxicity for PPS-treated patients," and that "more significant PPS exposure was associated with more severe atrophy."

54. Most recently, two physicians from Harvard Medical School published a case study indicating that the damage caused by Elmiron continues to progress long after cessation of the drug. [26] In their study, a patient continued to exhibit worsening symptoms of PPS-associated retinal maculopathy for at least 6 years after she stopped taking Elmiron.

55. The doctors noted "the present case adds a new layer of concern by demonstrating progressive maculopathy continuing for up to 6 years after cessation of PPS . . . this case emphasizes the need for a screening regimen that balances the demands on patients and physicians with the importance of prompt identification of early toxicity."[27]

56. The Interstitial Cystitis Network, a health publishing company dedicated to IC, launched its own patient survey on the heels of the Emory Eye Center findings. As of April 2019, the IC Network had almost 1,000 participants, of which 53% reported eye disease.

57. Patient reports on the IC Network Support Forum include:[28]

---

[24] *Id*.
[25] Derrick Wang et al., *Pentosan-Associated Maculopathy: Prevalence, Screening Guidelines, and Spectrum of Findings Based on Prospective Multimodal Analysis*, CANADIAN JOURNAL OF OPHTHALMOLOGY (in press, published online January 2020), http://www.canadianjournalofophthalmology.ca/article/S00008-4182(19)31272-4/fulltext.
[26] Rachel M. Huckfeldt and Demetrios G Vavvas, *Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium*, 50 OPHTHALMIC SURGERY, LASERS AND IMAGING RETINA 656–59 (2019), ncbi.nlm.nih.gov/pubmed/31671200.
[27] *Id*. at 658.
[28] Interstitial Cystitis Network Patient Support Forum. https://forum.ic-network.com/.

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

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

c. March 25, 2019: "After 4 excruciating years, I was diagnosed with IC in 2003. I started on Elmiron and have taken it since then. I was diagnosed with macular degeneration in 2014. My severity is mild to moderate. The left eye is definitely worse. I can no longer drive at night. I'm pretty comfortable driving to places I am familiar with during the day. I am only 58. I dread the day I will not be able to drive."

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

59. The European Medicines Agency, a decentralized agency of the EU responsible for scientific evaluations, supervision, and safety monitoring of medicines in the EU, is specifically warning patients about Elmiron and advising that "[a]ll patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly those with longterm use of PPS. In such situations, treatment cessation should be considered."[29]

60. Despite numerous signs of the potential for severe retinal side effects; multiple studies conducted at top institutes; research being published in major peer- reviewed journals; and

[29] EUROPEAN MEDICINES AGENCY, PRODUCT INFORMATION. ELMIRON - PENTOSAN POLYSULFATE SODIUM 3, https://www.ema.europa.eu/en/documents/product-information/elmiron-epar-product- information_en.pdf.

public warnings from a prominent EU health agency, Defendants failed to reasonably investigate the issue and have been silent as to the harm.

61. Nor have Defendants alerted patients to the need for ophthalmological monitoring while taking Elmiron, or differentiated whether risks increase with higher doses or longer durations, despite these types of warning being normal industry practice.

62. For example, the anti-malaria drug Plaquenil (hydroxychloroquine) is likewise associated with retinal toxicity. In the labeling for Plaquenil, manufacturer Concordia Pharmaceuticals, Inc., provides the following warning:

> Irreversible retinal damage has been observed in some patients who had received hydroxychloroquine sulfate. Significant risk factors for retinal damage include daily doses of hydroxychloroquine sulfate greater than
> 6.5 mg/kg (5 mg/kg base) of actual body weight, durations of use greater than five years, subnormal 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.[30]

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

63. To date, Defendants have not adequately notified or warned patients, the medical community, or prescribers in the United States that Elmiron causes, is linked to, and is associated with vision threatening retinal changes, including vision loss.

64. The labeling for Elmiron lists serious side effects that have been reported with Elmiron, but do not list vision threatening retinal changes. Defendants also did not make any mention of vision threatening retinal changes or the need for ophthalmological monitoring in any of the patient materials—including the Patient Education Flyer and ELMIRON Patient Brochure—the sources of information most likely viewed by physician and patients.

65. The labeling for Elmiron does not provide adequate warnings, does not caution that patients should be closely monitored, does not adequately inform patients and physicians that vision threatening retinal changes have been associated with Elmiron use, and does not contain any proper dosing considerations.

