UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

PATRICIA PARKER, Plaintiff, v. JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL PHARMACEUTICAL, LLC, JANSSEN RESEARCH & DEVELOPMENT, LLC, JANSSEN ORTHO, LLC, TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC. and TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., Defendants.	Case No.:

COMPLAINT

Plaintiff Patricia Parker ("Plaintiff"), by and through her undersigned counsel, herein brings this action against Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil Pharmaceutical, LLC, Janssen Research & Development, LLC, Janssen Ortho, LLC, Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., and Teva Branded Pharmaceutical Products R&D, Inc. (collectively, "Defendants"), and states and alleges upon information and belief and based upon the investigation of counsel, as follows:

INTRODUCTION

1. This is a personal injury action for damages arising from Plaintiff's use of Elmiron®, a prescription drug manufactured and sold by Defendants.

2. Defendants designed, marketed, and distributed Elmiron® in the United States, all the while knowing of significant risks that the drug poses to users, which were never disclosed to the medical and healthcare community, including Plaintiff's prescribing doctor, to Plaintiff, the Food and Drug Administration ("FDA"), and/or the public in general.

3. Defendants also failed to provide adequate warnings of the risks associated with using Elmiron® to patients and the medical community, including Plaintiff's prescribing physician.

4. Defendants also marketed Elmiron® while, at the same time, withholding material adverse events from the public, the medical community, and FDA. Specifically, Defendants failed to disclose the known link between using Elmiron® and the risk of harm to vision, including, but not limited to, pigmentary maculopathy.

5. Defendants' misleading conduct placed Plaintiff at risk of harm, caused harm to Plaintiff, and did the same for countless other patients who were prescribed Elmiron®.

PARTIES

6. At all times relevant hereto, Plaintiff Patricia Parker was a citizen and resident of Winston-Salem, Forsyth County, North Carolina.

The Johnson & Johnson Family of Defendants

7. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with a principal place of business located at 1 Johnson and Johnson Plaza, New Brunswick, New Jersey 08933.

8. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is, upon information and belief, a wholly-owned subsidiary of Defendant J&J and a New Jersey corporation with a principal place of business located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

9. Defendant Ortho-McNeil Pharmaceutical, LLC ("Ortho Pharma") is, upon information and belief, a wholly-owned subsidiary of Defendant J&J and a Delaware corporation with a principal place of business located at 1000 US Highway 202, Raritan, New Jersey 08869.

10. Defendant, Janssen Research & Development, LLC, ("Janssen R&D") is, upon information and belief, a wholly-owned subsidiary of Defendant J&J and a New Jersey limited liability company with a principal place of business located at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

11. Defendant Janssen Ortho, LLC ("Janssen Ortho") is, upon information and belief, a wholly-owned subsidiary of Defendant J&J and a Delaware limited liability company with a principal place of business located in Gurabo 00777, Puerto Rico.

12. Defendant Janssen Ortho's sole member is OMJ PR Holdings, a corporation incorporated in Ireland with a principal place of business in Puerto Rico.

13. At all relevant times, Defendants Janssen Pharmaceuticals, Ortho Pharma, Janssen R&D, and Janssen Ortho have been wholly-owned subsidiaries of Defendant J&J, with the profits of each inuring to Defendant J&J's benefit.

14. The Johnson & Johnson Family of Defendants—Defendant J&J and its subsidiaries, Janssen Pharmaceuticals, Ortho Pharma, Janssen R&D, Janssen Ortho— are involved in the research, development, sale, and/or marketing of pharmaceutical products, including Elmiron® in the United States and in the State of North Carolina.

15. Defendant J&J made consequential decisions and/or took significant actions concerning, *inter alia*, the design, labeling, marketing, advertising, promotion, and/or regulatory approval of Elmiron®.

16. The Johnson & Johnson Family of Defendants' decisions and/or actions with respect to Elmiron® impacted, *inter alia*, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or FDA-approval of Elmiron® in the United States.

17. The Johnson & Johnson Family of Defendants, directly or through their agents or employees, designed, manufactured, marketed, and sold Elmiron® in the United States to manage symptoms of interstitial cystitis.

The Teva Family of Defendants

18. Defendant Teva Pharmaceutical Industries Ltd. is, upon information and belief, an American-Israeli company with dual headquarters located at 5 Basel Street, Petach Tikva 49131, Israel, and 400 Interpace Parkway, #3, Parsippany, New Jersey 07054.

19. Defendant Teva Pharmaceuticals USA, Inc. is, upon information and belief, a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries Ltd. and a Delaware corporation with a principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

20. Defendant Teva Branded Pharmaceutical Products R&D, Inc. is, upon information and belief, a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries Ltd. and a Delaware corporation with a principal place of business located at 41 Moores Rd., Frazer, PA 19355.

21. The Teva Family of Defendants— Teva Pharmaceutical Industries Ltd., and its subsidiaries Teva Pharmaceuticals USA, Inc. and Teva Branded Pharmaceutical Products R&D, Inc.—made consequential decisions and/or took significant actions concerning, *inter alia*, the design, testing, labeling, packaging, marketing, advertising, distribution, sale, promotion, and/or regulatory approval of Elmiron® in the United States.

JURISDICTION AND VENUE

22. 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.

23. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because a substantial part of the events or omissions giving rise to the claim occurred in this District.

24. The Court has personal jurisdiction over Defendants. Defendants currently transact business within this District by selling their products, including Elmiron®, within this District and throughout the United States.

GENERAL ALLEGATIONS

A. Interstitial Cystitis

25. Interstitial cystitis is a chronic medical condition in the bladder that causes, among other things, bladder pressure and pain. There is no known cause of interstitial cystitis and no known cure. The symptoms can range from mild to debilitating.

26. The American Urological Association ("AUA") has established guidelines for the diagnosis and treatment of interstitial cystitis. The AUA guidelines further state that a given patient's initial treatment type and level should depend on symptom severity, clinician judgment, and patient preferences.

27. Treatments that may be offered are divided into first-, second-, third-, fourth-, fifth-, and sixth-line groups based on the balance between the potential benefits to the patient, the 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, such as amitriptyline, cimetidine, hydroxyzine, or pentosan polysulfate sodium (Elmiron®).

B. Elmiron® and FDA Approval.

28. In 1991, Baker Norton Pharmaceuticals ("Baker Norton") submitted a New Drug Application ("NDA") for pentosan polysulfate sodium (Elmiron®). At the time, Baker Norton was a division of Ivax Pharmaceuticals.

29. The FDA deemed the original NDA non-approvable in approximately 1993.

30. Baker Norton responded by submitting additional materials in support of its NDA for FDA review.

31. The FDA deemed the supplemented NDA non-approvable in approximately 1994.

32. Elmiron® was granted an Orphan Drug designation in 1995, and Baker Norton subsequently submitted additional materials in support of its NDA for further FDA review.

33. The FDA finally approved Elmiron® as a treatment for the pain or discomfort of interstitial cystitis in 1996.

34. Elmiron® is intended for long-term patient use. Patients who are prescribed Elmiron® are advised to take the drug for at least six months in order to determine whether they benefit from its use. For those patients who take the drug, the time of use is indefinite, and patients could take the drug for several years or even for life.

35. Defendants are aware that physicians prescribe Elmiron® for long-term use and, in fact, encourage and recommend long-term use of Elmiron®. According to Defendants' Elmiron® patient leaflet, the drug "must be taken continuously for relief…"

C. Elmiron® Is Licensed.

36. From approximately 1996, when the NDA was approved, until approximately 1997, Baker Norton owned the trademark for Elmiron®.

37. In approximately 1997, Baker Norton was purchased by Teva Pharmaceutical Industries, Ltd., and/or Teva Pharmaceuticals, Inc.

38. In connection with the purchase of Baker Norton, Teva Pharmaceutical Industries, Ltd. and/or Teva Pharmaceuticals, Inc. acquired all rights to Elmiron®, including trademark rights.

39. Elmiron® is a registered trademark of Teva Branded Pharmaceutical Products R&D, Inc., Teva Pharmaceuticals USA, Inc. and/or Teva Pharmaceutical Industries Ltd., under license to Defendant Janssen Pharma.

40. From approximately August 2002 until August 2004, Defendant Janssen R&D held the NDA for Elmiron®.

41. From July 2004 until August 2008, Defendant Ortho Pharma held the NDA for Elmiron®.

42. Since August 2008, Defendant Janssen Pharma has held the NDA for Elmiron® and continues to manufacture and/or distribute Elmiron® throughout the United States.

43. There is no FDA-approved generic form of Elmiron® sold in the United States.

D. Drug-Induced Retinal Toxicity

44. The retina is one of the most metabolically active tissues in the human body and, thus, is especially susceptible to the effects of systemic drugs.

45. The retina has minimal ability to regenerate and is at high risk of drug toxicity. Thus, it is critical that physicians, especially eyecare professionals, are aware of adverse drug effects impacting the retina.

46. For example, the anti-malarial drug Plaquenil (hydroxychloroquine), which is also prescribed for the treatment of lupus and rheumatoid arthritis, is known to be associated with retinal toxicity in patients taking it for these two illnesses. Accordingly, the FDA label for Plaquenil contains explicit warnings regarding the risk of injury for patients with lupus and rheumatoid arthritis, and stresses the importance of monitoring for signs of retinal toxicity.

47. Until June 2020, Elmiron®'s FDA label contained no warning of the risk of retinal toxicity or instructions relating to the risk of injury and monitoring for signs of toxicity.