66. JANSSEN PHARMA maintains a website promoting Elmiron, www.orthoelmiron.com. The website includes, among things, "About Elmiron," "How Elmiron Works," "Important Safety Information," and "Patient Information." Nowhere on the website does it mention the potential for vision threatening retinal changes associated with Elmiron use.[31]

TOLLING OF THE STATUTE OF LIMITATIONS

A. Discovery Rule Tolling

67. As a result of the acts and omissions of Defendants, Plaintiff could not have discovered, through the exercise of reasonable due diligence, that exposure to Elmiron was

[31] Last visited April 19, 2020.

associated with increased exposure to vision threatening retinal changes as set forth above. Thus, the applicable limitations periods did not begin to accrue until Plaintiff discovered, or through the exercise of reasonable diligence should have discovered, Defendants' wrongful acts and omissions. Plaintiff, ANGELO ZENEZ, did not discover the wrongful conduct until in and/or around November 2020.

B. Fraudulent Concealment Tolling

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

69. Defendants are under a continuing duty to disclose the true character, quality, and nature of Elmiron to Plaintiff. To date, Defendants have nevertheless failed to inform patients and doctors about the vision threatening retinal changes associated with Elmiron, as discussed above.

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

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

C. Estoppel

72. Defendants were, and are, under a continuous duty to disclose to Plaintiff the vision threatening retinal changes associated with Elmiron. Instead, they actively concealed the true character, quality, and nature of Elmiron and knowingly

made misrepresentations and/or omissions about the safety of Elmiron and the vision threatening retinal changes associated with it.

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

COUNT I
Strict Liability – Design Defect & Failure to Warn

74. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 73 as if fully set forth herein and further alleges as follows:

75. 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 test their product.

76. The Elmiron supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer orsupplier, it was in an unreasonably dangerous and a defective condition for its intended use and it posed a risk of serious and potentially irreversible vision issues and retinal harm to Plaintiff and other consumers which could have been reduced or avoided by the adoption of a feasible reasonable alternative design.

77. The Elmiron supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer orsupplier, Elmiron had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious and potentially irreversible vision issues and retinal harm to Plaintiff and other consumers.

78. Also, Elmiron's limited and unproven effectiveness did not outweigh the risks posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of Elmiron makes the product unreasonably dangerous.

79. The Elmiron supplied to Plaintiff by Defendants was defective due to inadequate

warnings or instructions concerning the true risks of its use.

80. Defendants knew or should have known through testing, scientific knowledge, advances in the field or otherwise, that the product created a risk of serious and potentially irreversible vision issues and retinal harm, and was unreasonably dangerous to Plaintiff and other consumers, about which Defendants failed to warn.

81. The Elmiron supplied to Plaintiff by Defendants was defective, 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 dangerous nature of Elmiron. Despite this knowledge and information, Defendants failed and neglected to issue adequate warnings or post-sale warnings that Elmiron causes serious and potentially irreversible vision issues and retinal harm.

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

83. By failing to adequately test and research harms associated with Elmiron use, and by failing to provide appropriate warnings 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 Elmiron use. 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 use and should or could be reported as an adverse event.

84. As a direct and proximate result of Defendants' conduct, including the inadequate

warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Elmiron, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT II
Breach of Express Warranty

85. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 73 as if fully set forth herein and further alleges as follows:

86. Defendants expressly warranted to physicians and consumers, including Plaintiff and Plaintiff's physicians, that Elmiron was safe and well- tolerated.

87. Elmiron does not conform to these express representations because it is neither safe nor well-tolerated. Instead it significantly increases the risk of serious and potentially irreversible vision issues and retinal harm.

88. As a direct and proximate result of the breach of Defendants' warranties, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT III
Breach of Implied Warranty

89. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 73 as if fully

set forth herein and further alleges as follows:

90. At the time Defendants marketed, sold, and distributed Elmiron, Defendants knew of the use for which Elmiron was intended, and they impliedly warranted Elmiron to be of merchantable quality, safe and fit for such use.

91. Defendants knew, or had reason to know, that Plaintiff and Plaintiff's physicians would rely on Defendants' judgment and skill in providing Elmiron for its intended use.

92. Plaintiff and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants as to whether Elmiron was of merchantable quality, safe, and fit for its intended use.

93. Contrary to such implied warranty, Elmiron was not of merchantable quality or safe or fit for its intended use, because the product was, and is, unreasonably dangerous, defective and unfit for the ordinary purposes for which Elmiron was used.

94. Also, Elmiron's limited and unproven effectiveness did not outweigh the risks posed by the drug. In light of the utility of the drug and the risk involved in its use, the design of Elmiron makes the product unreasonably dangerous.

95. As a direct and proximate result of the breach of implied warranty, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT IV
Negligence

96. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 73 as if fully

set forth herein and further alleges as follows:

97. At all times material herein, Defendants had a duty to exercise reasonable care and had the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, warning, post-sale warning, testing, and research to assure the safety of the product when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Elmiron.