48. In fact, from 1996, when Elmiron® was first approved by the FDA, until June of 2020, neither Elmiron®'s Package Insert nor its Medication Guide contained any warnings or information regarding the risk of serious visual complications, including, but not limited to, maculopathy.

E. The Link Between Elmiron® Use and Retinal Maculopathy.

49. Elmiron® is the "only game in town" to treat discomfort or bladder pain associated with interstitial cystitis, and has been regularly prescribed for long-term use to treat these conditions.

50. In recent years, an increasing number of independent studies have found a link between damage to the retina and exposure to pentosan polysulfate sodium (PPS), or Elmiron®.

51. For example, from 2015 to 2018, Emory Eye Center began observing a new eye disease in patients called "retinal maculopathy," a unique presentation that does not resemble any other hereditary or acquired maculopathy, where the pigment cells within the eye's retina changes color. This change in color causes significant vision loss and eye dysfunction.

52. In 2018, scientists at Emory Eye Center published a study documenting a link between Elmiron® use and retinal maculopathy. Pearce WA, Chen R, Jain N., Pigmentary Maculopathy Associated with Chronic Exposure To Pentosan Polysulfate Sodium. *Ophthalmology* 2018. The authors suggest that the retinal cells may be accumulating PPS over time and warn 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."

53. In letters to the editor, the study authors also stated that "[a]fter extensive investigations, which included molecular testing for hereditary retinal disease, we found

these cases to resemble no other retinal disease," and "[w]e encourage drug cessation in affected patients."

54. In 2019, an Emory Eye Center team submitted a second study further documenting a link between Elmiron® use and this unique change to the retina. Foote, et al. Chronic Exposure To Pentosan Polysulfate Sodium Is Associated With Retinal Pigmentary Changes And Vision Loss. AUA 2019 Abstract MP47-03. The authors of this study conclude that structural changes of the retina are occurring and that it is unclear whether stopping Elmiron® will alter the course of this new retinal disease. The authors recommend that affected patients should discontinue the use of Elmiron® and undergo comprehensive ophthalmic examinations.

55. In 2019, researchers using data from Kaiser Permanente reported that 24% of the Elmiron® users had the exact same Elmiron®-associated retinal pigmentary maculopathy and vision symptoms that were presented by the Emory Eye Center study, and that patients reported significant eye and vision problems. American Academy of Ophthalmology. The findings were presented at a meeting of the American Academy of Ophthalmologists in San Francisco. *See* More evidence linking common bladder medication to a vision threatening eye condition: New study shows about a quarter of patients with significant exposure to the drug show signs of retinal damage. ScienceDaily, 12 October 2019.

56. An additional 2019 study by Emory Eye Center found a statistically significant increase in the atypical retinal maculopathy in people who had taken Elmiron®

(PPS) for 7 years. Jain N, Li AL, Yu Y, et al. Association Of Macular Disease With Long-Term Use Of Pentosan Polysulfate Sodium: Findings From A U.S. Cohort. Br J Ophthalmology Nov. 6, 2019.

57. In January 2020, a UCLA study also suggested a "significant risk" of maculopathy in Elmiron®-treated patients. Derrick Wang, Adrian Au, Frederic Gunnemann. Pentosan-Associated Maculopathy: Prevalence, Screening Guidelines, And Spectrum Of Findings Based On Prospective Multimodal Analysis, Canadian Journal of Ophthalmology, January 2020,

58. Also, in January 2020, a study using the Kaiser Permanente database of patients with interstitial cystitis who had taken Elmiron® over the past 20 years reported that 23.1% showed signs of "definite" Elmiron®-associated maculopathy. Vora RA, Patel AP, Melles R, Prevalence of Maculopathy Associated with Long Term Pentosan Polysulfate Therapy Ophthalmology (2020).

59. When researchers at Emory Eye Center looked more closely at the Defendants' early clinical trials for Elmiron®, they found evidence of reported retinal eye damage that was never followed up on, never warned about or otherwise disclosed. Instead, Defendants chose to ignore it.

60. Specifically, the Emory Eye Center researchers found that in Defendant Janssen's own clinical trial of patients who took Elmiron® for up to four years, both vision and eye-related adverse events were reported, including optic neuritis and retinal hemorrhage.

61. Defendant Janssen performed no further tests or research to explore the connection, and none of these risks were disclosed on the Elmiron® warning label.

62. Further, the Adverse Event Reports concerning Elmiron® that Defendants received included serious visual complications believed to be associated with Elmiron® use, ranging from retinal hemorrhage to macular degeneration and unilateral blindness.

63. Reports of serious visual complications associated with Elmiron® use were not unique to the United States. Upon information and belief, serious visual complications were reported to Defendants and recorded in other adverse event reports databases maintained in other countries and continents around the world where Elmiron® is sold, including EudraVigilance—the European Medicines Agency's adverse event database.

64. It is widely recognized and accepted in the pharmaceutical industry that Adverse Event Reports represent only a small fraction of the total number of adverse events associated with and/or caused by a particular drug.

65. Moreover, beginning in approximately 2019, Defendants took steps to warn consumers and physicians *outside* of the United States of the risk of serious visual complications, including pigmentary maculopathy, associated with the extended use of Elmiron®.

66. In approximately September 2019, Defendants revised the Elmiron® label in Canada to warn of the risk of serious visual complications, including pigmentary

maculopathy, associated with the extended use of Elmiron®, as follows:

> 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 longterm use of PPS. If pigmentary maculopathy is confirmed, treatment discontinuation should be considered.

67. Likewise, in approximately 2019, Defendants "agreed" with a European Medicines Agency's Committee recommendation that the Elmiron® label be changed to warn of the risk of serious visual complications, including pigmentary maculopathy, associated with long-term use of Elmiron®.

68. The Elmiron® label in European Medicines Agency countries now warns:

> All patients should have an ophthalmologic examination after 6 months of use of PPS for early detection of pigmentary maculopathy, and, if there are no pathologic findings, regularly after 5 years of use (or earlier, in case of visual complaints). However, in case of relevant ophthalmologic findings, a yearly examination should be conducted. In such situations, treatment cessation should be considered.

69. The Elmiron® label used in European Medicines Agency countries further admits that "eye disorders" like pigmentary maculopathy are "uncommon" undesirable effects of the medication.

70. In approving these changes to the Elmiron® label, the European Medicines Agency Committee for Medicinal Products for Human Use ("CHMP") created a report, which Defendants are believed to have received. This report specifically noted that such a

warning regarding ophthalmological side effects of Elmiron® was needed, in part, because pigmentary maculopathy "might not be easily recognized by the urology community."

71. Notwithstanding Defendants' duty to ensure that the warning label for Elmiron® sold in the United States was adequate, and even though Defendants had a continuing responsibility to conduct post-marketing surveillance and to study the safety and efficacy of Elmiron®, Defendants did nothing to ensure that the Elmiron® label in the United States included a warning similar to the one introduced in Europe, or a warning of *any* type for that matter.

72. The Elmiron® patient leaflet did not disclose any ophthalmological side effects. Rather, Defendants limited the disclosed side effects to "hair loss, diarrhea, nausea, blood in the stool, headache, rash, upset stomach, abnormal liver function tests, dizziness and bruising."

73. It was not until June 16, 2020 that Defendants revised the Elmiron® label in the United States to include a warning of "Retinal Pigmentary Changes."

74. Prior to that date, Defendants did not warn, and made no effort to warn, healthcare professionals or patients in the United States of the risk of harm, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron® use.

75. Defendants continue to sell Elmiron® and, upon information and belief, continue to market Elmiron® as safe and efficacious for the long-term treatment of discomfort or bladder pain associated with interstitial cystitis.

F. Plaintiff Parker's Use of Elmiron®

76. Plaintiff was diagnosed with interstitial cystitis in or around 2003 and was prescribed Elmiron® shortly thereafter. Plaintiff took Elmiron as prescribed from approximately 2003 to early 2020.

77. In or around 2015, Plaintiff began experiencing vision issues, including blurred vision, distorted vision, eye pain, difficulty reading, nigh vision problems, and difficulty adapting to darkness, and in 2019 was diagnosed with pentosan polysulfate maculopathy.

78. Due to the absence of any warning by Defendants of the risks posed by Elmiron®, Plaintiff was unaware that use of Elmiron® could result in retina damage and vision impairment. This danger was also unknown to Plaintiff's healthcare providers or the general public due to Defendants' failure to warn.

79. Due to the absence of any instructions regarding how to identify and/or monitor Elmiron® patients for potential vision-related complications, Plaintiff was unaware that Elmiron® could result in retina damage and vision impairment. This danger was also unknown to Plaintiff's healthcare providers or the general public due to Defendants' failure to provide any such instructions.

G. Tolling and Estoppel of Statute of Limitations

80. Defendants have had actual knowledge for years that Elmiron® is unsafe for its intended use and that it failed to warn or otherwise disclose to patients, including Plaintiff, that testing of the drug established that it can cause – and, indeed, has caused –

significant ophthalmological side effects, including pigmentary maculopathy and other eye and vision problems.

Discovery Rule Tolling

81. During the period of any applicable statutes of limitation, Plaintiff could not have discovered, through the exercise of reasonable diligence, that Elmiron® is unsafe for its intended use and capable of causing significant ophthalmological side effects.

82. Plaintiff did not discover, and did not have knowledge of, facts that would cause a reasonable person to suspect that Elmiron® is unsafe for its intended use and capable of causing significant ophthalmological side effects.