98. Defendants had a duty to warn Plaintiff, Plaintiff's physicians, and the public in general of Elmiron's dangers and serious side effects, including serious and potentially irreversible vision issues and retinal harm, since it was reasonably foreseeable that an injury could occur because of Elmiron's use.

99. At all times material herein, Defendants failed to exercise reasonable care and the duty of an expert and knew, or in the exercise of reasonable care should have known, that Elmiron was not properly manufactured, designed, compounded, tested, inspected, packaged, labeled, warned about, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, or a combination of these acts.

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

a. Negligent and careless research and testing of Elmiron;

b. Negligent and careless design or formulation of Elmiron;

c. Negligent and careless failure to give adequate warnings that would attract

the attention of Plaintiff, Plaintiff's physicians, and the public in general of the potentially dangerous, defective, unsafe, and deleterious propensity of Elmiron and of the risks associated with its use;

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

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

f. Negligent representations that Elmiron was safe or well- tolerated; and

g. Negligent and careless failure to issue adequate post-sale warnings that Elmiron causes an increased risk of serious and potentially irreversible vision issues and retinal harm.

101. As a direct and proximate result of Defendants' negligence, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

COUNT V
Negligence Per Se
(Violations of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1)

102. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 73 as if fully set forth herein and further alleges as follows:

103. At all times herein mentioned, Defendants had an obligation to abide by the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, labeling, packaging, preparation for use, consulting, sale, warning, and post-sale warning, and other communications

of the risks and dangers of Elmiron.

104. By reason of its conduct as alleged herein, Defendants violated provisions of statutes and regulations, including, but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding Elmiron;

b. Defendants failed to follow the "[g]eneral requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.56;

c. Defendants failed to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.57;

d. Defendants advertised and promoted Elmiron in violation of 21 C.F.R. § 202.1; and

e. Defendants violated 21 C.F.R. § 201.57(e) by failing to timely and adequately change the Elmiron label to reflect the evidence of an association between Elmiron and the serious and potentially irreversible vision issues and retinal harm affecting Plaintiff.

105. These statutes and regulations impose a standard of conduct designed to protect consumers of drugs, including Plaintiff.

106. Defendants' violations of these statutes and regulations constitute negligence per se.

107. As a direct and proximate result of Defendants' statutory and regulatory violations, Plaintiff, a member of the class of persons intended to be protected by the above-mentioned statutes, suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the

losses in the future.

COUNT VI
Negligent Misrepresentation

108. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 73 as if fully set forth herein and further alleges as follows:

109. Defendants misrepresented to consumers and physicians, including Plaintiff and Plaintiff's physicians and the public in general, that Elmiron was safe or well-tolerated when used as instructed, and that Elmiron was safe or well- tolerated, when, in fact, Elmiron was dangerous to the well-being of patients.

110. At the time Defendants promoted Elmiron as safe or well-tolerated, they did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Elmiron was dangerous to the well-being of Plaintiff and others.

111. Defendants failed to exercise reasonable care and competence in obtaining or communicating information regarding the safe use of Elmiron and otherwise failed to exercise reasonable care in transmitting information to Plaintiff, Plaintiff's physicians, and the public in general.

112. Defendants made the aforesaid representations in the course of Defendants' business as designers, manufacturers, and distributors of Elmiron despite having no reasonable basis for their assertion that these representations were true or without having accurate or sufficient information concerning the aforesaid representations. Defendants were aware that without such information they could not accurately make the aforesaid representations.

113. At the time the aforesaid representations were made, Defendants intended to induce Plaintiff or Plaintiff's physicians to rely upon such representations.

114. At the time the aforesaid representations were made by Defendants, and at the time Plaintiff received Elmiron, Plaintiff or Plaintiff's physicians, and the public in general, reasonably believed them to be true. In reasonable and justified reliance upon said representations, Plaintiff used Elmiron.

115. As a direct and proximate result of reliance upon Defendants' misrepresentations, Plaintiff suffered bodily injury and resulting pain andsuffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of hospitalization, medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment in Plaintiff's favor as follows:

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

b. Awarding punitive damages;

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

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

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

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

DEMAND FOR JURY TRIAL

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

Respectfully submitted:

/s/Brian LaCien
Counsel for Plaintiff
Todd A. Smith
Brian LaCien
Andrew W. Mason
SMITH LACIEN LLP
Three First National Plaza
70 West Madison Street, Suite 2250
Chicago, Illinois 60602
(312) 509-8900
blacien@smithlacien.com