83. Until recently, only Defendants had knowledge of the fact that Elmiron® is unsafe for its intended use and capable of causing significant ophthalmological side effects. Indeed, Defendants only revised the Elmiron® label to include a warning of ophthalmological side effects on June 16, 2020.

84. Plaintiff could not have reasonably discovered the true extent of Defendants' illegal conduct in connection with the health and safety risks posed by Elmiron® as Defendants never disclosed it while marketing and selling it to Plaintiff.

85. For the foregoing reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

Fraudulent Concealment Tolling

86. All applicable statutes of limitation have also been tolled by way of Defendants' fraudulent concealment of Elmiron® test results and their knowledge of significant ophthalmological side effects the through the relevant time period.

87. Rather than disclose to Plaintiff that test results indicate a connection between Elmiron® and significant ophthalmological side effects, Defendants continued to manufacture, market, and sell the drug for several years without disclosing this information.

Estoppel

88. At all times relevant to this action, Defendants had a duty to disclose to Plaintiff, prescribing physicians, the medical community, and the general public, the serious risks posed to Elmiron® users. Defendants knowingly, affirmatively, and actively concealed or recklessly disregarded the aforementioned serious risks and persisted with the manufacturing, marketing, promoting, distributing, and selling of Elmiron®.

89. For the foregoing reasons, Defendants are estopped from relying on any statutes of limitations in defense of the allegations raised in this Complaint.

CLAIMS FOR RELIEF

COUNT I
Fraudulent Concealment

90. Plaintiff hereby realleges and incorporates by reference all allegations raised in the preceding paragraphs as if fully stated herein.

91. Defendants have a duty to disclose the truth regarding Elmiron® and the ophthalmological side effects that can result, and have resulted, from taking the drug, including pigmentary maculopathy. Defendants also have a duty to advise patients of the importance of regular ophthalmologic examinations for early detection of pigmentary maculopathy.

92. Defendants made material misrepresentations and/or omissions to Plaintiff, Plaintiff's prescribing physician, the medical community, and the general public regarding the safety (or lack thereof) of taking Elmiron®.

93. Plaintiff reasonably relied on Defendants' material misrepresentations and/or omissions regarding the safety of Elmiron®.

94. Defendants' failure to disclose that taking Elmiron® can result, and has resulted, in certain ophthalmological side effects was intentional. Defendants were aware of the health risks inherent in Elmiron®, but intentionally chose not to disclose this material fact to patients, including Plaintiff, as well as Plaintiff's prescribing physician, the medical community, and the general public.

95. As described above, the packaging and labeling of Elmiron® did not include any warning regarding ophthalmological side effects.

96. Defendants' fraudulent concealment of material facts regarding the safety of Elmiron®, coupled with its deceptive marketing, packaging, labeling, and representations, induced Plaintiff's prescribing physician to prescribe Plaintiff Elmiron®, and induced

Plaintiff to take the drug. Plaintiff would not have taken Elmiron® if the truth had been disclosed to her regarding the safety (or lack thereof) of the drug.

97. Plaintiff had a reasonable expectation that Elmiron® was safe to take as prescribed. Defendants should have reasonably anticipated and intended that Plaintiff purchased and took Elmiron®, in part, based upon such expectations and assumptions, and, indeed, Defendants intended her to do so.

98. Defendants' failure to disclose and omission of material facts regarding the safety risks inherent in Elmiron® occurred uniformly and consistently in connection with Defendants' trade or business, was capable of deceiving and, indeed, did deceive a substantial portion of patients to a serious health risk.

99. Defendants' failure to disclose the health risks of Elmiron® had the direct result of concealing material facts from and breaching Defendants' duty to disclose to Plaintiff.

100. Beyond failing to disclose the aforementioned information, Defendants chose to actively conceal this material information regarding the health risks posed by Elmiron®.

101. As a direct and proximate result of Defendants' concealment and suppression of material facts regarding the safety (or lack thereof) of Elmiron®, Plaintiff has suffered and will continue to suffer actual damages.

COUNT II
Negligence – Failure to Warn

102. Plaintiff hereby realleges and incorporates by reference all allegations raised in the preceding paragraphs as if fully stated herein.

103. At all times material hereto, Defendants designed and manufactured Elmiron®.

104. Defendants had a duty to Plaintiff to design and manufacture a drug that was free of defects, which would not cause ophthalmological side effects, including pigmentary maculopathy and other significant eye and vision problems.

105. Defendants had a duty to Plaintiff to test Elmiron® to ensure that patients, including Plaintiff, would not suffer ophthalmological side effects, and to ensure that the drug would not cause other significant eye and vision problems.

106. In the event that such tests confirmed to Defendants that Elmiron® could and would cause ophthalmological side effects in patients, as is the case here, Defendants had a duty to Plaintiff to disclose this fact.

107. Defendants had a duty to Plaintiff to ensure that Elmiron® complied with industry standards, testing, and safety guidelines.

108. Defendants had a duty to Plaintiff, prescribing physicians, the medical community, and the general public to forewarn regarding the known risk of ophthalmological side effects.

109. Defendants failed to exercise ordinary and reasonable care in the design of Elmiron® and the omission of any warning to patients that the drug it designed,

manufactured, marketed, sold, and continues to sell, contains a defect that would injure patients and cause ophthalmological side effects.

110. Defendants failed to exercise ordinary and reasonable care in the design of Elmiron® and breached the duties set out below.

111. Defendants breached their duty to Plaintiff to disclose or otherwise warn that testing established that Elmiron® causes significant ophthalmological side effects in patients.

112. Defendants breached their duty to Plaintiff to ensure that Elmiron® complied with industry standards, safety guidelines, and testing standards.

113. Defendants breached their duty to Plaintiff to disclose or otherwise warn that testing established that Elmiron® causes significant ophthalmological side effects in patients.

114. The negligence of Defendants, their agents, servants, and/or employees, includes the foregoing, as well as the following acts and/or omissions:

a. Designing, manufacturing, marketing, promoting, distributing, and selling Elmiron® without sufficient pre- and post-market testing of the product in accord with industry standards;

b. Designing, manufacturing, marketing, promoting, distributing, and selling Elmiron® while intentionally and negligently omitting, concealing, and failing to disclose clinical trial results, which confirmed to Defendants that the drug causes significant ophthalmological side effects in patients;

c. Intentionally and negligently omitting, concealing, and/or failing to disclose to regulatory agencies, prescribing physicians, the medical community, patients, and the general public that Defendants knew and/or should have known that Elmiron® was unreasonably unsafe and unfit for

its intended use because it causes significant ophthalmological side effects in patients;

d. Failing to warn Plaintiff, prescribing physicians, the medical community, patients, and the general public that the risk of harm inherent in Elmiron® is unreasonable and that there safer and effective alternatives are available for the treatment of interstitial cystitis;

e. Failing to provide adequate instructions, guidelines, and warning to patients who were reasonably foreseeable users of Elmiron®;

f. Failing to disclose to and inform prescribing physicians, the medical community, patients, and the general public that safer and effective alternatives are available for the treatment of interstitial cystitis;

g. Misrepresenting that Elmiron® is safe for its intended use when Defendants knew or should have known that the drug was unsafe and caused significant ophthalmological side effects;

h. Marketing, advertising, and promoting Elmiron®, while omitting, concealing, and/or failing to disclose the risk of significant ophthalmological side effects resulting from use of the drug, which was known to Defendants, but unknown to prescribing physicians, the medical community, patients, and the general public; and

i. Continuing to manufacture, market, promote, distribute, and sell Elmiron® while knowing that the drug is unreasonably unsafe and causes significant ophthalmological side effects.

111. Plaintiff has been damaged because Elmiron® is unsafe to take for its intended purpose and caused ophthalmological side effects, which was known to Defendants, but not disclosed.

112. Plaintiff has also been damaged as a direct and proximate result of the negligence, carelessness, recklessness, willfulness, and wanton behavior of Defendants as aforesaid, including, but not limited to, suffering significant damage to her eyes and vision.

113. As Defendants' conduct was grossly negligent, reckless, willful, wanton, intentional, fraudulent, or the like, Plaintiff is entitled to an award of punitive damages against Defendants.

COUNT III
Strict Liability – Defective Design

115. Plaintiff hereby realleges and incorporates by reference all allegations raised in the preceding paragraphs as if fully stated herein.

116. Elmiron® was designed, manufactured, marketed, advertised, promoted, distributed, sold, and introduced into the stream of commerce by Defendants.

117. When it left the control of Defendants, Elmiron® was expected to and did reach Plaintiff without substantial change from the condition in which it left Defendants' control.

118. Elmiron® was defective when it left Defendants' control and was placed in the stream of commerce, 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 other significant eye and vision problems.

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

120. Elmiron® was unfit for its intended use, and in a defective condition which could cause – and did cause – ophthalmological side effects, including pigmentary

maculopathy and other significant eye and vision problems, such as issues with night vision, adapting to darkness, and loss of central vision.

121. Plaintiff took Elmiron® as prescribed. At the time she took the drug, it was in substantially the same condition as when it left the control of Defendants, and in the manner intended.

122. Had Defendants altered the design of Elmiron® utilizing viable alternatives, the drug would not cause ophthalmological side effects, including pigmentary maculopathy and other significant eye and vision problems, and would not have damaged Plaintiff.

123. Better and safer methods of design of Elmiron® were available and could have been utilized by Defendants.

124. As a direct and proximate result of Defendants' defective design of Elmiron®, Plaintiff suffered damages and economic loss as set forth herein.

125. Defendants are strictly liable to Plaintiff for all damages and economic losses resulting from their defective design of Elmiron®.

126. As a direct and proximate result of the foregoing, Plaintiff suffered, and continues to suffer, physical damage and injury, financial damage and injury, and is entitled to all damages, in addition to costs, interest and fees, including attorneys' fees, as allowed by law.

COUNT IV
Breach of Express Warranty
Uniform Commercial Code – N.C. Gen. Stat. §§ 25-1-101, *et seq*.

127. Plaintiff hereby realleges and incorporates by reference all allegations raised in the preceding paragraphs as if fully stated herein.

128. Plaintiff purchased Elmiron® from pharmacies in North Carolina, which was manufactured, packaged, labeled, marketed, advertised, distributed, and sold by Defendants.

129. Plaintiff is a "consumer" under N.C. Gen. Stat. §§ 25-1-101, *et seq*., and purchased Elmiron® for personal use.

130. Defendants were at all relevant times sellers of Elmiron®.

131. Defendants, as the designers, manufacturers, marketers, advertisers, distributors, and/or sellers of Elmiron®, expressly warranted through the marketing, packaging, and labeling of Elmiron® that the drug "is used to treat the pain or discomfort of interstitial cystitis" and "must be taken continuously for relief."

132. Plaintiff has privity of contract with Defendants through her purchase of Elmiron®, and through the express warranties that Defendants issued to patients. Defendants' warranties accompanied Elmiron® and were intended to benefit end-users of the drug. To the extent that Plaintiff purchased the Elmiron® from third-party pharmacy, privity is not required because Plaintiff is an intended third-party beneficiary of the contracts between Defendants and third-party pharmacies, and because the express warranty is intended to benefit purchasers subsequent to the third-party pharmacies. In

other words, the contracts are intended to benefit the ultimate consumer who takes Elmiron®.

133. Defendants made the foregoing express representations and warranties to all consumers, which became the basis of the bargain between Plaintiff and Defendants.

134. In fact, Elmiron® is not safe to take for the treatment on interstitial cystitis because of undisclosed ophthalmological side effects that can result, and have resulted, from taking the drug, including pigmentary maculopathy. Accordingly, each of Defendants' express warranties is a false and misleading misrepresentation.

135. Defendants breached these warranties and/or contract obligations by placing Elmiron® into the stream of commerce and selling it to patients, when the drug is unsafe for its intended purpose and poses a significant health risk to patients. The lack of safety inherent in Elmiron® renders it unfit for its intended use and purpose and substantially and/or completely impairs the use and value of the drug.

136. Defendants breached their express warranties by selling Elmiron®, which is unsafe for its intended use, and cannot be used for its ordinary purpose of treating the symptoms of interstitial cystitis. Defendants breached their express written warranties to Plaintiff in that Elmiron® was not safe to take for its intended purpose at the time that it left Defendants' possession or control and was sold to Plaintiff, creating a serious health risk to Plaintiff.

137. Despite having notice and knowledge of the health risks posed by Elmiron®, Defendants failed to provide any warning to Plaintiff of the known ophthalmological side

effects, and otherwise failed to provide Plaintiff with an iteration of Elmiron® that did not pose such health risks.

138. The express written warranties covering Elmiron® were a material part of the bargain between Defendants and consumers. At the time they made these express warranties, Defendants knew of the purpose for which Elmiron® was to be taken.

139. Defendants were provided constructive notice of the aforementioned breaches of the above-described warranties through the results of its own early clinical trials for Elmiron®, which included reports of retinal eye damage, as well as through the above-described studies.

140. Elmiron®, as purchased by Plaintiff, was uniformly deficient with respect to its ability to treat the symptoms of interstitial cystitis without ophthalmological side effects, including, pigmentary maculopathy, which caused Plaintiff's damages, including the loss of the benefit of her bargain.

141. Plaintiff was injured as a direct and proximate result of Defendants' breach of their express warranties because she did not receive the benefit of the bargain, suffered the deterioration of her vision, and suffered damages at the point-of-sale, as she would not have purchased Elmiron® if she had known the truth about the unreasonable health risk it posed to her vision.

COUNT V
Violation of the North Carolina Unfair & Deceptive Trade Practices Act
N.C. Gen. Stat. §§ 75-1.1, *et seq*.

142. Plaintiff hereby realleges and incorporates by reference all allegations raised in the preceding paragraphs as if fully stated herein.

143. Defendants' foregoing acts and practices, including their omissions in the conduct of trade or commerce, were directed at consumers.

144. Defendants' foregoing deceptive acts and practices, including their omissions, were material, in part, because they concerned undisclosed risks posed to the health and safety of patients taking Elmiron® for its intended purpose. Defendants omitted material facts regarding the safety (or lack thereof) of the drug by failing to disclose the results of its clinical testing, the results of studies conducted by third parties, or that the drug can cause and has caused ophthalmological side effects, including, pigmentary maculopathy, in patients taking Elmiron® for the treatment of interstitial cystitis. Rather than disclose this information, Defendants marketed and labeled Elmiron® as safe and effective for the treatment of interstitial cystitis without any mention of the known side effect of vision impairment.

145. Elmiron® poses an unreasonable risk to the health and safety of patients who take it for the treatment of interstitial cystitis.

146. Defendants did not disclose this information to consumers, including Plaintiff.

147. Defendants' foregoing deceptive acts and practices, including their omissions while engaged in business, were and are deceptive acts or practices in violation of N.C. Gen. Stat. §§ 75-1.1, *et seq*., in that:

a. Defendants manufactured, labeled, packaged, marketed, advertised, distributed, and/or sold Elmiron® as safe and effective for the treatment of interstitial cystitis, when they knew through their own clinical testing that the drug caused ophthalmological side effects, including, pigmentary maculopathy;

b. Defendants knew that the unreasonable risk to the health and safety of patients and the results of their own clinical testing were unknown to and would not be easily discovered by Plaintiff, and would defeat her ordinary, foreseeable and reasonable expectations concerning the performance of Elmiron®; and

c. Plaintiff was deceived by Defendants' failure to disclose and could not discover the unreasonable risk to her health and safety posed by Elmiron®.

122. Plaintiff suffered damages when she purchased Elmiron®. Defendants' unconscionable, deceptive and/or unfair practices caused actual damages to Plaintiff who was unaware that Elmiron® posed an unreasonable risk to her health and safety because of the potential for undisclosed ophthalmological side effects, including, pigmentary maculopathy.

123. Defendants' foregoing deceptive acts and practices, including their omissions, were likely to deceive, and did deceive, consumers acting reasonably under the circumstances.

124. Consumers, including Plaintiff, relied upon Defendants' deceptive representations in purchasing Elmiron® and would not have purchased Elmiron® had they known about the unreasonable health and safety risk it posed to her, or the results of Defendants' clinical testing.

125. As a direct and proximate result of Defendants' deceptive acts and practices, including their omissions, Plaintiff has been damaged as alleged herein, and is entitled to recover actual damages and/or treble damages to the extent permitted by law, in an amount to be proven at trial.

126. In addition, Plaintiff seeks equitable and injunctive relief against Defendants on terms that the Court considers reasonable, and reasonable attorneys' fees and costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter a judgment:

A. Declaring that Defendants' conduct, as alleged herein, is unfair, deceptive, fraudulent, wrongful, and unlawful;

B. Awarding damages, including compensatory, exemplary, statutory, treble, and/or punitive damages, to Plaintiff in an amount to be determined at trial;

C. Granting restitution to Plaintiff;

D. Permanently enjoining Defendants from engaging in the wrongful conduct alleged herein;

E. Issuing a permanent injunction requiring Defendants to (i) recall all Elmiron® still in circulation that does not include a label warning of the potential for pigmentary maculopathy and advising regular ophthalmologic examinations for early detection; and (ii) cease distributing and/or selling any Elmiron® that does not include the aforementioned warning label;

F. Ordering Defendants to pay compensatory damages and/or actual damages and/or consequential or incidental damages and/or exemplary damages and/or restitution and/or statutory damages, as provided by applicable law, to Plaintiff;

G. Ordering Defendants to pay punitive damages, as allowable by law;

H. Awarding Plaintiff her reasonable litigation expenses and costs of suit, including reasonable attorneys' fees to the extent provided by law;

I. Awarding Plaintiff pre- and post-judgment interest at the highest legal rate to the extent provided by law; and

J. Awarding such further relief as the Court deems appropriate.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, on all claims in this Complaint so triable. Plaintiff also respectfully requests leave to amend this Complaint to conform to the evidence if such amendment is needed for trial.

Dated: August 25, 2020

Respectfully submitted,

GREG COLEMAN LAW PC

/s/ Martha A. Geer
Martha A. Geer (NC Bar No. 13972)
Jonathan B. Cohen*
800 S. Gay Street, Suite 1100
Knoxville, TN 37929
T: 865-247-0080
F: 865-522-0049
martha@gregcolemanlaw.com
jonathan@gregcolemanlaw.com

CRUEGER DICKINSON
Charles Crueger*
Erin Dickinson*
Krista Baisch*
4532 N. Oakland
Whitefish Bay, WI 53211
T: 414-210-4367
cjc@cruegerdickinson.com
ekd@cruegerdickinson.com
kkb@cruegerdickinson.com

WEXLER WALLACE LLP
Edward Wallace*
Michelle Perkovic*
55 W. Monroe, Suite 3300
Chicago, IL 60603
T: 312-346-2222
F: 312-346-0022
eaw@wexlerwallace.com
mp@wexlerwallace.com

Attorneys for Plaintiff

* Applications *pro hac vice* to be submitted